

30-DAY NOTICE LIST OF PUBLIC COMMENTERS			
#	NAME OF ENTITY	DATE REC'D	LATE
76	Quint, Julia	2/28/2013	
77	Renn Review_ESPR	3/3/2013	
78	Rubber Manufacturers Association	2/28/2013	
79	San Francisco Bay Regional Water Quality Control Board	2/28/2013	
80	San Francisco Public Utilities Commission	2/28/2013	
81	Santa Barbara County Public Works Department	2/26/2013	
82	Sass Review_ESPR	2/28/2013	
83	Semiconductor Industry Association of Korea	2/28/2013	
84	Semiconductor Industry Association of Taiwan	2/27/2013	
85	Sierra Club California	2/28/2013	
86	Sigma-Aldrich Corporation	2/28/2013	
87	Silicon Valley Toxics Coalition	2/28/2013	
88	SNR Denton	2/28/2013	
89	TDC Environmental	2/28/2013	
90	TechLaw	2/28/2013	
91	Test & Measurement Coalition	2/26/2013	
92	Toy Industry Association	2/28/2013	
93	Tremco	2/28/2013	
94	UC Research Policy Development	2/28/2013	
95	UCLA Sustainable Technology & Policy Program	2/28/2013	
96	Unifrax	2/28/2013	
97	Unilever	2/28/2013	
98	Valero Companies	2/26/2013	
99	Vinyl Institute	2/28/2013	
100	Western States Petroleum Association	2/27/2013	
101	Worksafe	2/28/2013	

February 28, 2013

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Comments on Text of Proposed Safer Consumer Products Proposed Regulations—
Post-Hearing Changes, January 2013

Submitted via Electronic Mail

Dear Director Raphael:

Thank you for the opportunity to comment on the latest version of the Safer Consumer Products Regulations. I commend you and your staff for the hard work that went into revising the regulations, and for your thoughtful consideration of the many comments you received from diverse stakeholders.

I strongly support many of the post-hearing changes that are reflected in the text of the January 2013 proposed regulations. These changes include:

- (1) **Using “potential” instead of “ability to” when referring to adverse impacts and exposures, and defining “potential”.** This change is in keeping with the purpose of the regulations to protect public health and the environment by acting on reliable information before toxic chemicals harm health and before they pollute the environment. The identification of Chemicals of Concern (COCs) based on animal data, instead of requiring human data, is consistent with the potential for harm concept.
- (2) **Removing the exemption for consumer products that are manufactured or stored in, or transported through California solely for use outside of California.** This recognizes potential health hazards to workers who may be exposed during the manufacture and transport of the products, indicates concern for users of consumer products outside of California who may be exposed to harmful chemicals in the products, and helps to prevent potential environmental contamination in California.
- (3) **Adding chemicals classified as respiratory sensitizers Category 1 in Annex VI to Regulation (European Commission) 1272/2008 to Section 69502.2.** This change can help reduce the asthma burden in California, which is particularly high among

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children in underserved communities, since many consumer products used in homes and workplaces contain respiratory sensitizers. Respiratory sensitizers are not formally identified by US authoritative organizations and often are not recognized as causing asthma.

I am opposed to the following post-hearing changes to the regulations:

- (1) **Referring to the list of chemicals as “Candidate Chemicals” instead of “Chemicals of Concern (COCs) in §69501. Purpose and Applicability and throughout the regulations.**

The listed chemicals *are of concern* based on determinations by authoritative organizations that they harm human health and/or the environment. Their presence in the priority products makes them subject to this regulation, but they are of concern regardless of whether they are in the limited number of priority products DTSC will identify. Consistent with the green chemistry goal of the SCP regulations, it is important to retain COC as the descriptor for the chemical list to reinforce the fact that the chemicals are potentially harmful, and to raise awareness that they should be avoided, to the greatest extent possible, when developing new products or when re-formulating existing products. The term “Candidate Chemical” does not convey any information about the listed chemicals, and adds a new term and an unnecessary complication to a regulation that is already complex. Recommend using “Candidate Chemicals of Concern” if there is a critical need to distinguish between the listed chemicals and the chemicals in the priority products.

- (2) **The definition (#57) of “Reliable information” on page 16, lines 11-20**

A study published in a scientifically peer-reviewed report or other literature (1a) is not comparable to and should not carry the same weight as the studies described in 1b-1d, i.e., studies in reports published by the US National Academies (1b), by an international, federal, state, or local agency that implements laws governing chemicals; and/or studies conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes. The level of peer-review and, in some cases public review, is substantially greater for the studies in 1b-1d.

Lines 19-20: In some cases, this information could conflict with the Code of Federal Regulations General Provisions for the Use of Human and Animal Data (CFR 29 §1990.143) pertaining to Identification, Classification, and Regulation of Carcinogens. It states that positive results will be used for the qualitative

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identification of potential occupational carcinogens even where non-positive human and animal studies exist.

(3) The definition (#58) “Reliable Information” as it pertains to demonstrating the occurrence or potential occurrence of exposures to a chemical

The listed data and information do not exist for many emerging chemicals, particularly organic solvents that are COCs such as N-methyl pyrrolidone (NMP) and 1-bromopropane (1-BP). Exposure monitoring is often not conducted on new or emerging chemicals, or chemicals that are not already under regulatory scrutiny. In addition, many organic solvent are not bioaccumulative or persistent, so reliable information demonstrating exposure based on these endpoints also may not exist. It is important that the regulations address emerging hazards that authoritative organizations have identified as chemicals of concern since it is an opportunity to prevent harm before it becomes widespread or significant. Additional factors like physiochemical properties (vapor pressure, etc.), concentration of the chemical in a product, and intended use should be used to demonstrate potential occurrence of exposure in addition to the factors described.

(4) DTSC Evaluation of engineering and administrative controls that reduce exposure concerns associated with the product as a factor for possible listing a product as a priority product

Engineering and administrative controls can reduce exposure concerns if they exist and if they are properly used. However, often this is not the case. Although employers are required to provide these controls to protect workers from harmful exposures to toxic chemicals, in reality exposure controls often are non-existent, especially for small businesses and independent contractors who use consumer products. An example is the recent worker death associated with the use of a methylene chloride-based paint stripper reported by the CDPH Occupational Health Branch. Another example is the use of solvent-based products in nail salons without adequate ventilation. It is important for DTSC to determine how consumer products are used in practice as opposed to their recommended uses before eliminating the product from consideration as a priority product.

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(5) Requirement for a product to be identified on the initial list of priority products as described in §69503.6.

The requirement that a consumer product must contain one or more candidate chemicals and one or more of the criteria in §69502.2 (2) is too restrictive. The criteria in §69502.2 (2) consist of lists that DTSC identifies as demonstrating exposure. However, as discussed in comment (3) above, the exposure criteria will eliminate from consideration emerging chemicals for which exposure data have not been collected, and many organic solvents. For example, widely used graffiti removers and paint strippers that contain N-methylpyrrolidone, a Candidate Chemical and developmental toxicant that is absorbed through intact skin, do not appear to meet the exposure criteria in §69502.2 (2). Degreasers, sold online in aerosol cans, that contain 90% 1-bromopropane, a Candidate Chemical and a male and female reproductive toxicant, developmental toxicant, neurotoxicant, and a candidate NTP carcinogen, also do not appear to meet the exposure criteria and would not be considered. The criteria should be expanded to include factors that indicate potential exposure that allow inclusion of emerging chemicals and organic solvent-based consumer products to be considered on the initial products list.

Respectfully,

Julia Quint, PhD

STATEMENT

Ortwin Renn

March 3, 2013

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

Statement:

According to my reading of the regulations for identifying and classifying chemicals, most of the reviewers’ comments have been incorporated. There is a clear differentiation between the characterization of the hazardous properties of a chemical and the corresponding risks, which includes exposure and dose-response effects. As mentioned in my earlier statements, I strongly recommend to use two main criteria for characterizing hazards, such as pervasiveness and

Scientific Factors: Peer Review Ortwin Renn

ubiquity of exposure, to alert the regulators to chemicals that have a high loading of these two characteristics even if negative impacts have not yet been observed¹. There is sufficient evidence that high persistency and ubiquitous exposure are normally highly correlated with some delayed environmental damage. Such damage could also affect human health.

With respect to the procedure of identifying and characterizing chemicals, the proposed legislation considers the potential identification pathways specified for the EU REACH regulation as well as for the existing Federal and state legislations in the United States. This appears sufficient in my view.

As a social scientist, I cannot comment the completeness or adequacy of the list of chemicals that have been attached to the existing documents. It is, however, essential that the list of chemicals is constantly monitored and updated. This can go in both directions: sometimes preliminary suspicions turn out to be unjustified, so that candidates on the list may be removed due to better evidence about their potential harm. Sometimes allegedly innocuous substances turn out to be more severe than estimated. Then they should be added to the list even if there were tested before. In particular in connection with nanoparticles, it is also mandatory to review from time to time some of the hazard criteria such as production volume, concentration in product and contamination pathways. As far as I can tell, I can see that such flexibility in changing the criteria and adapting them to new developments and innovative products is incorporated into the language of the proposed regulation.

In essence, I do not see any reasons for further changes.

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

¹ Mueller-Herold, U., Morosini, M. and Olivier Schucht, O. (2005): Choosing Chemicals for Precautionary Regulation: A Filter Series Approach. In: *Environmental Science and Technology* 39 (1): 683–69.

Scientific Factors: Peer Review Ortwin Renn

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.

Statement:

I totally agree with the change of the language from “ability to” to “potential of”. Within a more precautionary understanding of risk management, regulation should not wait for a final proof of negative impact. If there is sufficient evidence that a chemical can cause negative impacts and if there is a reasonable cause to assume that these impacts are likely to affect the environment or human health within the context in which this chemical is being used, regulatory action may be justified. I think it would be beneficial to stress that the potential to do harm, i.e. the description of the hazardous properties of a chemical, is not sufficient for being placed on the chemical candidate list. In addition, it should be requested that there is a realistic option that this potential for harm is released into the environment within the context in which this chemical is used. This may include potential pathways of exposure, the potential volume that is being incorporated or released into the environment, and the knowledge about dose-effect relationships. A chemical that can never reach a human being or is not released into the environment at all should be treated differently than a chemical that will affect humans or the environment in course of its destined use.

This line of argumentation provides a middle ground between a fully precautionary and a fully evidence-based approach to risk management². It does not require that harm is being confirmed either by animal studies or by epidemiological investigations. However, it is also not sufficient to list chemicals according to their potential of harmful effects, with the exception of high persistence and ubiquitous dispersion (see above). A chemical may enter the list if it contains specific hazards *and* if there is reasonable evidence to suggest that such a hazard can be released into the environment or incorporated by human beings.

² Renn, O (2007): Precaution and Analysis: Two Sides of the Same Coin? In: *EMBO Reports*, 8: 303-305

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.

Statement:

I fully agree with the changes that were made to the provisions on alternative analysis thresholds. In the first version this parallel route could have been interpreted as a loophole for reducing the amount of testing and for circumventing the more onerous procedure for being listed or removed from the list. I also go along with the narrow list of exemptions that is now being inserted into the language of the regulations.

I have two minor reservations: the first one refers to nanoparticles for which a volume-based threshold may be rather irrelevant³. Most of these nanoparticles impact on the environment or inflict harm on human health on the basis of surface exposure rather than on the overall dose. I'm not sure whether this specific hazard criterion has been included as an exemption to the list of exemption. Exemption rules that are purely based on volume may not be sufficient.

The second reservation concerns public scrutiny. It would be wise to allow for more public review if a chemical is pursuing the alternative analysis threshold route⁴. It may be beneficial to expand the time and intensity for public review if such a route is taken.

³ Pleus, R.C. (2013): The State of the Science: Human Health, Toxicology, and Nanotechnology Risks. In: J.A. Shatkin (ed.): *Nanotechnology. Health and Environmental Risks*, CRC Press, Taylor und Francis: Boca Raton, pp. 79-116

⁴ Klinke, A. and Renn; O. (2012): Adaptive and Integrative Governance on Risk and Uncertainty. In: *Journal of Risk Research* , 15: 3 (2012), 273-292.

Scientific Factors: Peer Review Ortwin Renn

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.

Statement

Since the term “adverse” has many meanings in the English language, it may be prudent to be more specific about its specific meaning within the context of this regulation. I feel now more comfortable with the explanations that have been inserted in the new version. However, there are still some weaknesses in the definitions and conceptualizations of the word “adverse”. I would recommend specifying the term to denominate negative impacts on ecosystem services, landscape appearance and biodiversity in relation to environmental impacts and on human health and well-being in relation to life quality. I believe that these categories cover everything what needs to be included in this term.

In my view, impacts and effects are very difficult to distinguish. Effects may be more specifically connected to causal chains, while impacts may also include intervening variables that are not yet known. Impacts characterize sequential and associative consequences related to a system of preceding events. There is also the word “consequence”, which means something similar. Yet I believe that the use of the two terms “impact” and “effect” are almost synonymous and therefore I do not recommend any changes in the latest version of the document.



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February 28, 2013

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Re: Safer Consumer Products Proposed Regulation, January 2013 Revised Proposed Regulations; Cal. Code Regs. Tit. 22, § 55 (2013)

I. Introduction

RMA is the national trade association representing major tire manufacturers that produce tires in the United States, including Bridgestone Americas, Inc., Continental Tire the Americas, LLC; Cooper Tire & Rubber Company; The Goodyear Tire & Rubber Company; Michelin North America, Inc.; Pirelli Tire North America; Toyo Tire Holdings of Americas Inc. and Yokohama Tire Corporation. RMA members are affected by the January 2013 Proposed Safer Consumer Products Rule because they manufacture tires, a consumer product, available for sale or placed into the stream of commerce in the state of California. We thank the Department of Toxic Substances Control (DTSC) for your consideration of these comments on the January 2013 proposal. Cal. Code Regs. Tit. 22, § 55 (2013).

RMA has been actively engaged in the rulemaking process for the Safer Consumer Products Regulation. We are encouraged by several changes DTSC made in the January 2013 proposed regulations including the increased consideration of other State and Federal laws throughout the regulations and the elimination of the certified assessor requirements. RMA also supports the continued application of end-of-life requirements for only finished products that are required to be managed as hazardous waste.

However, RMA has continued concerns about the application of the proposed regulations to tires. First, RMA has concern that the development of the Priority Products Work Plan does not provide a mechanism to remove chemical/ product categories based on public comments. Second, we have continued concern that the regulations lack adequate protection for trade secrets. Third, RMA has concern that the Alternatives Analysis process does not provide adequate time for tire manufactures to research, develop, and test potential alternative chemicals in tires. Last, the Alternatives Analysis threshold fails to provide a workable definition of a de minimis threshold. RMA would like to see these changes incorporated into a revised Safer

Consumer Products regulation. However, at a minimum we would like to see these changes explained further in the Initial Statement of Reasons for the California Safer Consumer Products regulation.

II. RMA recommends that DTSC expand the public comment process in the development of the Priority Products Work Plan to remove chemical/product category combinations that do not meet the criteria as outlined in §69503.2 of the regulations.

Section 69503.4 specifies that DTSC will issue a Priority Product Work Plan that identifies the product categories DTSC will evaluate to determine which chemical-product combinations DTSC will add to the Priority Products list, within one year after the effective date of SCP regulations. The Priority Product Work Plan must include a general description of DTSC's decision to select the product category. DTSC will issue subsequent work plans no later than one year before the three year expiration date of the current work plan. Section 69503.2 also includes provisions for revising the work plan to add one or more additional product categories, and specifies that prior to issuing a final work plan, DTSC will hold a public work shop. However, section 69503.4 does not contemplate removal of chemical-product combinations.

Section 69503.2 (Product-Chemical Identification and Prioritization Factors) lists the factors DTSC will use to prioritize product-chemical combinations. These factors include: the potential for the public, aquatic, avian, or terrestrial animal or plant organism to be exposed to the Candidate Chemical(s) in the product and the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts. DTSC will consider a number of factors including the market presence of a product (statewide sales by volume, statewide sales by number of units, and/or intended product use(s), and types of age groups of targeted customers) to determine whether there is exposure to a Candidate Chemical in the Priority Product. (Section 69503.3). DTSC will base their decision to identify and list a priority product on information that is "reasonably" available.

As with most products available for sale in California, tires contain chemicals. However, the process of manufacturing a tire involves vulcanization, which changes the chemical composition of the chemicals formulated into the tire in the initial states of the manufacturing process. As a result, the risk for exposure to chemicals in tires is reduced or eliminated as the chemicals in tire formulations undergo a chemical reaction during the vulcanization or heating of a tire during the manufacturing process. We recommend that DTSC include additional language in section 69503.4 to clarify that DTSC will revise a proposed Priority Products Work Plan based on public comments which indicate there is no adverse impact or exposure from the Candidate Chemical in the Priority Product. Specifically, RMA recommends the following words in quotation be added to section 69503.4, lines 17-18:

17 (d) Public Input. Prior to issuing each work plan, the Department shall hold one or more

18 public workshop(s) to provide an opportunity for oral comment. “The Department will revise each work plan based on public comment provided at the workshop.”

Providing this early “off-ramp” in the development of the Priority Products Work Plan will enable DTSC to focus time and resources on the Candidate Chemicals in Priority Products that pose the greatest risk.

III. RMA strongly recommends DTSC revise section 69509 to adequately protect trade secrets and confidential business information

RMA has continued concern that the proposed regulations are not sufficient to protect classified information. DTSC has made several changes to section 69509 that may cause trade secrets to be exposed. The proposed regulations require an extensive amount of information to support a claim of trade secret protection. These requirements as outlined in section 69509(a)(1) – 69509(a)(12) require information to substantiate a claim for trade secret protection that is beyond what is required by Federal law. Additionally, section 69509 is limited to protection for trade secrets rather than the broad category of confidential business information. We recommend that DTSC expand the scope of section 69509 to protect Confidential Business Information (CBI), which is, arguably broader than trade secrets.

Under the proposed regulations, a person who asserts a claim for trade secret protection must indicate how much the information would be worth to competitors and how easy it would be for competitors to acquire or duplicate the information. This information is extremely difficult for companies to quantify. Consequently, the information provided is likely to be based on broad assumptions and/or guess-work. RMA recommends that DTSC limit the information required to substantiate a claim for trade secret protection to information that is required under federal regulations. For example, the information required to assert a claim for business confidentiality under the Chemical Data Reporting (CDR) rule does not require a responsible entity to provide information on how much the information would be worth to competitors or the ease by which competitors could acquire or duplicate the information. We recommend DTSC limit the information that is required to substantiate a claim for trade secret protection to the information required in the CDR rule. 76 Fed. Reg. 50816.

A. Hazard Trait Submission (69509(f)) and Chemical Identity Masking When a Patent is Pending (69509(g))

A “hazard trait submission” is defined as “any health, safety, or environmental study of, or health, safety, or environmental information regarding a chemical submitted to the Department.” (Lines 12-18, Page 13 of 106). Hazard trait submissions include the “precise chemical identity.” Id. DTSC specifies in the revised initial statement of reasons, for the

proposed regulations, that they have included the definition of a hazard trait submission to “implement and make more specific Health and Safety Code section 25257(f).” Health and Safety Code section 25257(f) specifies that hazard trait submissions for chemicals, including chemical ingredients, cannot be protected as trade secrets.”

Section 69509(f) limits trade secret protection to chemical names for an alternative chemical for which there is a patent is pending until the patent is granted or denied. This section essentially forces responsible entities to file a patent application in order to keep the information as a trade secret.

RMA recommends DTSC remove section 69509(f) and allow responsible entities to file a claim for trade secret protection of chemical identities. We believe this provision apprehends the essence of what a trade secret is (i.e. processes that are not patented) and is a significant change from other Federal laws. For example, under TSCA section 14, manufacturers and processors are permitted to claim as CBI the specific chemical identity of a particular substance in connection with the TSCA inventory reporting requirements. TSCA section 14 prohibits EPA from disclosing confidential business or financial information submitted to the Agency under a claim of confidentiality. 15 U.S.C. §2613. Additionally, the CDR rule allows claims of confidentiality for chemical identity, site identity, and processing and use information. 40 CFR Part 2 and 40 CFR 711.30. CBI protection under the CDR rule is limited to data elements where their release would likely cause substantial harm to the business’s competitive position. Section 69509 should provide similar confidentiality protection.

B. Department Review of Claims for Trade Secret Protection

Under section 69509.1, the Department can request additional information from a company to substantiate a claim for trade secret protection. If the company fails to provide the requested information, the Department will notify the company that the information will be disclosed within 30 days. Thus, the burden is on the company seeking trade secret protection to defend any trade secret claim if the Department denies a company’s request for trade secret protection under § 69509. During the 30 day time period, the company can either correct the deficiency of the claim for trade secret protection or seek judicial relief. RMA believes the time frames for responding to the Department are too short. We recommend that companies or a submitter for trade secret protection have 60 days to provide additional information to DTSC to substantiate a claim for trade secret protection or seek judicial review.

C. Protection of trade secrets and confidential business information is crucial for the tire manufacturing industry

RMA members have a property interest in the ingredients in their tires. Ingredients in tire formulations have a recognized economic value. Tire manufacturers spend significant resources developing new tire formulations to improve performance characteristics. Tires differ not because of taste, color or appearance, but because the tire industry is always striving to achieve better performance. Protection of confidential business information is important for tire

manufacturers because they are always trying to gain an advantage over their competitors. All RMA members exercise practices to ensure tire formulations are kept confidential and not revealed to the public, and therefore competitors. Public disclosure of chemical identities will make the results of these investments in tire performance available to other companies who will not have to make similar investments.

IV. RMA asks that for certain consumer goods such as tires that DTSC adequately account for the time needed to complete safety and performance testing when setting deadlines for completing Alternative Analysis Reports.

Tires are highly engineered products. The time needed to assess whether there is a workable chemical substitute for an ingredient in tires varies depending on the chemical that is to be assessed for possible replacement. Each component of a tire is composed of a different rubber compound. Compounds vary depending on the function of the compound and the type of tire that contains the compound. Thus, the type of tire that contains the Chemical of Concern, the size of the tire, the type of compound in the tire and the purpose of the compound in the tire, all affect the amount of time needed to determine if there is a viable substitution.

Tire manufacturers may consider a number of factors during the process of reformulating various tire components or compounds. For example, tire manufacturers may conduct: laboratory studies to mix and cure new rubber samples, develop tire prototypes, perform machine and road testing, conduct initial production of reformulated tires in the plant, and test reformulated tires for performance (rolling resistance, traction, wear) and safety to comply with Federal Motor Vehicle Safety Standards established by the National Highway Transportation Safety Administration.

Several RMA member companies have replaced aromatic oils in tires in response to the European Commission proposal aimed at banning the use and marketing of PAH-rich oils in tire production. For these companies, the process to replace the use of aromatic oils in tires generally took ten years to complete. DTSC's default time frame of 12 month to complete a final Alternatives Analysis Report does not provide adequate time for tire manufacturers to complete chemical changes in tires even with the opportunity to obtain a 36 month extension to perform performance and safety testing. RMA asks that DTSC provide extended due dates for submitting final Alternative Analysis reports for certain consumer goods, such as tires, in order to complete the complicated and time consuming factors tire manufacturers must consider for substituting chemicals.

V. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (Section 69505.3)

RMA strongly supports the inclusion of an Alternatives Analysis Threshold in the final Safer Consumer Products regulation. Section 69505.3 in the revised regulations define the Alternatives Analysis Threshold as the practical quantification limit (PQL). RMA does not

support the Alternatives Analysis Threshold Exemption defined as a PQL. This change essentially means that no measurable level of a Chemical of Concern can qualify for the Alternatives Analysis Threshold exemption.

Prior drafts of the Safer Consumer Product regulation included a *de minimis* exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1% for all other chemicals. RMA recommends that DTSC revise the proposed regulations to include a default Alternatives Analysis Threshold Exemption of 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence. Additionally, we recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit similar hazard traits or environmental/toxicological end points.

This approach is consistent with other Federal and International regulations established by The Occupational Health and Safety Administration's (OSHA) Hazard Communication Standard requirements for development of Material Safety Data Sheets (MSDSs), the Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI) program and the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), that set a fixed *de minimis* level at 0.1% by weight, for individual chemicals. *See* Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988). For example, the EPA has established *de minimis* levels for the TRI program with a base *de minimis* level set at 0.1% for any non-persistent bioaccumulative toxin chemical and OSHA-defined carcinogens. Additionally, allowing for the default Alternative Analysis thresholds to be lowered or raised is consistent with the EU's Globally Harmonized System of Classification and Labeling of Chemicals which establishes chemical specific thresholds that may be lower or higher than 0.1% based on sound science and reliable information. Excluding products or product types that contain chemicals of concern in very low concentrations, and that have a low potential for exposure will enable DTSC to focus on priority products that pose the greatest risk which is envisioned by the statute (AB 1879, 2008).

VI. Conclusion

The tire manufacturing industry supports sustainable production and the development of methods to reduce the risks of exposure to chemicals used in products. However, the proposed regulation grants virtually unreviewable authority to DTSC to require substitution of chemicals in tires. This threatens tire manufacturers ability to meet and comply with Federal Motor Vehicle Safety Standards and the requirements of the January 2013 proposed Safer Consumer Products regulation.

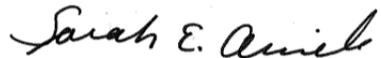
As written, the informal draft regulation cannot be applied to tires in any feasible way. RMA recommends that DTSC change the regulation to: (1) revise section 69503.4 to ensure DTSC will revise the work plan to remove chemical/product categories in response to public

Comments by the Rubber Manufacturers Association
February 28, 2013

comment; (2) revise Article 9 to provide adequate protection for confidential business information which includes trade secrets; (3) provide adequate time in section 69505.1 for tire manufacturers to research, develop, and test potential alternative chemicals in order to submit a final Alternative Analysis Report; and (4) revise section 69505.3 to provide a workable definition of the Alternatives Analysis Threshold.

RMA again thanks the California Department of Toxic Substances Control for this opportunity to comment on the informal draft regulation. Please contact me at (202) 682-4836 if you have questions or require additional information.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Sarah E. Amick".

Sarah E. Amick
Senior Counsel
Rubber Manufacturers Association

San Francisco Bay Regional Water Quality Control Board

February 28, 2013

Debbie Raphael, Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

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

Dear Ms. Raphael:

On behalf of the State Water Resources Control Board (State Water Board) and the Regional Water Quality Control Boards (Regional Water Boards), we thank you for another opportunity to comment on the Revised Proposed Safer Consumer Products Regulations (revised proposed regulations). We appreciate the revisions the Department included to address our concerns, as outlined in our previous comment letter. We also wish to commend you and Department staff for your efforts to conduct an open, transparent process for developing these regulations.

The State Water Board and nine Regional Water Boards are responsible for maintaining water quality in State waters to protect beneficial uses of surface and ground waters. As a result of discharges of chemicals available through ordinary commerce, we have found many water bodies in the State do not meet water quality standards. The Clean Water Act requires us to prepare resource-intensive plans to restore the beneficial uses of these waters, and programs to implement these plans are extremely expensive, both for us and for the regulated community. For many pollutants of concern, end-of-pipe treatment of wastewater and stormwater is not only prohibitively expensive, but technologically infeasible. The proposed Safer Consumer Products regulations have great potential to reduce public and environmental exposure to harmful and unnecessary chemicals.

We are generally very pleased to support the revised proposed regulations and encourage the Department to move forward with the regulations so implementation of the Safer Consumer Products program can begin.

Clean Water Act Section 303(d)

We appreciate that the 303(d) list was added to the list of Candidate Chemicals in the regulations under section 69502.2(a), Chemicals of Concern Identification (pg. 21, line 21). The 303(d) list represents our greatest water quality challenges, and its inclusion within the proposed regulations offers a new opportunity for creative and efficient solutions.

Alternatives Analysis Threshold

We appreciate that the revised approach to Alternatives Assessment is based on a “practical quantification limit,” with the Department given discretion to set product-specific values. Different

pollutants and different products have different potencies. The case-by-case language allows for variations in product usage and environmental sensitivities.

Initial Priority Products

We appreciate that the Department modified the proposed regulations to better address non-human environmental pollution, including serious water quality concerns. We understand that the initial final list of Priority Products will be limited to five Priority Products (§ 69503 (b)) to keep the initial implementation of the regulations manageable. To further strengthen the regulations, we ask you to consider the following modification:

- Include at least one water-polluting product in the final initial list of Priority Products.

Transparency and Public Involvement

We appreciate that opportunities for transparency and public involvement were strengthened. In particular, we appreciate that Preliminary Alternatives Assessment Work Plans must now identify exposure pathways and “must include a description of the process that will be used to identify the factors and associated exposure pathways and life cycle segments that are relevant for the comparison, as required under section 69505.6(a).” To further strengthen the regulations, we ask you to consider the following modifications:

- Provide a sample Preliminary Alternatives Assessment Report as a guide for manufacturers. Preliminary Alternatives Assessment Reports should summarize chemical information in a manner the public can understand, thereby allowing the public to provide substantive comments. A matrix format, as proposed, will assist in this endeavor if it summarizes chemical information, but the public may not readily comprehend a matrix presentation of the entire chemical data set.
- Provide a formal public comment period of at least 60 days for all exemption requests.

Costs

We appreciate that the Department meaningfully expanded the assessment of the economic impacts on communities exposed to unregulated chemicals. Specifically, we appreciate that the wastewater, stormwater, and end-of-life costs associated with unregulated chemicals are better recognized. Further, we appreciate that the criteria for selecting regulatory responses has been improved to give the Department authority to select remedies on the basis of the public costs associated with polluting products and pollutants in waste, the speed of environmental benefits, and the demands of other regulatory requirements. To further strengthen the regulations, we ask you to consider the following modification:

- Include language in section 69506.7 that would provide for performance standards to be developed in collaboration with manufacturers, stewardship organizations, and other affected stakeholders. End-of-Life Management Programs should be created in consultation with all affected stakeholders so as to ensure program viability and reduce long-term costs.

Schedule

We applaud the Department for identifying a formal public comment period for the Alternatives Assessment process; however, the Department has not specified a minimum comment period. The maximum comment period of 45 days is too short for many public entities to provide substantive comments. Many public agencies are resource-constrained and have lengthy approval processes for

providing public comments. To further strengthen the regulations, we ask you to consider the following modification:

- Specify a minimum comment period for the Alternatives Assessment process of at least 60 days to allow for more thorough review. When possible, we encourage the Department to allow 90 days for comment.

We appreciate the improvements made to the regulatory response process; however, it would be better if the Department specifies criteria for its decisions on the acceptability of extensions during the Alternatives Assessment process (§ 69505.7(k)). The regulatory response selection principles (§ 69506) list the types of criteria the Department might weigh. To further strengthen the regulations, we ask you to consider the following modification:

- Include specific criteria for allowing Alternative Assessment extensions in section 69505.8. These criteria should allow Department staff to consider timely completion as a key factor in extension decisions.

End of Life Management

We applaud the Department for including “adverse waste and end-of-life effects” in the Product-Chemical Identification and Prioritization Factors (§ 69503.2), and for improving requirements for manufacturers to provide consumer communication regarding product end-of-life management (§ 69506.3). To further strengthen the regulations, we ask you to consider the following modification:

- Include the opportunity for the Department to require management programs during phase-out periods when necessary. Removing a chemical from a consumer product or removing a consumer product from the marketplace may take many years, at the expense of public or environmental health, or both, during the phase-out period. Therefore, management of these products may be necessary during the phase-out period. Language in section 69506.1(a)(3) may interfere with such management as proposed in section 69507(a). Similarly, the criteria in section 69506.6 may need to be modified to avoid precluding use of engineering or administrative controls to prevent water pollution during phase-out periods.

Thank you for this opportunity to offer our input regarding the Safer Consumer Products regulations, and for your hard work and persistence in drafting these revised regulations. We very much appreciate your responsiveness to our concerns, and we are confident that the Safer Consumer Products regulations will greatly benefit water quality throughout the State. If you have any questions, please contact Dylan Garner at (510) 622-2116 or by e-mail at dgarner@waterboards.ca.gov.

Sincerely,

Thomas Mumley
Assistant Executive Officer

cc:

State Water Board Executive Director and Deputy Directors
Regional Water Board Executive Officers and Assistant Executive Officers



February 28, 2013

Debbie Raphael, Director
California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
Attn: Krysia Von Burg, Regulations Section; gcregs@dtsc.ca.gov
P.O. Box 806
Sacramento, CA 95812

Subject: Comments on Proposed Safer Consumer Products Regulations

Dear Ms. Raphael:

The City and County of San Francisco Public Utilities Commission respectfully submits the following comments on the proposed Safer Consumer Products Regulations. We strongly support the adoption of the regulations and we look forward to their implementation.

These regulations have the potential to control problem pollutants that enter waterways via treated wastewater or stormwater runoff. Controlling these pollutants at the source, in consumer products, will help public agencies such as the SFPUC comply with permits issued under the Clean Water Act and State Water Code.

We appreciate the recent modifications to the proposed regulations, including the addition to the section on *Candidate Chemicals Identification* of pollutants causing impairment of California waterways and identified on the Clean Water Act 303(d) list.

We understand that the *Initial Priority Products List* (§69503) will address not more than five consumer products prior to 2016. We hope that this initial effort will include at least one priority product-chemical combination impacting waterways. We suggest that the Department consider zinc, which enters our combined sewer system via roadway runoff.

This revised version of the proposed regulations incorporates additional references to cost savings to public agencies from addressing problem chemicals in consumer products. We also suggest that potential cost savings to public agencies be included in Article 3 as a factor for prioritizing product-chemical combinations.

These regulations will become an important tool in protecting California waterways. We look forward to participating in this program. If you have any questions or concerns, please do not hesitate to contact my staff member, Karri Ving, at 415-695-7366 or kving@sflower.org.

Sincerely,

Tommy T. Moala
SFPUC Assistant General Manager
Wastewater Enterprise
525 Golden Gate Avenue
San Francisco, CA 94102
415.554.2465
LP/TTM/vm

Edwin M. Lee
Mayor

Art Torres
President

Vince Courtney
Vice President

Ann Moller Caen
Commissioner

Francesca Vietor
Commissioner

Anson Moran
Commissioner

Harlan L. Kelly, Jr.
General Manager





February 26, 2013

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

RE: Comments on Draft Regulations for Safer Consumer Products

Dear Director Raphael:

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

While we strongly support DTSC's proposed regulations, we respectfully request that you consider 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

AA /EEO Employer

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) Documentotio[n]. 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.*

If you have any questions about these comments, please contact Leslie Robinson, Public Works Program Specialist, at (805) 882-3615 or lrobin@cosbpw.net.

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

Sincerely,



Mark Schleich
Deputy Director, Public Works Department

SASS review 2013

Jennifer Sass, Ph.D.
Senior Scientist, Natural Resources Defense Council (NRDC) and,
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NRDC, 1152 15th St NW, Ste. 300, Washington, DC 20005
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February 28, 2013

SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

Thank you for this opportunity to provide external scientific peer review of specified issues of the Safer Consumer Products Proposed Regulations, as revised January 2013. I used the following two documents for my review:

The Revised Proposed Regulations for Safer Consumer Products (January 2013):
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf>

The unofficial version, without underline and strikeout, of the Revised Proposed Regulations:
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text-NU.pdf>

The Statement of Work described for the scientific peer review is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices for the following four topics. I have presented my responses to each of the four topics below. Overall I find the proposed regulations to be scientifically sound, with some significant improvements to strengthen them since the last draft.

Topic 1. Does the chemicals list developed by the sources named in the regulations accurately identify chemicals with hazardous traits that have public health and environmental concerns and so may be used to produce an initial Candidate Chemicals list? The revised regulations now include two additional lists: the chemicals classified as Category 1 respiratory sensitizers by the EU; and, chemicals identified as priority pollutants in CA under the federal CWA has been expanded to include section 303(d) (impaired waters list) chemicals in addition to 303 (c) chemicals.

The addition of the pollutants from the 303(d) list of the Clean Water Act is a significant improvement to the proposed regulations. This list includes any contaminant that contributes to an impaired water designation. It can include contaminants affecting California waters specifically, and those which have environmental impacts but may not necessarily affect human health. These can include metals, pesticides, and organics such as poly-chlorinated biphenyls (PCBs) and de-icing fluids. Metals such as copper from consumer products including marine antifouling paint, pool and spa algacides, and vehicle brake pads may impair aquatic environments, but have no or limited human health effects. The incorporation of the 303(d) list into § 69502.2 (Candidate Chemicals Identification) will address

consumer product contaminants like copper that are recognized by the State of California a threat to environmental quality. For example, SB 346 requires that the use of copper in vehicle brake pads sold in California be reduced, and also includes a provision linking it with the Safer Consumer Products regulations.

Tri-TAC, representing California wastewater treatment facilities, submitted comments on the proposed safer consumer products regulations, recommending among other things that the 303(d) list of impaired waters be included as a means of identifying candidate chemicals. In their comments, Tri-TAC expressed great concern at the “growing tide” of chemical contaminants in the receiving waters that may compromise the ability of wastewater treatment technologies to operate effectively. We essentially have a toilet-to-tap water system, where wastewater from homes, industrial facilities, and land runoff can go through a wastewater treatment plant, be discharged into groundwater, lakes, or reservoirs, and eventually end up as well water or in a public water system and from there to kitchen tap water in homes around the country. Therefore, protecting all waterways is the best way to protect our source water for human consumption, bathing, and swimming, as well as protecting our environment.

The inclusion of this list into § 69502.2 (Candidate Chemicals Identification), along with the chemicals from the 303(c) list of the federal Clean Water Act is a significant improvement, and will provided a more comprehensive scientific listing of contaminants candidate chemicals of concern.

Topic 2: Are the evaluation criteria for prioritizing the product-chemical combinations in Article 3 sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products? Do the revised regulations specify the key prioritization criteria factors necessary to identify potential Priority Products? 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.

After reviewing the text of the January 2013 proposed regulations for Article 3, as well as the changes from the earlier draft it is my opinion that the regulations as currently proposed provide fairly extensive and comprehensive adverse impact and exposure factors by which to identify potential Priority Products. The descriptions of adverse impacts [§ 69503.3(a)] and exposures [§ 69503.3(b)] are comprehensive and will be effective at identifying potential Priority Products. The inclusion of chemicals that are structurally or mechanistically similar to chemicals with known toxicity profiles [§ 69503.3(a)(3)] is an important factor that will allow the State to identify potential Priority Products even where little data is available.

Article 3 specifies that any product-chemical combination identified and listed as a Priority Product (slated for an Alternative Analysis) must meet both the criteria of having a potential for exposure to the Candidate Chemical(s), and the potential for exposure to contribute to or cause significant widespread adverse impacts [§ 69503.2(a)(2)]. While I support this requirement in principle, I have two concerns. First, what constitutes a “significant” or “widespread” adverse impact is not well-defined. Second, if the phrase “significant or widespread adverse impacts” is to be used to determine priority products, it should apply to the chemical, not the product-chemical combination, since the adverse environmental or health impacts attributable to a single product-chemical combination may be impossible to determine, although the chemical has documented significant and/or widespread adverse impacts.

Regarding the first concern, it is not clear to me what either “significant” or “widespread” mean in this context, who will decide, by what criteria, and for whom? Is impairment of one lake significant? Is two lakes? What about impairment of one river that is use for recreation, but not for drinking water? If the product-chemical combination only poses a risk (exposure plus hazard criteria are met) for people with severe asthma, is that significant or widespread? What if the product-chemical combination poses a risk to people with estrogen-sensitive cancer? Is that significant and/or widespread? What if the adverse effect is significant or widespread (or both), but not severe? What if a product-chemical combination causes a severe effect (such as permanent learning disabilities or severe asthma), but to a limited population so it is neither widespread nor statistically significant across the whole population of the state? I suggest either deleting the words, “significant or widespread” altogether, or adding severity, so that the potential for one or more exposures to contribute or cause severe adverse impacts be considered an additional principle for prioritization. Regarding the second concern, I recommend that the prioritization criteria be applied to the chemical, not the product-chemical combination.

I support the addition of the word “potential” at numerous places throughout this section, and the definition of “potential” to mean that the phenomenon described is reasonably foreseeable based on reliable information. This is both precautionary and reasonable, based on information that is “reasonably available” [§ 69503.2(b)]. In fact, without consideration of potential risks (exposures and adverse impacts), the Safer Consumer Products regulations would not serve its purpose of averting harm.

Topic 3: Are the principles that are outlined in the proposed regulations that will allow DTSC to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products scientifically understood and practical? In the revised regulations the Alternatives Analysis Threshold is now defined as a Practical Quantitation Limit (PQL). A threshold exemption will only apply if a Priority Product contains the COC solely as a contaminant (not for intentionally added ingredients) and the concentration of each Chemical of Concern does not exceed the Alternative Analysis Threshold. The DTSC believes it 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.

Article 5 (Page 35) discusses the Alternative Analysis. The section on Threshold Notification in Lieu of Alternatives is discussed in § 69505.3 (Page 41) of the proposed regulations. The PQL is defined as the lowest concentration of a chemical that can reliably be measured within specified limits of precision and accuracy using routine laboratory operating procedures (§ 69501.1 Definitions, Page 13). I agree that the principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold as a PQL for a COC that is present in a Priority Product solely as a contaminant, and not intentionally added, is scientifically understood. It may be practical in the majority of cases.

I am concerned about some cases, probably rare, where the contaminant COC may be at trace levels, even below the PQL, but is still potentially harmful. For example, there is evidence that asbestos is a contaminant of NY State talc powder, and is causally associated with mesothelioma, asbestosis, and excess lung cancer in miners of the talc, although it’s hard to know how much of it is being used in consumer products. However, there are some cases in the courts today of plaintiffs/consumers with asbestos-related disease who claim that their only known exposure is from historical talc in consumer products. Further complicating matters, the company mining the NY State talc denies that its talc is contaminated with asbestos, although independent scientists have claimed to have detected it. The PQL may be inadequate to detect it at low but dangerous levels, since detection may depend on the extent

of effort expended using high-powered microscopic equipment. In another case, in Libby, Montana there is an epidemic of asbestos-related disease, and there is great concern about environmental exposures as the cause, although the asbestos has not been detected (i.e. levels of ambient exposures are likely below the PQL). This is likely because a bulk analysis of the mineral is very difficult, since trying to separate asbestos fibers from soil and rock samples is problematic even using rigorous analytical methods.

If there is reasonable grounds to believe that a COC may be present in a product, even as a contaminant, and if there is a potential that the product-chemical combination may present a risk even at levels below the PQL, than a threshold exemption should not be issued. DTSC needs to preserve its right to not issue a threshold exemption.

Topic 4: Can a qualitative or quantitative determination of adverse impact or effect be made? Will it be adequately protective of public health and the environment when reliable information is available?

I agree that the proposed regulations adequately describe measures of adverse impact so that a scientifically-defensible determination can be made. The section of Definitions (§ 69501.1) includes specific criteria to recognize adverse ecological impacts, adverse public health impacts, adverse soil quality impacts, adverse water quality impacts and others. In many cases the definitions include exceedances of an enforceable state or federal regulatory standard, descriptions of reduced function, altered properties, deterioration of quality, or endangerment. These determinations of adverse impact or effect should provide a significant measure of protection for health and the environment, when addressed and complied with.

Dear Ms. Von Burg:

On behalf of the Semiconductor Industry Association of Korea(KSIA), we are writing to provide our views on the “Safer Consumer Products” proposal of the California Department of 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).

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

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 SIA in Korea have reviewed the comments of these other technology associations and we endorse these comments.

As discussed in detail in those comments, we believe that these proposed regulations are flawed in several respects. We believe that the proposal, if finalized, would be too complex to be useful for the average consumer, and 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 is flawed 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 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 provide for an adequate implementation period of the process prior to compliance requirements taking effect. And throughout the development of this regulation, DTSC has discounted numerous comments from the regulated community, including the prior comments of the technology associations.

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

Sincerely,

Seungjong Ko
KSIA ESH Chair

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 Taiwan Semiconductor Industrial Association on Safer
Consumer Products Proposed Regulations

Dear Ms. Von Burg:

On behalf of the Semiconductor Industry Association (SIA) of Taiwan, 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).

Semiconductor Industry Association (SIA) of Taiwan is the trade association of the semiconductor industry in Taiwan. More information about our organization can be found at www.tsia.org.tw.

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 Semiconductor Industry Association (SIA) of Taiwan 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, would be too complex to be useful for the average consumer, and 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 is flawed 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 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 provide for an adequate implementation period of the process prior to compliance requirements taking effect. And throughout the development of this regulation, DTSC has discounted numerous

comments from the regulated community, including the prior comments of the technology associations.

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

Sincerely,

T. Y. Wu CEO of Taiwan Semiconductor Industry Association (TSIA)
tywu@tsia.org.tw

F. M. Hsu Chair of ESH Committee of TSIA
fmhsua@tsmc.com

A handwritten signature in black ink, appearing to read 'F. M. Hsu', is positioned to the left of the TSIA logo.



February 28, 2013

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

Re: Safer Consumer Products Draft Regulation

Dear Director Raphael:

Sierra Club California strongly supports the Department of Toxic Substances Control's (DTSC) proposed regulation on Safer Consumer Products (SCP) and urges its swift adoption. California needs protection from dangerous exposure to toxic chemicals in products and must not delay such important environmental and public health safeguards.

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

Sierra Club California appreciates the following revisions found in the new draft.

1. The addition of the Water Board/EPA 303(d) list and respiratory sensitizers to the list of chemicals will capture more chemicals that have been proven to wreak havoc in the environment and on public health.
2. The new draft has eliminated most of the disparities between human health and environmental protections.
3. There are more considerations for end-of-life impacts and costs to other governmental agencies and non-profit organizations that are charged with managing waste and environmental cleanup.
4. The criteria for selecting regulatory responses has been improved to give DTSC authority to select solutions on the basis of public costs associated with polluting products and pollutants in waste; speed of environmental benefits; and the demands of other regulatory requirements.
5. There are public comment opportunities throughout the implementation process which will ensure transparency and public trust. However, we are concerned that

trade secret claims may make Alternative Assessment (AA) reviews challenging because of missing information in the redacted version.

6. In section 69505.7 (k) (1), the specification that the AA work plan “must include a description of the process that will be used to identify the factors and associated exposure pathways and life cycle segments that are relevant for the comparison of the Priority Product and the alternatives under consideration, as required under section 69506.3 (b) (4)” will encourage a well thought-through process from manufacturers.
7. We appreciate the clarification that “reliable information demonstrating the occurrence, or potential occurrence, of exposure to a chemical” can be based on monitoring data from treated wastewater sludge and other environmental samples. This will provide DTSC with additional readily available information that can help determine impacts from toxic chemicals.
8. The new draft has clarified the requirement to inform consumers if products must be managed as hazardous waste at the end of life (§ 69506.3 (b) (4)). This will increase the recovery rate of products that need stewardship and arm the public with helpful information on proper disposal.
9. The replacement of the term “ability to” to “potential to” cause harm throughout the regulation decreases the burden of proof that is consistent with the enabling legislation. It is important that manufacturers and DTSC consider early signs of harm from chemicals and contemplate preventative actions.

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

1. Any exemption requests from regulated parties should be open to public input.
2. Longer AA comment period is needed to ensure meaningful scientific input (§69505.1 (d) (2)). Since there is no longer an Assessor Certification program as proposed in previous drafts, DTSC will have to rely on the public and non-profit organizations like ourselves to ensure acceptable AAs are submitted. A comment period of 45 days or less will not provide enough time for meaningful scientific input. We are extremely concerned that DTSC has not established a minimum comment period. We recommend a comment period of no shorter than 90 days for Preliminary AA Reports, draft Abridged AA Reports, and Alternate Process AA Work Plans.
3. Restriction to have the preliminary AA report be in a table format will hinder readability (§69505.7 (g)(1)). The Preliminary AA report should “summarize” rather than “present” all the chemical information collected and the comparison of alternatives in a matrix. Matrices will be unreadable if they are the required format for presenting all of the information, but are acceptable for summarized information. Since the public will be providing the quality assurance reviews of AAs, it is essential that they be readable.

4. There should be criteria for decisions on acceptability of extensions (§69505.7 (k)). Currently, there is no guideline on extensions, and this loophole will create major delays. DTSC should consider providing criteria that will determine whether or not a request for extension should be approved. Potentially, the department can base its decision on a determination as to whether the extension would provide information that is both timely and necessary for regulatory response decisions based on the regulatory response selection principles in section 69506.
5. End of life management requirements need to be established by DTSC (§ 69506.7 (a)). DTSC should set clear standards for collection and management programs in order to ensure proper handling of products at the end of their useful life. We recommend that this be done in consultation with the manufacturers and any stewardship organization that is established. Additionally, § 69506.7 (a) seems to conflict with § 69506.1 (a) (3), therefore might take away DTSC's authority to require management of products that contain a Chemical of Concern (COC) during a long phase-out period.
6. Allowing regulated entities to use private nondisclosure agreement as a reason to keep information from DTSC is problematic (§ 69509). According to this section, those who can provide a nondisclosure agreement that was privately agreed upon between companies are allowed to withhold information from DTSC. This would be an extremely troubling precedent.
7. DTSC should remove the limitations on the initial pilot implementation phase that allows only chemicals that are harmful to people, therefore leaving out environmental pollutants (§ 69503.6 (a)). The first phase, which will set the tone for the rest of the implementation process, should not discriminate against pollutants that pose risks to the environment and natural habitat. If DTSC does not remove these unfortunate limitations, it should commit to including at least one product that harms the non-human environment among its first group of priority products.
8. As currently written, it appears that DTSC would not be able to require engineering control to prevent environmental releases and to provide interim mitigation for environmental impacts (§ 69506.6 (b)).

In addition to specific changes to wording, we would also like DTSC to consider the following general comments.

1. Implementation of the regulation should be immediate and robust to meet expectations established by the enabling legislation, retain public support, and protect the environment and public health.
2. We continue to believe that the initial program is too small at 2 to 5 products, even for a pilot phase. DTSC can only retain public support if it immediately launches the regulatory process to establish its workplan for priority products that will be reviewed starting January 1, 2016. Starting in 2013 will ensure that the formal regulations to select the next group of priority products are in place before 2016.

3. In renaming the list of chemicals to “Candidate Chemicals” instead of “Chemicals of Concern”, the state has made it harder to communicate to the public that these chemicals are known to harm humans and/or the environment. DTSC must not allow this politically chosen name to obfuscate the fact that “Candidate Chemicals” are harmful and should be avoided.
4. We appreciate that the regulation considers regrettable substitutes, but our organization is still concerned that the design of the regulation may facilitate regrettable substitutions, particularly by assemblers. We suggest that DTSC establish strong communications networks with assemblers and at the time of each priority product listing, provide information about safer alternatives to assemblers to minimize transitions to harmful alternatives.
5. The department should conduct outreach to clarify that the re-introduction of a COC into a product after its removal would again be subjected to an AA, as it will be considered a new product.

Thank you for the opportunity to provide these comments. We strongly support the regulation and feel that they will move us toward safer consumer products.

Sincerely,

A handwritten signature in cursive script that reads "Annie Pham". The signature is written in black ink and includes a long horizontal flourish extending to the right.

Annie Pham
Policy Advocate

February 28, 2013

VIA EMAIL
gcregs@dtsc.ca.gov

Ms. Krysia Von Burg
Regulations Section
California Dept. of Toxic Substances Control
1001 "T" Street
P.O. Box 806
Sacramento, CA 95812-0806

Re: Comments on the January 2013 Draft Safer Consumer Products Regulations R-2011-02

Dear Ms. Von Burg:

Sigma-Aldrich Corporation, along with Avantor Performance Materials, Inc., Life Technologies Corporation, Thermo Fisher Scientific Inc., and Alfa Aesar (a Johnson Matthey company) appreciate the opportunity to comment on this latest draft of the California Department of Toxic Substances Control's (DTSC) Safer Consumer Products regulations. Sigma-Aldrich Corporation submits these comments on behalf of these companies.

Company Information

Sigma-Aldrich Corporation is a leading life science and high technology company, operating in 38 countries with nearly 9,000 employees. Our chemical and biochemical products and kits are used in scientific research, including genomic and proteomic research, biotechnology, pharmaceutical development, the diagnosis of disease and as key components in pharmaceutical, diagnostic and other high technology manufacturing. Sigma-Aldrich provides thousands of chemicals for such uses, often in small or limited quantities. Sigma-Aldrich currently has over 6,000 customers located in California, including research laboratories, universities and testing laboratories.

Avantor Performance Materials, Inc. manufactures and markets high-performance chemistries and materials around the world under several respected brand names, including the J.T.Baker[®], and Macron Fine Chemicals[™] brands. Avantor products are used in a wide range of industries including in academic, industry and quality control laboratories for research, pharmaceutical production and medical lab testing. Avantor Performance Materials supplies its products to many customers located in California though both direct sales and through distributors.

Life Technologies Corporation (NASDAQ: LIFE) is a global biotechnology company with customers in more than 160 countries using its innovative solutions to solve some of today's most difficult scientific challenges. The company provides more than 50,000 products for agricultural biotechnology, translational research, molecular medicine and diagnostics, stem cell-based therapies, forensics, food safety and animal health. Life Technologies is headquartered in Carlsbad, California and employs more than 10,000 people, including roughly 3,000 Californians.

Thermo Fisher Scientific Inc.'s mission is to enable our customers to make the world healthier, cleaner and safer. With revenues of \$12 billion, we have approximately 39,000 employees and serve customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as in environmental and process control industries. We create value for our key stakeholders through three premier brands, Thermo Scientific, Fisher Scientific and Unity Lab Services, which offer a unique combination of innovative technologies, convenient purchasing options and a single solution for laboratory operations management. Our products and services help our customers solve complex analytical challenges, improve patient diagnostics and increase laboratory productivity.

Alfa Aesar, part of the Johnson Matthey group of companies, is a leading global manufacturer and supplier of research chemicals, metals and materials. For more than 45 years, Alfa Aesar has supplied high purity raw materials to researchers involved in a wide variety of R&D applications. Our high purity compounds and metals have been used frequently by electronics companies, physics laboratories, and academics, including 50,000 researchers in California. We supply virtually every college and university lab in the state. Today, through our comprehensive catalog and web site, we offer over 40,000 products, usually in gram to low kg quantities. We are a one-stop source for research chemicals, metals and materials.

Collectively, we support green chemistry initiatives that are grounded in sound science. However, it is imperative that such initiatives be reflective of how potentially-subject chemicals are sold and used. Our customers include sophisticated laboratories, universities and companies engaged in research and development ("R&D"), and some of the largest industrial and pharmaceutical companies in the world. These customers purchase our highly-specialized products for very specific purposes upstream and separate from the direct manufacture of consumer products. The employees of these customers are trained extensively in the safe use, handling and management of our products. We sell products business-to-business, rather than to the average retail consumer. Among our customers are the advanced research laboratories of the University of California system and leading private research institutions, such as Stanford University and the Salk Institute. Nonetheless, the current draft of the Safer Consumer Products Regulations would arguably subject virtually every product available for purchase in California, or that travels through California, to the costly and burdensome review required by the regulations, regardless of the type of product, specific needs of the purchaser, or sophistication of the purchaser.

Some of our customers produce FDA-approved therapeutics and devices – finished products that are exempted from the subject regulations. The proposed regulations, however, risk choking off the very R&D that enables such breakthrough products to be developed. The proposed regulations would likely have a severe and negative impact on biotechnology advances in California which, by their very nature, involve hazardous work, but only in the most controlled and regulated settings. It is within the purview of the DTSC to "gap fill" this anomaly by extending the exemption for FDA-approved products to the preceding R&D environment or through one of the exemptions proposed below, and we strongly urge the DTSC to do so.

We have many of the same concerns that other commenters have detailed with respect to the proposed regulations, such as a concern about dual and conflicting obligations with other regulatory programs, the need to protect valuable intellectual property, commercial information and trade secrets, and the very short timelines for conducting alternatives analyses. We also support reasonable *de minimis* limits for Chemicals of Concern in final consumer products. However, because these issues have been addressed by others, we are focusing this comment on the need for codified exemptions to the Safer

Consumer Products Regulations to protect important research conducted in environments that are far removed from retail customers. We propose exemptions for research and development materials, chemicals used in a laboratory setting, chemicals manufactured and used in low volumes and bulk chemicals. Moreover, it is necessary that such exemptions be self-implementing; otherwise, many of the cost and burden benefits of such exemptions can be lost through the need to prepare, submit and review applications.

Fundamental Concepts Applicable to Each Proposed Exemption

Two fundamental concepts apply to each of the exemptions proposed herein. First, workers employed in laboratory, R&D and manufacturing settings are sophisticated in handling and using chemicals, and are already protected by a myriad of laws designed to prevent harmful human and environmental exposure to chemicals. Second, and in the laboratory and R&D settings in particular, chemicals are often used for a very specific purpose for which there is no functional alternative. Without these exemptions, the very lengthy and costly alternatives analysis process set forth in the proposed regulations could be triggered, the results of which will tell us what we already know with respect to the subject chemicals: Because so many of these chemicals are used for very specific uses, like diagnostic tests, laboratory and analytical work, or R&D work, there is no effective substitute. To go through DTSC prioritization, let alone an alternatives analysis, is not an efficient use of DTSC or industry's resources, nor does it provide any increased protection of the environment or human health.

DTSC Should Include an R&D Exemption in the Safer Consumer Products Regulations

As the term "consumer products" is currently defined in the draft regulations, thousands of products that are used only in a laboratory or R&D setting and pose no risk to retail consumers would be included. It could include thousands more that are used in both the laboratory/R&D setting and retail product setting. As such, these regulations could have a chilling impact on California's substantial R&D industry by preventing or limiting the research that can be done by universities, pharmaceutical development companies and other institutions.

Regulatory programs currently exist which are designed to warn and inform researchers of the hazards associated with chemicals they use in their work. These programs regulate the handling and use of such chemicals and are enforced by regulatory bodies such as OSHA, Cal OSHA, US EPA, California EPA, the Department of Transportation, and the Department of Homeland Security. As a practical matter, for many chemicals that may be deemed to be a hazard to human health, there are no "safer alternatives" as called for in the proposed regulations because of the very specific purposes or functional requirements of the chemicals. Ironically, if the draft regulations are implemented without an R&D or laboratory exemption (as discussed below), DTSC and industry may be unable to procure the analytical products and research standards needed in order to test for Chemicals of Concern.

Without an R&D exemption, many key substances and reagents may become unavailable to the academic, biotechnology, electronics and pharmaceutical markets in California. These substances and reagents have been vital in elucidating the human genome, finding novel ways to treat and cure disease and protecting the environment through discovery of novel renewable fuel sources. Should they become unavailable, the societal and economic impact to California and elsewhere could be substantial. An R&D exemption is vital to maintain the supply chain of value-added substances into the academic, biotechnology, electronics and pharmaceutical manufacturing and development laboratories.

For these reasons, we recommend that the DTSC incorporate an exemption into the Safer Consumer Products regulations to exempt products (i) manufactured for R&D use or manufactured in an R&D setting, or (ii) manufactured for use as standards or for other tests used to determine whether Chemicals of Concern are present in the environment or in a particular product or material. A model for this exemption already exists in Section 5(h)(3) of the federal Toxic Substances Control Act, which exempts manufacturers and processors who manufacture or process a substance “only in small quantities solely for the purposes of scientific experimentation or analysis, or chemical research on, or analysis of such substance, or another substance, including such research or analysis for the development of a product.” This exemption (and the regulations promulgated to apply it in 40 C.F.R. Part 720) is well-understood in the relevant industries, and would allow for consistency between the federal toxic chemicals regulatory program and the Safer Consumer Products Act regulations.

DTSC Should Include a Laboratory Exemption in the Safer Consumer Products Regulations

For many of the same reasons that an R&D exemption is justified, an exemption for laboratory use is also justified. Laboratory workers are typically very familiar with the chemicals with which they work, existing laws protect the health and safety of laboratory workers, and the chemicals often used in laboratory work are specific to the application and there is no functional substitute. Although there would be overlap between some R&D settings and a laboratory setting, there is not complete overlap because some R&D work may not take place in a traditional laboratory, and not all laboratory work is traditional research and development (medical diagnostic work, for example). Accordingly, we request that DTSC include in the final Safer Consumer Products regulations an exemption for chemicals intended for laboratory use.

DTSC Should Include a Low Volume Exemption in the Safer Consumer Products Regulations

In addition to the *de minimis* limit, we suggest adding a low volume exemption. As many chemical substances are actually made in ‘laboratory-scale’ or ‘gram’ quantities, it is financially onerous to conduct exhaustive toxicology and alternatives assessments, especially when the product is meant for contained use by technically qualified individuals. It will also be onerous for the DTSC to review all such applications. As noted above, if the regulations constrain academic and commercial R&D, product development will be curtailed and downstream applications benefiting the public and the environment may be stymied.

DTSC Should Reinstate the Bulk Chemicals Exemption in the Safer Consumer Products Regulations

The exemption for bulk chemical products, which was included in the October 2011 informal draft regulations, should be reinstated. This provision exempted “[a] bulk chemical that is placed into the stream of commerce in California and that meets the definition of a “consumer product,” as defined in Health and Safety Code Section 25251, but that is not packaged for sale to, or end-use by, a retail consumer.” Such bulk chemicals, whether manufactured in quantities of milliliters or tons, are not intended for direct sale to unsophisticated retail consumers; rather, they are intended for intermediate uses, e.g., by manufacturers for the purpose of manufacturing end-use products that will then be made available to others, perhaps including retail consumers.

This exemption would help DTSC maintain focus on retail consumer products that are typically used in the home, which, because of the lesser sophistication of the consumers, pose greater management challenges and therefore, perhaps, greater risk. This is the class of products that the DTSC can most impact in terms of the protection of human health and the environment. These are also the products that are the target of the law that forms the very foundation of this regulatory program.

Importantly, this exemption would not altogether exempt chemicals from review under the Safer Consumer Product regulations. Such chemicals would still be reviewed if, after sold by the manufacturer in bulk, they are later incorporated into a retail consumer product. The exemption we propose would simply allow chemicals to be exchanged in commerce upstream of the retail setting (between a chemical manufacturer and an end-use product manufacturer, for example) without the unnecessary burdens imposed by the draft regulations. Once a chemical becomes an ingredient in a retail consumer product, however, the manufacturer of that retail consumer product could be required to comply with the draft regulations. This is a more appropriate place for the obligations such as the alternative analysis to lie, because the retail product manufacturer will have better access to the technical and commercial information required by the draft regulations to be considered. A bulk chemical manufacturer that does not sell to retail consumers is unlikely to have this information, particularly for bulk chemicals that may have dozens or hundreds of different downstream applications.

Conclusion

As indicated, we are supportive of green chemistry efforts, but believe that those efforts must reflect the realities of the many different ways in which chemicals are used, and must not sacrifice innovation. These exemptions may not seem significant to many, but they would go a long way towards protecting the work of universities, medical diagnosticians, analytical laboratories, and researchers and developers, without sacrificing the goal of protecting human health and the environment.

We appreciate your consideration of these comments. Should you have any questions, please do not hesitate to contact Leigh Davidson, Sigma-Aldrich Regulatory Affairs Attorney, at (314) 286-7416.

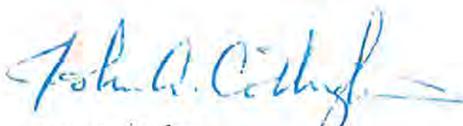
Sincerely,



George L. Miller
Senior Vice President, General Counsel and Secretary
Sigma-Aldrich Corporation



Michael F. Rettig
Executive Vice President and General Counsel
Avantor Performance Materials, Inc.



John Cottingham
Chief Legal Officer
Life Technologies Corporation



Seth H. Hoogasian
Senior Vice President, General Counsel and Secretary
Thermo Fisher Scientific Inc.



Amy L. Donohue-Babiak
Associate General Counsel
Johnson Matthey Inc. (for Alfa Aesar)



Silicon Valley Toxics Coalition
PO Box 27669
San Francisco, CA
94127

February 28, 2013

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

RE: Comments on Draft Regulations for Safer Consumer Product Alternatives

Dear Director Raphael:

The Silicon Valley Toxics Coalition (SVTC) has long been an advocate for the development of a 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. **We support the development of regulations that would promote the re-design of these problem products.**

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

While **we 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:

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.

(3) 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:

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*

- (8) 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.~~*

We believe California should be a leader in creating producer responsibility systems that drive green design and innovation for sustainability.

Sincerely,



Sheila Davis
Executive Director
Silicon Valley Toxics Coalition

February 28, 2013

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

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

Re: Comments on Revisions to Proposed Regulations (Released January 29, 2013)

Dear Ms. Von Burg:

On behalf of one of our clients, this letter provides comments on the January 2013 revised proposed regulations ("Revised Proposed Regulations") known as the Safer Consumer Products Regulations (proposed 22 CCR §§ 69501 - 69510). The comments are ordered according to section.

Equivalent Federal or State Regulation

We applaud the provisions in section 69501(b) stating that regulations do not apply to consumer products that are regulated by one or more federal or state programs and that provide equivalent protections. We also support the consideration of equivalent programs in the prioritization process, as reflected in section 69503.2(b) of the Revised Proposed Regulations.

Key Prioritization Factors

The July 2012 key prioritization factors present a superior basis for prioritization. There is no basis upon which one can say that "potential exposure" and "potential . . . to contribute to or cause significant or widespread adverse impacts" is more important than "a significant ability to contribute to or cause adverse public health and environmental impacts" and "a significant ability . . . to be exposed . . . in quantities that would contribute to or cause adverse public health or environmental impacts." The prior language is more concrete and describes a more compelling subject of green chemistry focus. Thus, we urge the Department to utilize the key prioritization factors identified in the prior version of section 69503.3.

The Regulations Should Focus on Consumer Products

The Revised Proposed Regulations expand the factors to consider for prioritization to include the "workplace presence" of a chemical in proposed section 69503.3(b). This consideration is inconsistent with the statute's repeated focus on "consumer products," a category of products that by definition is not present in the workplace. The Department should not adopt this expansion of the regulations to emphasize workplace exposures.

Conclusion

As we have noted previously, the definition of person is unduly broad and conflicts with the statute's focus on consumer products. We also have noted serious concerns about the trade secret provisions of the regulations. We continue to believe strongly that the definition of person should be narrowed and that serious revisions should be made to better protect trade secrets and to ease the burden of compliance.

Sincerely,



Gary M. Roberts

GMR:aa

30398863IV-1



February 28, 2013

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

RE: Safer Consumer Products – Revised Regulations

Dear Debbie:

My sincere thanks to you—and the entire regulatory team—for your dedication to development of practical, meaningful, scientifically sound, and legally defensible regulations that promote development of safer consumer products. I have thoroughly and carefully reviewed the revised regulations. As a member of DTSC’s Green Ribbon Science Panel, I am pleased to be able to reaffirm my assessment that the proposed regulations have a solid scientific basis.

Although I lament the removal of the Assessor Certification program, which was the major quality assurance mechanism for Alternatives Assessments, I found many changes that will improve the quality of the regulatory program. I particularly commend DTSC for improving its capability to address impacts of consumer products on the non-human environment (particularly the addition of California’s Clean Water Act Section 303(d) list to §69502.2(a)) and enhancing the practicality of the regulatory program through the revised approach for selection of the Alternatives Analysis Threshold and the improved and clarified regulatory response selection principles in §69506.

While the regulations could be adopted as proposed, I recommend that DTSC strongly consider a few minor corrections before finalizing the regulations. These are listed below.

A. Alternatives Assessments – Public Comment Periods

As drafted, the regulations could allow public comment periods on Preliminary Alternatives Assessments (AAs) to be as short as one day. I doubt this was DTSC’s intent. Since DTSC intends to rely on scientists like myself to provide quality assurance reviews, it must provide sufficient time for these reviews. When DTSC selects a public

review time period, it needs to account for the fact that many reviewers will need to fit their reviews within the context of their already busy professional scientific workdays.

One element of my professional work is reviewing similarly complex scientific documents (pesticides environmental risk assessment work plans) on for government agencies. In my experience, quality scientific reviews cannot be completed in less than 60 days. Before U.S. EPA established a mandated minimum review period, my colleagues and I faced review periods as short as nine days, which precluded meaningful input. My colleagues and I struggle to complete scientifically robust reviews and to finish peer reviewed scientific comment letters within U.S. EPA’s usual 60-day comment periods.

Based on my professional experience, I strongly recommend that DTSC establish a minimum comment period of 60 days. To provide for appropriate management-level oversight of scientific reviews conducted by your government agency colleagues, and as a professional courtesy for the scientists that DTSC anticipates will provide pro-bono scientific reviews, a 90-day review period is preferable.

DTSC could potentially make a very minor modification in §69505.1(d)(2) to rectify this problem:

(2) 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. The notice shall include the time period, not less than sixty (60) days and not to exceed forty five (45) ninety (90) days, during which the public may submit comments, and the method(s) for submitting comments. Any public comments on these documents must be submitted to the entity that submitted the document to the Department with a copy submitted simultaneously to the Department.

B. Alternatives Assessments – Criteria for DTSC Decisions on Time Extensions

The revised regulations do not specify criteria for DTSC’s decisions on potential time extensions for submittal of AAs. Timeliness of the AA process is critical to the success of the regulations. Without standards, DTSC will have difficulty refusing extension requests. DTSC needs to be able to balance the management value of the information that would be obtained with an extension against the need for timely action on the priority product. The regulations already include a regulatory response principle (§69506 (c)(1)(A)) requiring similar balancing of interests.

Although this may seem like a very small item, experience with similar processes in the pesticide regulatory world shows that this small provision could have major repercussions for DTSC’s ability to obtain timely regulatory responses on priority products. California Department of Pesticide Regulation (DPR) has a process called “Reevaluation” to address harm to environmental or human health that occurs after a pesticide is registered. Like the Safer Consumer Product regulatory process, DPR’s

Reevaluation process involved identifying products to place into Reevaluation, requiring manufacturers to conduct scientific evaluations of the product, and then using the information to make regulatory decisions. Although state regulations specify that the scientific study portion of this process should not last more than two years, California pesticide Reevaluations have lasted an average of more than ten years. A major reason that Reevaluations are so lengthy is that manufacturers request for more time for scientific studies—and then request additional time for follow-up studies. DPR’s regulations do not provide criteria for evaluation of these requests, which are ordinarily granted based on the desire to make a well-informed regulatory decision. In the meantime, the product continues to be sold and used in the same manner that it was prior to the initiation of the Reevaluation.

A minor modification in §69505.8 (b)(4)(A) could potentially address this, for example:

(A) 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. The Department shall specify a due date twelve (12) months from the date the Department issues the notice of compliance, except that if it determines that an extension could provide information with the potential to substantially modify the Department’s weighing of the selection factors in §69506 (c)(1)(A), the Department may specify an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report if the responsible entity submits a request under section 69505.7(k)(1)(B), if the Department determines that an extension could provide information with the potential to substantially modify the Department’s weighing of the selection factors in §69506 (c)(1)(A).

C. Regulatory Response – End-of-Life Management for Priority Products with Long Phase-Out Periods

The drafting of the End-of-Life management requirements in §69506.7 (a) does not clearly include Priority Products that will remain in commerce pending development and distribution of a selected alternative (§69506.1 (a)(3)). I encourage DTSC to clarify that products with long phase-out periods may require interim end of life management programs. This could be accomplished with a minor modification to §69506.7 (a):

(a) Applicability. A manufacturer of a selected alternative, or a product listed in §69506.1 (a) Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall comply with the requirements of subsection (c) except as otherwise provided under subsections (d) and (e).

D. Regulatory Response – Engineered Safety Measures or Administrative Controls

In its effort to maintain consistency with the law’s goal of promoting development of safer products, DTSC crafted a very narrow authority to require engineering controls that prevent human and/or environmental exposures to chemicals of concern or replacement candidate chemicals in Priority Products. This authority is so narrow that it appears to preclude the use of engineering or administrative controls for pollutants that harm the non-human environment. DTSC may wish to be able to require such controls, particularly in the case of Priority Products that will remain in commerce for long periods pending development and distribution of a selected alternative. For example, during the 15-year transition to very low copper brake pads, the state could have required installation of a device on vehicles to collect brake pad wear debris (there exists a simple, currently patented device that could collect most copper emitted from brake pads), thus mitigating the impacts of the lengthy transition period.

It would also be helpful to clarify that §69506.6 applies to all categories of products subject to DTSC’s regulatory response authorities (i.e., all products listed in §69506.1 (a)).

Only minor modifications to §69506.6 would be necessary to accomplish these changes, for example:

- (a) Requirement for Controls. The Department may require a manufacturer to engineer safety measures that integrally contain or control access to, and/or implement administrative controls that limit exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s) in a selected alternative, or ~~the Chemical(s) of Concern in a Priority Product for which an alternative is not selected~~ any product listed in §69506.1 (a), to reduce the potential for adverse impacts.
- (b) Criteria. Engineering or administrative controls may be required if one or more of the following applies:
 - (1) Reliable information indicates the presence of the Chemical(s) of Concern or replacement Candidate Chemical(s), or its/their degradate, metabolite, or reaction products, in a particular subpopulation that has one or more routes of exposure to the chemical(s);
 - (2) Reliable information indicates an elevated level of the Chemical(s) of Concern or replacement Candidate Chemical(s) in an indoor building or other enclosed environment; and/or
 - (3) Improper product handling increases the potential for release of, or exposure to, the Chemical(s) of Concern or replacement Candidate Chemical(s).
 - (4) The Priority Product will remain in commerce pending development and distribution of a selected alternative (§69506.1(a)(3)) and has adverse environmental impacts or adverse waste and end-of-life effects.

E. Presentation of Alternatives Assessment Results

In §69505.7(g)(1), DTSC seeks to ensure that Alternatives Assessments include easily readable summary matrices. Such summary matrices are standard practice in Alternatives Assessments. Read literally, however, this section does not require an easily readable matrix—it requires that all of the information required in §69505.5 be “presented” in a matrix format (i.e., the matrix is the sole method for presenting the information in the report). This would result in an unwieldy, unreadable table no matter how hard the preparer attempted to create the required easily understood visual comparison.

As a consultant, I have faced scopes of work with similar wording, which have required preparation of large format tables with tiny font. These tables served no functional purpose. Such tables cannot readily be printed, nor readily viewed on a computer screen—a frustration for reviewers.

DTSC can make a simple one-word change to §69505.7(g)(1)(B) that will ensure that it receives summary tables with accompanying text that together present and summarize the information:

(1) The Preliminary AA Report must include the information collected and the comparison conducted under section 69505.5 for the Chemical(s) of Concern and the alternative replacement chemical(s). The information and comparison must be ~~presented~~ summarized in a matrix, or other summary format, that provides a clear visual comparison among the chemicals and their associated adverse impacts.

Conclusion

Thank you for the opportunity to assist DTSC with the scientific portion of the development of these regulations in my role as a member of the Green Ribbon Science Panel. I look forward to assisting DTSC with the science behind their implementation.

My professional work, which centers on solving water pollution problems, continues to unearth new linkages between consumer products and water pollution. DTSC’s Safer Consumer Product Regulations provide the much-needed pathway toward improving water quality, environmental quality, and human health in a scientifically solid, practical manner that does not inadvertently create new pollution problems. I urge you to move forward quickly with adopting and implementing these regulations.

Sincerely,

/s/

Kelly D. Moran, Ph.D.
President

Dear Ms. Von Burg:

We understand that the ultimate goal of the SCP program is elimination of problematic constituents from society, to the greatest extent practicable. We further recognize that traditional risk assessment focuses on a subset of the possible spectrum of exposure and that the Alternatives Assessment process, as advanced by the State of California, seeks to evaluate the potential for adverse impact at every stage of the manufacturing, use and disposal sectors of commerce/commercial products. A major failing in the traditional Alternatives Assessment is the omission of a defensible exposure assessment to underpin the public health impact analysis. An assessment of the mechanism of delivery and degree of exposure (dose) is fundamental in such decisions requiring good science. An assessment of the potential for public health impact, which does not take into account the mechanism of exposure and dose will not be effective and may be untenable in practice over the long term.

Much has been made of the uncertainty underpinning exposure assessment (within the context of risk assessment) as a process to support Alternatives Assessment. Elimination of risk assessment and an exposure analysis will not improve the overall process. The uncertainty associated with assumptions regarding exposure is not the most significant influence for consideration. The seminal studies upon which toxicity classifications are predicated, and their application, are often associated with significant uncertainty – it is not difficult to appreciate the concept of extrapolation from high dose/short term studies in animals to chronic/very low dose exposures in humans. The additional uncertainty and modifying factors which adjust the promulgated criteria themselves, is significant. Risk assessment has been the chosen format for assessment of public health for decades and enjoys a level of development, maturity, and acceptance within most health-centric programs, fundamental to American society.

It is our understanding that in Stage Two of the Alternative Analysis process, as described, there is the opportunity to consider relevant information inclusive of “public health impacts” in a comparison of alternative constituents. Much of any legislative initiative is open to interpretation, so our comment is simply to urge your department to ensure that there is the opportunity to assess health impact predicated on actual exposure within the context of the Alternative Analysis, as described. One cannot ignore the form of a given constituent in the marketplace and if the opportunity for direct or indirect contact is effectively nil, this fact should be considered in any defensible management decision.

We appreciate the opportunity to comment on this important piece of legislation and we thank you for your time and attention.

Sincerely,

for TechLaw, Inc.

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Test & Measurement Coalition Comments on Proposed
Safer Consumer Product Regulations (Green Chemistry) of July 2012/3

Introduction:

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

The Test & Measurement Coalition has previously provided comments on informal drafts of the California Safer Consumer Product Regulations when it was understood to impact the industrial manufactured products sector. We are now providing a second comment on the draft regulations to further request the clarification of the scope of the Regulation, especially considering the title of "safer consumer" and the definition of 'consumer' inherent in the scope of products to be covered by the regulations. As a starting basis for the definition of "consumer products", the United States Consumer Product Safety Act has an extensive definition of **consumer product**, which begins:

The term "consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include— (A) any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer,

This definition clearly aims to exclude Professional Sale to non-households, Industrial sale to non-households, and in general the Business to Business (B2B) transactions. The definition in the Health and Safety Code section 25251 (referenced in the Green Chemistry Regulation) is very broad, and not specific. The Coalition members are very concerned about the impact the overly-broad definition of the terms 'consumer' and 'consumer product' in the regulations will have on the test and measurement industry and consequently on the competitiveness of downstream customers who require test and measurement equipment to enable innovation in design, quality in manufacturing and accuracy in data acquisition.

The design and qualification process, volume of product placed into commerce, product life, and customer base related to the industrial test and measurement sector are very different than those for typical manufactured consumer products, and the cost involved in analysis of these products is disproportionate. They cannot be treated in the same fashion as consumer based manufactured products which enjoy a much more rapid design and manufacture cycle, and large development teams. We therefore respectfully request that industrial test and

measurement equipment be excluded from the scope of the Safer Consumer Product Regulations as was done for professional medical devices, which have similar design imperatives.

General Comments:

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

The T&M consortium acknowledges that we have an obligation to ensure our products are designed to be environmentally sensitive (low power consumption, low weight, easy to disassemble and recycle, designed with as few hazardous substances as possible, and of course, safe). However, the proposed regulation of full chemical analysis of our complex products is a disproportionate burden, and will require a large investment in internal and external resources, as well as take away resources for development of new products.

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

Specific Comments by Section:

Section 69501. Purpose and Applicability

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

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

Section 69501.2 Definitions

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

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

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

Conclusions

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

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

For the Test & Measurement Coalition:



Eric McLean
Anritsu Company
Morgan Hill, Ca. 95037
408-201-1907



February 28, 2013

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

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

Dear Ms. Von Burg:

Below please find a summary and detailed discussion of key concerns from the Toy Industry Association (TIA) regarding the Department of Toxic Substances Control (DTSC or Department) Proposed Regulations for Safer Consumer Products (Proposed Regulations) under Assembly Bill 1879 and Senate Bill 509 (2008). We remain concerned about the current structure and requirements of this proposed regulation, and believe that without further changes many provisions will be unworkable and the regulation will not achieve its intended purpose.

TIA appreciates that the Department has made significant efforts to attempt to address concerns in some areas of the regulation, however other areas have been made more burdensome and/or complex, or remain flawed. Overall these regulations lack the transparency and predictability necessary to both operate and achieve the goals of a program of this magnitude. TIA strongly believes that through some additional changes and restructuring, it is possible for DTSC to create a regulatory proposal that protects human and environmental health, while minimizing negative effects on commerce and product innovation.

These comments are in addition to, and incorporate where relevant, previous comments submitted to the Department by TIA on July 20, 2010, November 1, 2010, December 3, 2010, December 30, 2011, May 30, 2012, and October 11, 2012. TIA continues to urge the Department to seriously consider compromise and progress toward reaching a workable solution that is consistent with existing requirements in other states. Considering the stringent regulations and burdens already imposed on our industry consistency between states on key issues is critical to workable Green Chemistry Regulations.

TIA is a not-for-profit trade association representing more than six-hundred (600) toy makers, marketers and distributors, large and small, located throughout North America. California is responsible for roughly 22.0% of the nation's total toy industry activity, more than any other

state. Additionally, Toy Industry Association members employ more than 32,000 employees in California with a direct economic impact of more than \$6 billion to the state.

TIA is founded on the mission of bringing fun and joy to children's lives. In that pursuit protecting the safety of our young consumers is our top priority, and TIA and our members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S. risk-based standards are widely recognized and used as models around the globe. TIA regularly conducts education seminars on these industry standards, and to educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

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

Part of the Department's charge in crafting regulations is to take the most effective and least burdensome approach to meeting its statutory mandate. Additionally, it is a basic tenet of good regulation that those being regulated must understand what is being regulated and be able to predict the effect of that regulation on their products; in this the Department continues to be unsuccessful. Addressing the following issues would create a more effective and workable program, while minimizing the burden these regulations will place on the California and United States economies:

Changes Necessary to Prioritization Factors

- 1) Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2]:** As DTSC acknowledges in their "Initial Statement of Reasons" (ISOR) [Section 69503.2], there is little to no exposure to a "Chemical of Concern" (CoC) from inaccessible components. TIA agrees with the Department's assessment on this issue; however the regulation only loosely addresses it as a factor for the Department to consider during prioritization.

In order to provide appropriate focus to the prioritization process, there is a need to define "inaccessible components" and remove these components from prioritization. This approach is consistent with California's statute – § 25252(a) of the statute directs DTSC to consider potential exposure and exposure pathways which supports the exclusion of inaccessible components from coverage by the regulation. It is also consistent with similar laws regulating chemicals in children's products in Washington State and Maine, and on the federal level under the Federal Hazardous Substances Act and the Consumer Product Safety Improvement Act. Internationally, chemical regulation in Canada and the European Union also recognizes and exempts inaccessible components.

Failure to remove inaccessible components from prioritization will result in costly and burdensome testing and analysis of components from which there is no exposure risk to the consumer. Additionally, the Department will waste valuable time and resources evaluating these components instead of focusing where there is potential for exposure.

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

We further suggest that if a definition of “inaccessible” is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 is appropriate for children’s products up to age eight, and can potentially be modified for other types of products.

- 2) **Link Between Priority Products and Potential Exposure [Section §69503.2]:** Currently, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include “reliable information regarding exposures.” What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. TIA is interested to know on what basis DTSC determines that a specific product is a significant contributor to the pollution or bioburden, or even that it contributes at all? The current stance of the Department places the burden of proof (to prove a negative) on those being regulated, rather than the Department having a duty to establish with a reasonable degree of certainty that a specific product is a significant contributor to the exposure.

In order for this regulation to be both workable and effective, when determining priority products DTSC must demonstrate:

- 1) **That a priority chemical poses a significant hazard to human health and the environment;**
- 2) **That a priority product may reasonably be expected to contain the priority chemical in a significant quantity;**
- 3) **That a human and environmental exposure exists (of which the only acceptable evidence is consistent presence in air or water monitoring data or in biomonitoring data); AND**
- 4) **That the priority product is a significant contributor to the observed exposure data.**

Products that are a minimal contributor to exposure should not be listed as a “Priority Product.”

- 3) **Definition of “Complex Durable Products” [Section §69503.5]:** TIA understands that the Department’s intent in denoting a class of products which are “complex durable products” is to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products

with far fewer than 100 components may still be quite complex, and it is arbitrary and capricious to summarily discriminate against children's product makers by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children's products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

- 4) **Consider All Factors Related to Impact and Exposure [Section §69503.2]:** The Department's product-chemical identification and prioritization process in Section 69503.2 requires the department to consider "one or more" factors related to impact and "one or more" facts related to exposure. **The Department should be required to consider in totality "...all factors listed in § 69503.3 (a) or § 69503.3 (b) for which information is readily available..."** TIA recommends the Department strike "one or more" where it is utilized in section § 69503.3 (a) and (b).

Alternatives Analysis Process Needs Restructuring

- 1) **Alternatives Analysis (AA) Threshold/ De minimis:** TIA appreciates that the Department has recognized the distinction between "intentionally-added" ingredients and "contaminants" in this draft of the regulation. However, the regulation establishes that the AA threshold only applies to contaminants present below the Practical Quantification Limit (PQL). We are disappointed to see that DTSC has rejected the concept of a *de minimis* level, or a clear and predictable AA threshold level, being exempt. Additionally, TIA questions how DTSC expects entities to file an "AA Threshold Notification in Lieu of AA" stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured.

The regulation should exempt "contaminants" below a set de minimis level or where a manufacturer has a "due diligence" system – Manufacturing Control Program (MCP) – in place, as other states have done. We continue to recommend the following structure in order to focus Responsible Entity and Department time and resources where they will be most effective:

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

- 2) **AA Threshold Notification in Lieu of AA [§69505.3]:** The overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department and manufacturers will be overwhelmed by unnecessary paperwork under this provision, and consumers will be overwhelmed with information that is likely to be confusing and misleading. The process requires the release of proprietary data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

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

- 3) **Alternatives Analysis Process [Article 5]:** TIA appreciates that the Department has removed the “certified assessor” requirement from the AA process. However, under the new structure, AAs (including preliminary and abridged AAs) would be subject to a public review and comment process. This provision is overly burdensome for the Responsibly Entity, and it is not clear what the Department hopes to achieve through this process given that public comments may or may not be based on reliable or credible information. TIA previously provided comments to resolve issues created with “certified assessors.” If the Department has now rejected that concept, then we recommend that DTSC alone should review and approve AAs. Additionally, only Final AA Reports should be made public in order to protect Confidential Business Information (CBI). If a public comment process is established there should be requirements that comments be based on reliable and credible information.

Additionally, alternatives assessment is core to developing safe consumer products and TIA supports a pragmatic and science-based approach. TIA believes the AA Industry Coalition’s “Product development and improvement paradigm” (submitted to DTSC on October 8, 2012) is a solid basis for an appropriate framework. TIA shares the concerns noted in previous comments from the European Union (EU) that requirements in the draft Regulations for conducting an AA are highly complex, both technically/content-wise and administratively, and DTSC has not documented any feasibility analysis or “beta-testing” to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate.

Regulatory Response Clarification and Focus on Compliance Assistance Requested

- 1) **Focus on Compliance [Article 6]:** Since this Regulatory Program is groundbreaking in terms of its expansive scope, and data submission and analysis requirements, TIA hopes it is the Department's intent to focus heavily on **compliance assistance** in the initial years of implementation, and to avoid unnecessary regulatory responses or penalties on Responsible entities that are working in good faith with the Department to comply with regulation.
- 2) **Listing of Information on the Department's Website [§69501.2, 69501.5, 69501.4 & 69507.1]:** The Department intends to post a Failure to Comply List, regulatory determinations and other information to their website. **It is imperative that any and all information posted to this list or other sections of the Department's website be done only after responsible entities are provided ample opportunity to object to the listing or posting of information, or remedy any compliance issues.**
- 3) **Product Information for Consumers [§69506.3]:** The regulation mandates information required to be made available to consumers prior to product purchase including "A list of any Chemicals of Concern and the known hazard traits." TIA is unclear on the Department's intent with this provision. If a CoC is determined through the AA process to be the safest, most effective material, will products still be required to list the CoC and all the hazard traits even though there is no safer alternative?

Additionally, from a practical standpoint it would be impossible to get all of this information in multiple languages on product packaging or store signage. Having a website address on your package where the info could be found should be acceptable. If the Department intends for this provision to remain in the regulation, **TIA recommends that "Communication to Consumers" requirements be met by "either" website or point-of-sale information, rather than "both" to make this provision manageable for companies.**

Other Key Issues of Concern

- 1) **Regulatory Duplication Applicability [Section §69501 & 69503.1]:** Per the mandates of AB 1879, products where another federal or California State regulation addresses the same risk of injury or environmental threat that has resulted in DTSC prioritizing a chemical or product, must be excluded from further duplicative regulation. The revised regulations provide an exemption for products already regulated, however the Departments retains broad discretion over the determination over this applicability. TIA recommends that the Department strike the subjective language – "meaningfully enhance" – to provide clarity and a true applicability exemption for products already regulated by other laws. It is apparent that this last-minute addition creates a requirement which is beyond the scope of the department's mandate under the statute, and the language is just as clearly unconstitutionally vague.

- 2) **Trade Secrets Protection/CBI issues [Article 9]:** Since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected (Article 10). The nature of the data required to be submitted - once a priority product and chemical concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. **Moreover, Confidential Business Information, which may not fall within the definition of “trade secrets,” should also be protected. Specifically, CBI should be protected during the Product Notification process, and not posted on the Department’s website.**
- 3) **Department Responsibilities and Timelines [Articles 5, 6 & 7]:** This regulation imposes extensive and specified time restrictions on responsible entities, yet relieves the Department of the burden to appropriately respond to deadlines that it has created. This leaves responsible entities without the predictability they need for business plans, and without information they need to plan for investment, budgets, etc. For example, Section 69505.8 establishes that DTSC will review and issue a notice of compliance or disapproval, or ongoing review, within 60 days of receiving an AA. However, Section 69505.1 states that failure of the Department to make a determination for AA within the specified timeframe shall not cause an AA report to be deemed compliant.

Similarly, Section 69505.1 requires responsible entities to file for an AA extension request at least 60 days before its original due date stating that the Department will respond within 30 days. Yet failure of the Department to issue a decision within 30 days does not constitute an approval of the extension request. Finally, in Sections 69507.4 & 69507.6, the regulation gives responsible entities a 30 day timeframe to file a Request for Review while establishing that the Department has 60 days to issue an order granting or denying the Request for Review, OR a notice of ongoing review which only provides an estimated date that the Department expects to issue an order. If a responsible entity has hired resources to assist them with the complex AA process and then they are left awaiting a determination for unspecified period of time this will create additional costs and complications. Additionally, leaving responsible entities with this uncertainty forces them to hold off on making important business decisions and plans which disrupts commerce.

Given the expansive scope of this program, it is likely the Department will be overwhelmed with reports, complexity, questions, etc. By allowing the option to not respond in a timely manner, the regulations lay the groundwork for the Department’s role in this process to become the bottleneck and raises issues of compliance. If a request for an extension is submitted 60 days out and the Department doesn’t respond for an additional 60 days and denies the request, will this be deemed non-compliant? **TIA recommends that the regulations should specify that a responsible entity has met their filing deadlines, and the Department does not respond by its deadlines, all relevant timelines are put on hold until the Department responds.**

- 4) **Responsible Entities [Section §69501.1 & 69501.2]** – The regulation still includes “Retailers” as a “Responsible Entity” even though Retailers, have little, if any, part in the design or manufacturing of the products, and are therefore, unlikely to be able to influence the chemical composition of the product, or have the ability to conduct an AA of the product. Therefore, it is wholly inappropriate for them to share the regulatory burdens in the regulations, even if their responsibilities are the last step in the chain of responsibility after Manufacturers and the Importers.

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

TIA Section Comments

Article 1: General

Section 69501 – Purpose and Applicability

“Potential”: The Department has added the qualifier "potential" to "adverse impacts posed by" the chemicals of concern in the priority products. Adding "potential" as a qualifier will increase the scope of the regulations' impact. The regulations define “potential” to mean that the phenomenon described is reasonably foreseeable based on reliable information. What does "reasonably foreseeable" mean?

This term “potential” is too vague, even as defined ("reasonably foreseeable based on reliable information") and will encompass products that do not have any real risk of exposure. Reliable information is applied to the demonstration of "potential occurrence" of exposures to a chemical. Exposure information is scientifically available by peer-reviewed sources, but "potential" occurrence of exposure unnecessarily broadens the scope of exposure beyond what is scientifically acceptable and proven.

TIA recommends that term “potential” be deleted or appropriately defined.

Section 69501.1 Definitions

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

“Adverse Ecological Impact” – This definition contains several subjective terms that lack standards and clear definition for determining an actual adverse effects. Specifically, “Deterioration or loss of environmentally sensitive habitats” and “changes in ecological

communities” are terms that lack clear definition and exposition regarding how the DTSC will evaluate these impacts.

Alternatives Analysis Threshold”: The regulation defines AA threshold as the PQL for a Chemical of Concern present solely as a contaminant present below the Practical Quantification Limit (PQL). We are disappointed to see that DTSC has rejected the concept of a *de minimis* level, or a clear and predictable AA threshold level, being exempt. Additionally, TIA questions how DTSC expects entities to file an “AA Threshold Notification in Lieu of AA” stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured. TIA recommends for the following structure for an AA Threshold:

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

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

- (21) “Component” means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:*
 - (A) Is required to complete or finish an item*
 - (B) Performs a distinctive or necessary function in the operation of a product or part of a product*
 - (C) Is intended to be included as a part of a finished item*
- (22)(A) “Consumer product” or “Product” means any of the following:*
 - 1. A “consumer product” as defined in Health and Safety Code section 25251;*
 - 2. A component, or uniquely identifiable material within a component, that is identified under section 69503.4(a) (2) (B), as the minimum required focus of an AA.*

“Inaccessible component” – For assembled products there is a need to define “inaccessible components”; which also should be referenced in several key places in the regulation to prevent the regulations from overreaching and focusing on components

where there is no reasonable likelihood of exposure. We further suggest that if a definition of “inaccessible” is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

“Responsible Entity” – Per above comments, the regulation still includes “Retailers” as a “Responsible Entity” even though Retailers, have little, if any, part in the design or manufacturing of the products, and are therefore, unlikely to be able to influence the chemical composition of the product, or have the ability to conduct an AA of the product. Therefore, it is wholly inappropriate for them to share the regulatory burdens in the regulations, even if their responsibilities are the last step in the chain of responsibility after Manufacturers and the Importers.

Section 69501.2 – Duty to Comply and Consequences of Non-Compliance

Failure to Comply List: As discussed above, it is imperative that any and all information posted to this list or other sections of the Department’s website be accomplished only after responsible entities are provided ample opportunity to object to the listing or remedy any compliance issues.

Section 69501.5 – Availability of Information on the Department’s Website

Listing of Information on the Department’s Website: It is imperative that any and all information posted to this list or other sections of the Department’s website be done only after responsible entities are provided ample opportunity to object to the listing or posting of information, or remedy any compliance issues.

Article 2: Process for Identifying Candidate Chemicals

Section 69502.2 – Chemicals of Concern Identification

List of Chemicals: The inclusion of such a broad list of chemicals of concern (CoC), that is estimated to contain 1,200 chemicals, does not provide predictability and certainty to companies. There must be a clear risk & safety-based approach to prioritizing chemicals of concern within these regulations. This is the basis of international chemical regulations; such as the European Union REACH process and the Canadian Domestic Substances List program. Additionally, states like Maine and Washington State have adopted step-wise processes for prioritizing chemicals. While all stakeholders may not agree on the chemicals selected at each prioritization step, this process is necessary to providing predictability and direction to the market-place.

Finally, Alternative Assessments must not fall into the same trap, a rigid prohibition on replacing a CoC with anything on a list, but instead take a more holistic approach – i.e. any proposed alternative must on balance improve the safety and environmental profile of the product. This would not only fulfill the department’s mandate and the intent of the statute, but recognize that improvements will often be incremental, multi-stage efforts.

Article 3: Process for Identifying and Prioritizing Product-Chemical Combinations

Section 69503.1 – Applicability

Regulatory Duplication: As discussed above, the regulations provide an exemption for products already regulated by another entity with respect to the same potential impacts, however the Departments retains broad discretion over the determination over this applicability. TIA recommends that the Department strike the subjective language – “meaningfully enhance” – to provide clarity and a true applicability exemption for products already regulated by other laws.

Section 69503.2 – Priority Product Prioritization

Prioritization Process: Per the comments above, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include “reliable information regarding exposures.” What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. **In order for this regulation to be both workable and effective, when determining priority products DTSC must demonstrate:**

- A) That a priority chemical poses a significant hazard to human health and the environment;**
- B) That a priority product may reasonably be expected to contain the priority chemical in a significant quantity;**
- C) That a human or environmental exposure exists (of which the only acceptable evidence is consistent presence in air or water monitoring data or in biomonitoring data); AND**
- D) That the priority product is a significant contributor to the observed exposure data.**

Products that are a minimal contributor to exposure should not be listed as a “Priority Product.”

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

Section 69503.3 Adverse Impact and Exposure Factors

Use of “Potential”: The regulations have been revised to consider "potential" impacts etc. Again, this qualifier will broaden the reach of the regulations to include Candidate Chemicals that may not actually have any impacts, based on the "potential" for impacts.

Additionally, (G) establishes as a factor, the “potential for the Candidate Chemical to degrade, form reaction products or metabolize into another Candidate Chemical” to be considered an Adverse Impact essentially allows any possible chemical reaction that could create a new Candidate Chemical to be considered as a factor. If Candidate Chemical A could potentially be reacted with any other chemical, to form reaction product Candidate Chemical B, Chemical A would be considered to have an adverse impact even if it was highly unlikely it would ever be combined with the other chemical to create the reaction product B. Anytime potentially is used as a condition, it simply opens the door to any interpretation. TIA suggests a more restrictive adjective such as ‘likelihood’ or ‘probability’ would be more appropriate for this provision.

Exemptions: The regulations no longer exempt from being named a Priority Product: (1) a product that is manufactured or stored in, or transported through, California solely for use outside of California; and (2) a product used in California solely for the manufacture of one or more of the products exempted from the definition of “consumer product”. These conditions will be evaluated during the product prioritization process, during which DTSC will decide whether or not to include such products as Priority Products. This gives DTSC extraordinary discretion to include products that may never have any impact or effects in the State of California.

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

Section 69503.4 Priority Product Work Plan

Work Plan: It is unclear from the regulations if the work plans are a pre-requisite to listing of a Priority Product. Will DTSC give 3 years notice via the work plan for future Priority Product listings? If so, then the second listing of Priority Products will be in 3 years, correct? TIA requests that the Department clarify that there will be no Priority Products listing annually until 3 years after the first work plan (the first three years there will only be the first 5 Priority Products). This would provide greater notice of possible product-chemical combination listings by requiring three-year advanced notice of work plan. No implementation or designation of Priority Products until after 3 years notice would allow product design time to eliminate telegraphed product-chemical combinations from products prior to the listing, which would serve the goals of the underlying statute and minimize the costs to the government.

Section 69503.5 Priority Products List

Complex Durable Products: Per comments above, TIA understands that the Department's intent in denoting a class of products which are "complex durable products" is to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is *arbitrary and capricious to summarily discriminate against children's product makers* by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children's products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

Section 69503.6 – Initial Priority Products List

APA Process: It is unclear from the regulation where DTSC intends the Initial Priority Products List to be subject to the same Administrative Procedures Act (APA) process as future lists. This should be clarified as it is critical that the Initial Priority Products list be given the same review as future lists.

Article 4: Petition Process for Identification and Prioritization of Chemicals and Products

Section 69504 – Applicability and Petition Contents

Waiting Period: This section requires a 3 year waiting period before a petition can be filed to remove a list of chemicals, or a product-chemical combination. If there is evidence supporting removal of a list or product-chemical combination, petitions should be filed and reviewed immediately.

Article 5: Alternatives Analysis

Section 69505.1 – Alternatives Analysis General Provisions

Public Comment Process: As discussed above, AAs (including preliminary and abridged AAs) would be subject to a public review and comment process. TIA is concerned that as drafted DTSC would make the proprietary work and knowledge that a company must perform to complete an Alternative Assessment report publically available. We believe that by making a company's Alternative Assessment report, and their conclusions, public (even if the report is redacted) would jeopardize a company's ability to protect certain information as confidential business information (CBI).

Additionally, this provision is overly burdensome for the Responsibly Entity, and it is not clear what the Department hopes to achieve through this process given that public

comments may or may not be based on reliable or credible information. TIA previously provided comments to resolve issues created with “certified assessors.” If the Department has now rejected that concept, then we recommend that DTSC alone should review and approve AAs. Additionally, only Final AA Reports should be made public in order to protect Confidential Business Information (CBI). If a public comment process is established there should be requirements that comments be based on reliable and credible information.

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

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

Section 69505.3 – AA Threshold Notification in Lieu of AA

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

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

Additionally, TIA questions how DTSC expects entities to file an “AA Threshold Notification in Lieu of AA” stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably measured.

Article 6: Regulatory Responses

Section 69506 – Regulatory Response Selection Principles

Focus on Compliance: As discussed above, since this Regulatory Program is groundbreaking in terms of its expansive scope, and data submission and analysis requirements, TIA hopes it is the Department’s intent to focus heavily on **compliance assistance** in the initial years of implementation, and to avoid unnecessary regulatory responses or penalties on responsible entities that are working in good faith with the Department to comply with regulation.

Section 69506.3 – Product Information for Consumers

Communication to Consumers: Per above comments, the regulation mandates information required to be made available to consumers prior to product purchase including “A list of any Chemicals of Concern and the known hazard traits.” TIA is unclear on the Department’s intent with this provision. If a CoC is determined through the AA process to be the safest, most effective material, will products still be required to list the CoC and all the hazard traits even though there is no safer alternative?

Additionally, from a practical standpoint it would be impossible to get all of this information in multiple languages on product packaging or store signage. Having a website address on your package where the info could be found should be acceptable. If the Department intends for this provision to remain in the regulation, **TIA recommends that “Communication to Consumers” requirements be met by “either” website or point-of-sale information, rather than “both” to make this provision manageable for companies.**

Article 9: Trade Secret Protection

Section 69509 – Assertion of a Claim of Trade Secret Protection

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

A. Add to definition section, Confidential Business Information: *Any information in the custody of a business entity that the business entity reasonably expects to be preserved as confidential in order that the business may obtain or retain business advantage from its rights in the information.*

B. Add a section to the Trade Secrets Provision: *In addition to trade secrets, a claim for Confidential Business Information will be reviewed by the Department to determine if disclosure of such information would cause substantial harmful effects to the claimant, including revealing capital and marketing costs, specialized technical expertise, unusual processes, or unique ingredients, or give competitors access to customers or information that may give them a competitive advantage. The claim shall include details of the substantial harmful effects to claimant, as well as a redacted form of the information.*

Chemical Identity: The trade secret protection provisions pertaining to hazard trait submissions have been revised to allow masking of precise chemical identify only for an alternate chemical being considered or proposed for which a patent application is pending. Masking will only be allowed until the patent application is granted or denied. This provision still does not take into account "recipes" which may not be subject to patent, but provide a competitive business advantage and therefore constitute "confidential business information."

Conclusion:

Product safety is a vital consideration for toy manufacturers. A core requirement of our industry is to perform rigorous testing to stringent federal requirements and in many cases stringent international environmental and safety regulations.

TIA appreciates the hard work that has gone into the development of these Proposed Regulations and attempts to balance many stakeholder interests. TIA asserts that significant revisions are nevertheless still needed before this regulation can be considered workable for industry and the Department.

Once again, TIA remains committed to working to ensure that these Regulations provide a workable solution to chemicals management issues in California that promote public and environmental health without placing undue and unnecessary burdens on business that is not commensurate with the benefit derived.

Thank you for the opportunity to comment. Please feel free to contact TIA directly via Jennifer Gibbons at: jgibbons@toyassociation.org if you have any questions or concerns about these comments or would like to discuss in more detail.

TIA Comments
Proposed Regulation: Safer Consumer Products
February 28, 2013

Respectfully,



Jennifer Gibbons
Director of State Government Affairs

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

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February 22, 2013

Krysia Von Burg
Department of Toxic Substances Control
Regulations Section
PO Box 806
Sacramento, CA 95812-0806

RE: January 2013 Draft of DTSC's Safer Consumer Products Regulation- Comments and Concerns

Dear Ms. Von Burg:

On behalf of Tremco Commercial Sealants and Waterproofing (CSW), I am writing to express both positive comment as well as some concerns over the language in the latest draft of the *Safer Consumer Products Regulation (SCPR)*.

Introduction to Tremco CSW:

CSW is manufacturer of sealants, air barriers, glazing products and coatings based in Cleveland, Ohio. CSW supplies these goods to the commercial construction market globally. CSW is a significant piece of Tremco Incorporated, a global business centered on construction products for the entire building envelope and structure. Tremco, Incorporated in turn is part of RPM International, Incorporated, a publicly traded \$3.8 billion organization with holdings throughout the specialty chemical products industry, many divisions of which supply customers with products used in the construction, renovation and maintaining of the built environment.

Personal Credentials:

Personally, I have devoted my career to sustainability and becoming a top expert in the field:

- Acting Chair- ASTM Committee E60 (Sustainability)
- Chair- Adhesives and Sealants Council Regulatory Affairs Committee
- Lecturer- The University of Akron
- Steering Committee Member- US-EPA DfE Phthalates Alternatives Assessment Program
- Presenter- California DTSC Alternatives Analysis Symposium II
- Member- ASHRAE 189.1 SSPC
- Author of over two dozen papers, articles, etc.

General Comments on the Latest Draft and the SCPR:

CSW is generally supportive of the concept of the SCPR. We recognize the need for our products to continue to evolve in terms of efficacy, formulation, etc. as chemistry and chemical knowledge evolves. We are also very supportive of the scientific, data driven approach endorsed by the SCPR. CSW is also a big believer and has integrated into its operational mission concepts that sustainable product development and business practices can lead to a market advantage for companies; a key premise of the SCPR.

Favored Changes from the Previous SCPR Informal Draft:

CSW is very pleased to see the following changes from the last SCPR Informal Draft of October 2012:

- Removal of the state-accredited alternative assessor requirement: This would have been burdensome on businesses of all sizes and to manage for the State. It is also not required if enforcement is properly utilized and/or auditing occurs.
- The addition of language suggesting harmonization to other laws: This helps business streamline operations by minimizing complexity in product offerings and by reducing the risk of being in a regulatory paradigm should any regulations conflict, etc.
- Better defining "contaminants" to include trace intermediaries: This reduces the burden of managing our supply chains as an end producer of goods. While many companies may be providing products, few are fully integrated to the point where they can control all aspects of the raw materials they purchase. This creates unfair market dynamics with which many companies, especially smaller and mid-size ones, would be burdened.

Areas of Concern and Possible Solutions:

CSW does have some concerns with this rule. We believe that some added clarity in a few areas defined below would make the rule easier to follow and more succinct in nature:

Economically Feasible:

Page 12 Line 22 – 23:

Current Verbiage:

(29) "Economically feasible" means that an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin.

Point of Comment:

Defining "significantly" would be beneficial to interpretation and in defining a goal for manufacturers to aim for in evaluating alternates.

Useful Life:

Page 18 Line 40 - 42:

Current Verbiage:

(76) "Useful life" means the period of time during which a product can be used as intended, expressed in either terms of a single use, number of applications, days, months or years of use.

Explanation of Concern:

This definition needs to define and distinguish if needed whether useful life includes shelf-life (maximum amount of time allowed from manufacture to initial use or installation) and service life (amount of time from initial use/installation that a product will function as intended).

Point of Clarity- How is useful life determined in either case? Is it based upon some standard for the industry, an industry test method, or claimed warranty life? If it is the latter of the three, this is an opportunity for manufacturers to make erroneous claims to make products look better. The most viable way to avoid this is to reference product category rules that have been defined by an industry association, which does not always exist (less than half of product types in construction as an example).

Suggested Alternative Verbiage:

(76) "Useful life" means the period of time during which a product, once applied or placed into service, can reasonably perform as originally intended without additional applications, modifications, restoration, etc. This may be expressed in terms of a single use or multiple uses, number of applications or a time measure. Where an industry accepted standard useful life is available, that value is the useful life.

End of Life Management Requirements:

Page 83 – 86, Section too Large to Duplicate Herein:

Explanation of Concern:

Point of Concern- This type of program could not only be costly to industry (costs which would be passed on to consumers) but may undermine the growing recycling and reclaim industry. Local reclaim and recycling industries benefit the local economy and eliminate the potential of the ecological impacts of shipping materials thousands of miles. This is the reason the concept of regionality has been integrated into LEED and needs considered here.

Suggested Additional Verbiage:

Where applicable, California-based reclaim and recycling solutions of end-of-life products may be specified as an alternate to a managed product stewardship program, so long as the following criteria are met:

The product manufacturer(s) or their industry alliances shall provide a list of resources for consumers to locate qualified recycling/reclaim companies.

Such companies must be registered and licensed in the State of California as a waste hauler and recycler.

Such companies must be accredited by a pertinent industry association as a recycler/reclaimer of wastes of the type being disposed of.

Such companies may be subject to an audit by DTSC or another California EPA agency to insure appropriate recycling techniques are employed.

Such companies meet all pertinent criteria as outlined for a product stewardship plan as defined in this section.

Advancement of Green Chemistry and Green Engineering:

Page 86, Section too Large to Duplicate Herein:

Explanation of Concern:

Point of Concern- This program places the onus on the manufacturer of the finished product and none on the suppliers of chemicals further back in the supply chain to create new chemistries.

Suggested Alteration:

Rework the program to place funding either in part or full on the manufacturers of the chemistries of concern. This would encourage new development of base chemicals that would not only benefit the specific product categories of concern, but others the DTSC has yet to consider.

Close:

CSW looks forward to being able to work with the DTSC and provide any and all feedback and assistance that may be requested.

Should you have specific questions, please feel free to contact me directly at 216.292.5058.

Sincerely,



Michael Schmeida, MSc., LEED AP
Divisional Sustainability and Regulatory Affairs Manager
Tremco Commercial Sealants and Waterproofing

February 28, 2013

VIA EMAIL
gcregs@dtsc.ca.gov

Ms. Krysia Von Burg
Regulations Section
California Dept. of Toxic Substances Control
1001 "I" Street
P.O. Box 806
Sacramento, CA 95812-0806

Sent via e-mail to: regs@dtsc.ca.gov

RE: Comments on the January 2013 Draft Safer Consumer Products Regulations R-2011-02

Dear Ms. Von Burg:

The University of California (UC) system (that comprises research universities at Berkeley, Davis, Irvine, Los Angeles, Merced, Riverside, San Diego, San Francisco, Santa Barbara, and Santa Cruz), and the University of California-managed Department of Energy-funded Lawrence Berkeley National Laboratory, appreciates the opportunity to comment on the CTDC's proposed Draft Safer Consumer Products Regulations R 2011-02.

UC generally supports regulations aimed at protecting public health and safety, and a number of our faculty researchers have been involved in the state's green chemistry initiatives, including the Green Chemistry Leadership Council.

However, UC believes that it is essential that any proposed regulations not unduly restrict research, including research about the health and environmental effects of certain chemicals as well as other kinds of research that may require continued access to such chemicals. We have some concern that the well-intended proposed regulations that appear aimed to ensure the safety of consumer products may have an unintentional consequence of impeding availability of certain chemicals needed in legitimate research. We are familiar with the joint comment letter submitted by Sigma-Aldrich Corporation, along with Avantor Performance Materials, Inc., Life Technologies Corporation, Thermo Fisher Scientific Inc., and Alfa Aesar (a Johnson Matthey company, and share many of their concerns and support the exemptions they request.

Our analysis of the proposed regulations remains on-going and their effect on UC's research and education activities is not entirely clear. We have only a few specific comments to offer at this time:

Our initial assessment is that the UC research enterprise would not meet the definition of a manufacture or importer under the proposed regulations. However, the proposed regulations

could be interpreted to characterize UC as an “Assembler”, that is, any person who assembles a product containing a component that is a product subject to the requirements of the proposed regulations. [Sec 69405.4(16)] This is because “product” is defined so broadly as “product or part of the product that is used, brought, or leased for use by a person for any purposes.” CHSC 25251.

If UC is characterized as an Assembler under the proposed regulations, it could potentially place an onerous and untenable burden on our ability to conduct research. It is foreseeable that on a frequently occurring basis, UC could purchase a Chemical of Concern from an out-of-state company (a Manufacturer) that has not completed the Alternative Analysis. A UC researcher could plan on using the chemicals in an experiment to make a novel compound to study. There may be circumstances where UC would, as an Assembler, be required to undertake an unfunded, expensive evaluation of a more environmentally friendly chemical substitute and complete an Alternative Analysis for a Chemical of Concern and also make the Alternative Analysis publically available. A possible regulatory alternative to this requirement might be to limit the Alternative Analysis only to priority products that contain a “Chemical of Concern”. If this change were made, it would be unlikely that UC’s research enterprise would be producing these and would therefore not be subject to the proposed regulation.

It is likely that at least some of the chemical manufacturers on which UC relies for research materials would be characterized as “Importers” under the proposed regulations. There may be costs to UC from the possibility that these manufacturers would raise prices of certain chemicals (to account for the burden of having to conduct the required analyses) or that the chemicals might become harder to obtain.

UC endorses green chemistry efforts, and in many instances, our scientists are leaders in this field. But discoveries that occur in academic research require flexibility to allow innovation and creative use. We are very interested in collaborating with the CTSC to revise the proposed regulations to promote our shared interest in permitting important research to go forward while protecting the public’s health and our environment.

Thank you for considering our comments. Please contact (who?) if you have any questions.

Sincerely,

Jeff Hall
Director, Research Policy Development
UC Office of the President

Comments to January 29, 2013 Safer Consumer Products Proposed Regulations (AB 1879), R-2011-02

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Section	Sub-section	Topic	Comment
69501.1(a)		Definitions	
		Exposure Pathway	Definition of exposure pathway needs to be developed since it is a significant concept for both prioritization of priority products and in the Alternatives Analysis.
	4	Adverse environmental impacts	Most of the environmental criteria listed here are actual <i>impacts</i> or risks and not simply hazards. By contrast, public impacts are hazard traits. This mixing of hazard, risk, and impact is problematic.
	5	Adverse impacts	Definition means adverse public health impacts and/or adverse environmental impacts. The problem with this definition is that while the adverse public health impacts are not impacts but hazards traits, most the adverse environmental impacts identified are not hazards but estimates of actual impacts.
	6	Adverse public health impacts	This definition is confusing because it mixes both hazards and impacts. All of the criteria referenced chapter 54 article 2 and 3 are hazards and not <i>impacts</i> . On the other hand, the definition also includes exceedances of standards which are clearly impacts.
	29	Economically feasible	<p>This proposed definition of economically feasible – “that an alternative product or replacement chemical does not significantly reduced the manufacture’s operating margin” – is extremely ambiguous, does not conform to the standard definition of the term, and does not conform to the intent of the statute. As written, the definition suggests that the benchmark for economic feasibility analysis is the operating margin of the manufacturing firm – i.e. “does not significantly reduce the manufacture’s operating margin.” If this were the case, for a large successful firm manufacturing hundreds of products, an alternative to one of their targeted products may be considered economically feasible even if expenses for the alternative were substantially higher than revenue because this loss may not have a significant impact on overall profitability of the firm.</p> <p>If the impact on the overall profitability of the manufacturer is not the proper benchmark then what is?</p>

Section	Sub-section	Topic	Comment
			<p>The proper benchmark for an analysis of the economic feasibility of an alternative should be taken from the perspective of the alternative. From this perspective, the threshold question for economic feasibility should be ‘what is the minimum profit margin necessary to proceed with manufacturing the alternative?’</p> <p>This conception of economic feasibility is echoed by <i>The Cambridge Business English Dictionary</i>, which defines economic feasibility as “the degree to which the economic advantages of something to be made, done, or achieved are greater than the economic costs.” (Cambridge University Press).</p> <p>This definition conforms to the definition developed by the European Chemical Agency (ECHA) in their guidance for authorization of chemicals of concern under REACH. (See <i>ECHA, Guidance on the Preparation of an Application for Authorization, January 2011</i>). ECHA defines the economic feasibility of an alternative as having a positive net present value (NPV) based in existing revenue for the product or possibly increased revenue if the cost for the alternative exceeds existing revenue.</p> <p>NPV is a particularly appropriate economic instrument to use since firms use this specific measure in decision making about whether to invest in a project; a positive NPV adds value to the firm, a negative NPV subtracts value to the firm. When calculating NPV, the ‘weighted average cost of capital’ is typically used to determine the discount rate -- the rate used to discount future cash flows to the present value. In addition, as with the REACH guidance, when determining NPV, the extent of price elasticity for the product should be considered.</p> <p>In sum, defining economic feasibility as achieving a positive NPV is the standard business practice used by firms to evaluate the economic feasibility of any alternative, properly focuses the attention of micro-economic impacts on the viability of the alternatives, conforms to the standard business definition of the term, and harmonizes with the guidance developed for European regulation of chemicals under REACH.</p>
69503.2	(b)	Identification and	The last sentence of this subsection should read: “The Department shall additionally consider paragraph (3).”

Section	Sub-section	Topic	Comment
		Prioritization Process	Paragraph (3) pertains to safer alternatives. Requiring the Department to consider viable safer alternatives will provide a strong signal to firms who believe they may have a viable safer alternative to develop the evidence base for this to be considered during the prioritization of product-chemical combinations. The higher the quality of study the more likely the Departments would take this into consideration. The existing language, which states that the Department “may, at its discretion, consider paragraph (3)” creates too much uncertainty to incentivize the generation of AAs for potentially viable alternatives.
69503.2	(b) (3)	Safer Alternatives	The word “may” in this subsection should be changed to “shall”. See above. Again, this will incentivize the generation of high quality AAs by manufactures of potentially safer viable alternatives.
69505.5		Alternatives Analysis: First Stage	Elimination of an alternative on the basis of only public health or environmental impacts is ill-advised. Those two types of impacts by definition do not include consideration of exposure. Thus, one could eliminate an alternative simply based on hazard traits when in fact the exposure profile is such that it is inherently safer than the Priority Product.
69505.6	(a)(1)(A)	Material contribution	Beyond determining which factors make a material contribution it is essential to weight the importance of each factor making a material contribution. For example, both carcinogenicity and skin sensitivity may both make material contributions but the decision maker may weight one more highly than the other. Explicit weighting of factors is essential to any transparent decision making. When factors are not weighted explicitly then some form of implicit non-transparent weighting is used. Given the regulatory context of this evaluation of alternatives the transparency of the weighting of factors is essential.
69505.6	(a)(1)(B)	Material difference in factors	This subsection suggests retaining factors that make a material contribution only when there is a material difference between the priority product and an alternative or between alternatives. The degree of similarity is essential when comparing priority products with alternatives. Say you have identified 20 key public health impact factors and the priority product and the alternatives are comparable on 19. If you throw out the

Section	Sub-section	Topic	Comment
			<p>19 then the 20th factor may make it look like there is a substantial difference in public health impact when in fact, taking all 20 into account, they are very similar.</p> <p>In addition, removing factors when they are the same for the priority product and the alternatives eliminates the ability to measure the cumulative impact of each option and possibly overemphasize the importance of less important factors. In the example above, if the 20th factor is carcinogenicity and carcinogenicity is highly weighted then even though the options may be very similar the fact that they differ on carcinogenicity makes them significantly different. If the 20th factor was skin sensitivity and skin sensitivity was not highly weighted then the fact that they differ on only this one factor suggests they are not significantly different.</p> <p>Analytic tools are specifically designed to take into account the degree of similarity, the degree of difference between options and the importance of each factor. It is essential that the degree of similarity be retained for these analytic tools to work correctly.</p>
69505.6	(a)(2)(B)	Product function and performance	Under subsection 3, economic feasibility is listed. Since this section pertains to production function and performance, economic feasibility needs to be moved to the next section entitled "Economic Impacts."
69505.6	(a)(1)(C)	Economic Impacts	This section is incomplete because it does not consider economic feasibility – see above
69506	(a)	Need for Regulatory Response	<p>Removed word "selected". If alternatives analysis identifies alternatives that are not selected but that pose a potential adverse public health or environmental impact, one or more regulatory responses should be considered for these alternatives.</p> <p>If regulatory response is not taken on these non-selected alternatives, these very alternatives may make their way into the market by non-regulated firms, thereby creating regrettable substitutions within the sector.</p>
69506.5	(a)	Product Sales Prohibition	Removed word "selected." This should pertain to any identified alternative containing one or more Chemical(s) of Concern or replacement Candidate Chemical(s). If this authority is not provided this may encourage to use non-selected alternatives by non-regulated firms. Thus, including all alternatives avoids the possibility of

Section	Sub-section	Topic	Comment
			regrettable substitution across the sector.
69506.5	(b)(2)(A)	Social utility	Social utility should be defined.



**Comments of Unifrax I LLC
Notice of Public Availability of Post Hearing Changes
Safer Consumer Products**

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

February 28, 2013

Introduction

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF) and other manmade mineral fiber products, offers the following comments on the January 2013 proposed regulations for Safer Consumer Product Alternatives, also known as the "green chemistry" regulations. Unifrax previously commented on the July 2012 proposal, the final peer review reports and all prior versions of the proposed regulations.

Unifrax offers the following comments on the current proposal:

1. The prior exemption for bulk chemical products should be reinstated;
2. The exemption for existing regulation should be revised to remove the requirement for equivalent protection;
3. The final regulations or statement of reasons should clarify that existing regulation of a potential exposure pathway is adequate where additional regulation has been investigated and found to be unwarranted;
4. The final regulations or statement of reasons should be revised to clarify that existing regulation includes product stewardship programs that have been determined by regulatory authorities to provide adequate protection;
5. The definition of technological feasibility should be limited to alternatives that are currently available;

6. The final regulations or statement of reasons should clarify that in picking priority products, the quantity of the available scientific studies will not outweigh the study results; and
7. The provision allowing consideration of engineering and administrative controls in the priority process should be retained.

These points are discussed in detail below.

Bulk Chemical Products

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

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

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

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

Existing Regulation

Under earlier versions of the proposed regulations, a product could be exempted from the listing and subsequent regulatory processes if the Department determines that existing regulation is adequate throughout the life cycle of the product and there are no significant gaps in regulatory coverage. This exemption was been deleted from the 2012 proposal and replaced with a provision that makes existing regulation only one of many considerations in the priority process.

The post-hearing draft reinstates the exemption for existing regulation. Unifrax supports this approach as consistent with the governing statute. Section 25257.1 provides: "(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency. (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." This language is clear: existing regulation cannot be superseded or duplicated. Thus, an exemption is required for potential exposure pathways already regulated. Demoting this consideration to one of many in the priority process, which the Department presumably could overrule in some cases, would have been a violation of the statute.

The Department also should clarify that existing regulation of a potential exposure pathway is deemed adequate where additional regulation has been investigated by regulatory authorities and found to be unwarranted. As discussed in our prior comments, such conclusions have been drawn with respect to RCF by the federal authorities at EPA, OSHA and NIOSH. The 2010 proposal responded to this comment by proposing the following exemption for products otherwise regulated:

The requirements of this chapter do not apply to a chemical or consumer product that the Department has determined is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination, address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the basis for the product being listed as a Priority Product. The Department may, at its discretion, re-evaluate a determination previously made pursuant to this paragraph and rescind that determination if the Department finds that the facts and/or assumptions upon which the determination was based were not, or are no longer, valid.

Unifrax supported the language exempting products "regulated by one or more federal and/or other California State regulatory program(s) . . . that, in combination, address the same public health and environmental threats and exposure pathways . . ." This provides maximum flexibility to exempt products adequately regulated through a combination of existing state and federal "programs," including product stewardship programs endorsed by regulatory authorities as discussed further below.

While the new draft retains the exemption for products regulated under other authorities, the language is different from the 2010 proposal. The new draft includes the language quoted above but adds a new requirement that the existing regulations must "provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product."

This new requirement is problematic and should be removed. It appears that to qualify under this new language, a manufacturer would have to demonstrate that the various existing regulations are at least as effective as the outcome of an alternatives assessment for the product. However, it would be virtually impossible to know in advance what the results of such an assessment would be. Further, in some cases

such as workplace regulation governed by state workplace standards, consideration of alternatives is not appropriate.

As discussed above the statute is clear: DTSC has no authority to supersede existing regulations or to adopt conflicting regulations, regardless of whether they provide equivalent protection. As noted by peer reviewer John S. Applegate, this approach is dictated by resource concerns as well:

It cannot be doubted that the safer products legislation and the CCSPAR envision a major undertaking to identify potentially dangerous chemicals, identify the products containing COCs, and take appropriate regulatory action. There is not, as far as I am aware, a major additional funding stream to support these activities, nor does it seem likely that large amounts of general state funds will be available. Therefore, the CCSPAR must use existing resources as much as possible . . .

Unifrax urges DTSC to remove this new requirement and return to the language that appeared in the 2010 proposal on this issue.

Feasibility

The current proposal adopts new definitions of technological and economic feasibility. An alternative product or replacement chemical is economically feasible if it does not significantly reduce the manufacturer's operating margin. An alternative or replacement product is technologically feasible if the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period.

The new definition of technological feasibility should be revised. Feasibility determinations should be based on acceptable alternatives that are currently available. They should not be based on speculation as to products that are "expected to be

sufficient." The new definition will lead to required alternatives that have not been demonstrated to be feasible, and in fact are not feasible, in various relevant markets.

This point was discussed in the comments of peer reviewer Dr. Deborah H. Bennett with respect to removal of contaminants:

[I] feel it is important to consider both the technical and economic feasibility of removing contaminants . . . While the reasons for lowering the threshold are all very valid, it is not clear how that would be weighed against the technical difficulties related to removing things such as unintended contamination or level set below analytical method limits of detection. More guidance should be provided to understand how these two competing factors would be weighted (p. 4).

The 2010 proposal defined technological feasibility as "the extent to which a functionally acceptable alternative is currently available in the marketplace." Unifrax urges a return to this approach in the final regulations.

Product Stewardship

Our prior comments contained a detailed description of our industry product stewardship program, which has been endorsed by various federal regulatory authorities and the California Occupational Safety and Health Standards Board. As discussed above, we interpret the exemption for existing regulation to allow consideration of our program. However, we urge DTSC to acknowledge this explicitly in the final regulations or Statement of Reasons.

We also note that product stewardship programs would be required in end of life management plans under these regulations, and that the elements of such programs as provided in the regulations are virtually identical to our program. In essence we are already implementing the program that these regulations would require. This is yet another reason to give low regulatory priority to RCF products subject to our program.

Availability of Information

The current proposal includes a new provisions stating that in making the priority product determination, “the Department shall consider the extent and quality of information relevant to the following factors that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. This provision appears to be a response to the comments of peer reviewer Dr. William H Farland:

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

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

Engineering and Administrative Controls

The current proposal includes a new provisions allowing consideration, in the priority product process, of “engineering and administrative controls that reduce exposure concerns associated with the product.” Unifrax supports this approach, as recommended by peer reviewer Dr. Nicholas A. Ashford:

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

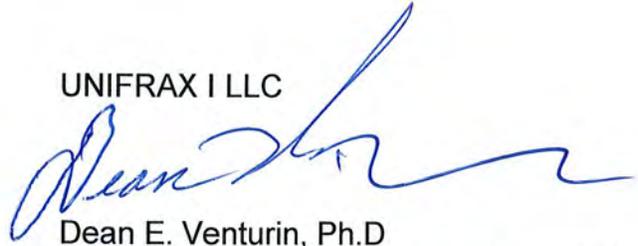
Conclusion

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

1. Reinstate the prior exemption for bulk chemical products;
2. Revise the exemption for existing regulation to remove the requirement for equivalent protection;
3. Clarify that existing regulation of a potential exposure pathway is adequate where additional regulation has been investigated and found to be unwarranted;
4. Clarify that existing regulation includes product stewardship programs that have been determined by regulatory authorities to provide adequate protection;
5. Limit the definition of technological feasibility to alternatives that are currently available;
6. Clarify that in picking priority products, the quantity of the available scientific studies will not outweigh their results; and
7. Retain consideration of engineering and administrative controls in the priority process.

Respectfully submitted,

UNIFRAX I LLC

A handwritten signature in blue ink, appearing to read "Dean E. Venturin", with a long, sweeping flourish extending to the right.

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

Via E-Mail GCRegs@dtsc.ca.gov

February 28, 2013

Krysia Von Burg, Regulations Coordinator
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Re: Unilever's Comments to the Proposed "Safer Consumer Products" Regulation

Dear Ms. Von Burg:

We are contacting you with Unilever's comments in response to DTSC's January 2013 Post-Hearing Proposed Regulations for Safer Consumer Product Alternatives (updated proposal).

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

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

I. Introduction

Unilever manufactures a wide range of personal care products for the California market. We assess the safety of these products to ensure that they will be safely used by our consumers.

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

The Green Chemistry Alliance (GCA) has advocated the crafting of regulations to enable the DTSC to fully and successfully implement AB 1879 and SB 509, which would provide for comprehensive chemical management and in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development. In a proactive fashion and in response to DTSC's requests for comments, GCA stakeholders have invested countless hours over the last several years developing regulatory text and comments for implementing the regulation. This work has been the result of a focused and proactive effort by a broad array of individuals from around the world with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy.

We recognize the extensive DTSC staff efforts that have gone into the proposed regulatory revisions from 2011, 2012, and now 2013, plus the support of Director Raphael's efforts to make the Safer Consumer Products regulation "practical, meaningful, and legally defensible." As we have stated previously, Unilever is hopeful that, upon adoption, the final regulation will still:

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

II. Proposed Regulation: Improvements

We acknowledge that many changes in the revised regulation are significant improvements over previous versions of the regulation.

First and foremost, the elimination of the certified assessor requirement lifts a huge burden from manufacturers and will allow them to more efficiently utilize their innate expertise to more effectively innovate. We applaud DTSC for eliminating this requirement.

Other noted improvements include the following:

- Adding language that explicitly states nothing in the regulation authorizes DTSC to supersede the requirements of any other California, state or federal regulatory program;
- The change in nomenclature to "Candidate Chemicals" from "Chemicals of Concern";
- 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 designated Candidate Chemicals;
- Unilever supports the change that eliminates exemption notifications, which removes a potentially large paperwork burden for manufacturers not producing the product-chemical combination.

III. Proposed Regulation: Major Areas of Concern

a) Public Review and Comment on Alternative Assessments (AA)

The requirement that AA reports be made available for public comment creates serious concerns, for the reasons listed below. This provision should be eliminated in favor of requiring DTSC staff to review the reports, with appropriate training by industry and others made available to them.

It is also likely that the general public will not be able to understand, in the depth required, all the technical and economic information which leads the manufacturer to the best decision in the AA process. Companies employ experts in chemistry, toxicology, environmental toxicology, microbiology, process engineering, chemical engineering, procurement, manufacturing, transportation, finance, etc. to help define, develop, and then launch new products. Because companies do not want to divulge information, which it considers confidential, to the general public and thus, to their competitors, the public AA reports will be subject to considerable redaction and therefore have limited utility.

A comprehensive AA will provide detailed descriptions of a manufacturer's supply chain and manufacturing capabilities, the economic considerations which are particular to each manufacturer, in addition to technical capabilities which are maintained as confidential and/or trade secrets by the manufacturer. Most of this information is not patentable, for various reasons. For example, just disclosing the limitations and capabilities of the equipment used in a facility could give a competitor, regardless of location, valuable information which can be used against the manufacturer anywhere in the world. The manufacturer does not even have to do business in California. It is also important to note that most major companies require each employee to sign confidentiality agreements as a way to protect its company confidential business information and trade secrets.

As the AA reports will 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 competitors of, customers of, and suppliers to the company submitting the AA. This public dissemination will actually act as a deterrent to companies who are trying to market innovative products in the state of California. Such public dissemination could thus hamper the robust consideration of alternatives contemplated in the statute and regulations.

Unilever's recommendation is that DTSC be the only group which can review and assess the full AA reports, since it is required to maintain business confidentiality and cannot disclose confidential business information contained in a company's submission.

b) Regulatory Duplication

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 up front and straightforward analysis in the applicability stage of the regulation: the determination simply focuses on whether the potential health or environmental impact from the chemical in the product is or is not regulated by another regulatory agency. If it is regulated by another agency, then it should not be in the scope of the proposed regulation.

Previous language that appropriately exempted products in the supply chain of exempted products has been deleted in the current regulation. This suggests that the Department believes that it can select a priority product-chemical combination upstream in an exempted product supply chain, including food products and other categories subject to significant federal oversight. The regulation should once again state that it exempts products in the supply chain of exempted products.

c) Food Contact Materials

The statute exempts “A food as defined in subdivision (a) of 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.

The food industry has repeatedly made comments for the regulation to incorporate precise language in the regulation which excludes food contact materials, as these are already subject to a comprehensive federal regulatory program that ensures their safety for the public health and environment. Food contact materials are already 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. Further regulation of these materials would be a waste of resources and could result in regulatory confusion and inconsistencies, since it would potentially be in direct conflict with the existing federal regulatory scheme.¹

d) Elimination of *de minimis*

The updated proposal fully eliminates the concept of *de minimis* as a consideration, making the regulation virtually unworkable. 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.

Industry has 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. 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. Even the EPA’s drinking water standards provides the maximum levels of many contaminants; they are not “0”.

In 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

¹ 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.”

chemical of concern. In the updated proposal, it seems that the Department has completely shifted to the impractical position of other stakeholders. The revised approach begins appropriately by distinguishing between intentional ingredients and contaminants, which is 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 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. 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. California should be consistent with other national and international laws. The basis for these laws is that low, but measurable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low.

The Department should 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, Unilever believes that a discrete, non-zero threshold should be set by DTSC for each product-chemical combination on a case-by-case basis using scientifically sound hazard and exposure (i.e., risk) assessments, independent of whether the chemical is a contaminant or ingredient.

e) Intentionally Added Ingredients vs. Contaminants

The updated proposal includes the concept of intentional ingredients, those chemicals purposefully included in a product to perform a function. Unilever agrees with the renewed focus only on ingredients intentionally added to a formulation. Chasing unintentional trace levels that have no impact will significantly diminish the public health and environmental benefits of the program, as unnecessary resource will be spent by trying to eliminate ingredients which have no impact on the product's safety profile.

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, the regulation should make it clear in § 69503.2 that chemicals considered in product prioritization decisions must be intentionally added to and have a function in the product.

IV. Other Unilever Concerns

a) Presence vs. Ability to Cause Effects

Unilever does not agree with the increased emphasis on “presence” as an exposure criterion and the shift from the term “ability” to cause effects to “potential” to cause effects.

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. Unilever agrees with the GMA recommendation that the underlined phrase below 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”.

b) 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 of priority products to be assessed in the AA process, and the determination of regulatory responses. The proposed regulations raise significant concerns that there is no intention to do so, but rather it seems possible that the proposal could be used to react to the latest, unfounded scare story in the news. 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. The use of peer-reviewed reports must take into consideration the qualifications and any biases of those reviewing the article to ensure the most robust assessment and conclusions are made.

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.
- DTSC should utilize the Klimisch scoring system to accurately portray the robustness of a safety study, thereby formally minimizing the results of studies which did not satisfy stringent criteria for completeness and sound science.

c) Alternative Analyses Timeframes

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.

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.

Unilever would like to see DTSC adopt a flexible approach during the initial phase of the implementation of the regulation to determine if the time frames are actually workable. If not, DTSC should quickly move to modify the current proposal to extend the times allowed to meet the regulatory requirements. Otherwise, we agree with other comments that the timeframes be expanded to at least 12 months for the Preliminary Report and 24 months for a company's Alternative Assessment report. If consortia are used, the time frames should be 18 and 30 months, respectively, due to the time it takes establish a consortium under appropriate anti-trust guidelines.

d) Consumer Acceptance

The AA report should identify relevant factors critical to achieving a focused and efficient AA process. Consumer acceptance of the proposed alternatives are relevant and important, especially since in the end it is the consumer, through purchasing behavior, who will determine whether the alternative is successful. 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).

e) Economically Feasible Alternatives

In (§ 69501.1.(a)(29)), "*Economically feasible*" means an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin. A specific manufacturer's operating margin is not the optimum 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, manufacturing capability and infrastructure, research and other overhead costs, among others. 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. We support the GMA recommendation to revise § 69501.1.(a)(29) 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.

f) 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.

Unilever considers that product formula information, the processing methods used, the equipment required to make the formulation, the supply chain details, both upstream and downstream, and economic information are critical parts of a company's trade secrets and confidential business information. Many of these facts cannot be patented but nonetheless are maintained by companies as trade secrets or confidential business information in order to maintain competitive advantage and the ability to innovate. Employees typically sign agreements stating that they will not divulge such intellectual property or confidential information. Because of this, significant 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. DTSC staff must maintain confidentiality of a company's records, when appropriate safeguards are taken, but the public is not restrained by such agreements. Companies must take all necessary steps to maintain and protect their most valued information.

That the AA also requires manufacturers to provide a listing of all retail sales where a product is sold is not feasible, since many products are sold to retailers and distributors outside California for shipment into their California stores. In many cases customers are also considered confidential business information.

g) Life Cycle Considerations

Throughout the regulation comments are made about life cycle considerations with regard to waste and other end-of-life concerns, which we consider as downstream impacts. It is also important, when assessing alternatives, to consider the upstream impacts on the environment. In many cases the choice of an alternative could depend on environmental issues directly attributable to the sourcing of an ingredient or other raw material. These cannot be neglected in the overall assessments and subsequent conclusions.

V. Conclusion

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

If you have any questions regarding our statements, do not hesitate to contact me.

Regards,

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cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency
Miriam Barcellona-Ingenito, Deputy Secretary for Environmental Policy, California
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Michael E. Rossi, Senior Advisor for Jobs and Business Development, Office of the Governor
Dr. Patrizia Barone, Director Regulatory Affairs Unilever NA



February 26, 2013

VIA E-MAIL

Kryisia Von Burg
Regulations Section
Department of Toxic Substances Control
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Sacramento, CA 95812-0806

Electronic submittal: gcregs@dtsc.ca.gov

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

Dear Ms. Von Burg:

The Valero Companies (“Valero”) appreciate this opportunity to provide these comments regarding the Department of Toxic Substances Control’s (“DTSC”) proposed regulation for Safer Consumer Products (SCP), as posted for public comment on January 29, 2013. Valero owns and operates two refineries in the state of California with a combined throughput capacity of over 305,000 barrels per day and markets our products on a retail and wholesale basis through an extensive pipeline distribution system. Valero is one of the nation’s largest retail operators with a significant presence in California as well as 37 other states.

As per our comments on the original draft SCP regulation, Valero strongly urges DTSC to provide a specific exemption and/or exclusion for all transportation fuels from the SCP regulation. While we appreciate the additional exemption for products that are regulated such that “equivalent or better” protection is provided, Valero believes this exemption will be too subjective in its application and fails to explicitly acknowledge the many regulations already in-place concerning transportation fuels. The goal of the SCP regulation is to “create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.” Valero supports such measures when applied in a manner that recognizes both products that are already inherently “safe” and products that are handled to such an extent that risks are minimized to ensure product safety. Valero continues to support the position that transportation fuels are already regulated and managed to an extent that ensures product safety and minimizes chemical risks, eliminating the need to access applicability under the SCP rule. We incorporate herein our comments on the original SCP draft rule dated October 11, 2012. Additionally, we offer the following comments on the proposed revisions in the second draft rule.

1. Transportation fuels are already heavily regulated/reformulated to ensure product safety and should be granted a specific exemption under the SCP rule.

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

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

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

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

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

2. The exemption for products not designated for use in California should be reinstated

DTSC has removed from the second draft the exemption for products manufactured, stored in, or transported through California solely for use outside California. DTSC has instead stated that this factor will be used in determining “product prioritization”. The implication is that products not intended for the California market may ultimately be subject to the SCP regulation, depending on the “priority”. Valero contends that this approach runs counter to the very definition of “consumer product”, as products not bound for the California market cannot, by definition, impact consumers within the state. Concerns regarding risks and/or exposures due to manufacturing, storage and/or transport are not only outside the scope of this regulation but fail to acknowledge the many regulations already in-place concerning workplace exposure and safe materials transport.

We further contend that “product priority factors” and “product prioritization” are too broad and subjective for the regulated community to know and understand how this regulation may impact them. Lacking the regulatory definition of the substances and industries that would ultimately be impacted, we contend it not possible for the public review and comment requirements of the regulatory process to be sufficiently observed under the law. The universe of businesses and

chemicals that may be regulated is lacking boundaries and conditions such that industry would know where and how to provide meaningful comments. This type of “open-ended regulation” circumvents public notice and comment requirements by drafting regulations lacking in the details necessary for industries to understand who and what is regulated. We recommend that DTSC reinstate the upfront applicability exemption for products manufactured, stored in, or transported through California solely for use outside California.

Finally, we contend that regulating products which are not bound for the California market may constitute a violation of the U.S. Commerce Clause. We request that DTSC initiate a formal review of this regulation to determine any potential conflicts with the Commerce Clause and provide the results of this analysis to all stakeholders.

3. The Alternatives Analysis evaluation of economic impacts should not be limited as proposed

The second draft is revised such that the Alternative Analysis (AA) economic impacts would be limited to a monetized comparison of public health and environmental costs, and costs to government agencies and non-profit organization that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife. Valero contends that this approach fails to acknowledge the full picture of economic impacts with regards to manufacturing, marketing, etc. A meaningful analysis of potential alternatives must include all costs; otherwise a distorted picture of the consumer product is presented that is neither practical nor instructive. While DTSC acknowledges that these “production costs” should be included if the AA analysis selection retains the Priority Product, this full economic analysis should be an integral part of the entire AA evaluation for all potential alternative selections. We recommend that DTSC revise this language back to the original proposal.

4. DTSC authority to halt all product sales/distribution, based on their regulatory response, must be balanced with an appeal/3rd party review process to minimize disruption to the economy

The decision to halt the sale of a consumer product, inclusive of that which has already been produced and distributed prior to any DTSC decisions regarding a Priority Product, can have significant impacts not only to manufactures but to distributors and retails. In the case of transportation fuels, any decision to “freeze” sales based on DTSC’s review would literally strand millions of bbls of transportation fuels, bringing the California economy to a sudden halt. The consequences of wielding this authority can negatively impact almost all sectors of the California economy and we highly recommend that DTSC provide an appeal process such that additional parties can be invoked to ensure that a thorough and supportable analysis has been done to support any such decision.

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

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

Sincerely,



Matthew H. Hodges
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Valero Companies
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February 28, 2013

Ms. Krysia Von Burg
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Via E-mail: gcregs@dtsc.ca.gov

RE: Comments on proposed post-hearing changes of the Safer Consumer Products Regulation (R-2011-02)

Dear Ms. Von Burg:

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

In general we are writing to express our support for the comments filed by the American Chemistry Council (ACC). Like ACC, we continue to be concerned about over-reaching, inconsistent and confusing provisions in the proposed rules. They seem to reflect unwillingness on DTSC's part to understand the realities of today's manufacturing industries and the advances in protecting health and the environment achieved as a result of existing government policies along with rigorous business management practices. We believe these latest proposed regulations are likely to produce increased public confusion and concern rather than improved health and environmental performance.

In particular, we are concerned about the absence from the proposal of *de minimis* concentrations of chemicals below which no concern exists. Instead, manufacturers would be required to measure the practical quantitation limit (PQL) or lowest detectable level of any intentionally added chemical. They would also be required to perform an alternatives analysis.

PQL is an analytical term. For any material, PQL is subject to change with instrumental technology and methods development. It is in no way related to the potential harm that could be caused by chemicals. It has no bearing on whether these barely detectable materials could migrate from the product or, if they did, whether such migration would result in any detectable **exposure** for users of the product.

RE: Vinyl Institute Comments on proposed post-hearing changes of the Safer Consumer Products Regulation (R-2011-02)

With today's analytical tools, it is possible to detect a residual monomer in a polymer despite the fact that, in most cases, the polymer production process already incorporates steps to reduce that residual monomer -- in many cases to the point where it is barely quantifiable. Given that a monomer is essential to the formation of a polymer and not substitutable, and given that a process is already in place for removal of the monomer, the idea of doing an alternatives assessment based on the detection of residual monomer, regardless of the potential real impact, seems superfluous.

Moreover, other states have recognized that setting a *de minimis* level for such residual materials is not only reasonable, but practical. Those states have set a *de minimis* level at a known and stable concentration that is not subject to the week-to-week developments in an analytical laboratory.

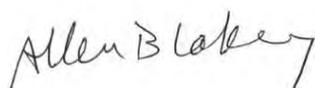
We also urge DTSC to make the following changes:

- Include a weight-of-evidence approach as a basis for assessing hazards. We often see published studies using simplistic methodologies whose authors claim far-reaching implications linking potential chemical exposures and adverse health effects. Such studies alone, or in small numbers, should not be considered adequate to identify a candidate chemical when weighed against extensive research and product experience showing no meaningful adverse health effects.
- Create a mechanism by which manufacturers and others may demonstrate the safety of their products and thereby obtain exemption from alternatives analysis.

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

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

Sincerely,



Allen Blakey,
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Western States Petroleum Association
Credible Solutions • Responsive Service • Since 1907

Catherine H. Reheis-Boyd
President

February 27, 2013

Via email: gcregs@dtsc.ca.gov

Ms. Krysia Von Burg (KVonburg@dtsc.ca.gov)
Department of Toxic Substances Control
Regulations Section
PO Box 806
Sacramento, CA 95812-0806

Re: Proposed Safer Consumer Product (Green Chemistry) Regulations

Dear Ms. Von Burg:

The Western States Petroleum Association (WSPA) is a trade association representing 27 companies that explore for, develop, refine, market and transport petroleum and petroleum products and natural gas in the Western United States. Many WSPA members have extensive operations in California and are impacted by new and proposed regulations that could impact the environment and facility operations. WSPA has been an active participant in the policy discussions concerning the development of the Department of Toxic Substances Control (DTSC) Safer Consumer Product Regulations ("Green Chemistry") over the past several years and we appreciate the continuing opportunity to engage on this important topic.

Overview of the Regulations

WSPA was pleased to see that the January 29, 2013 version of the proposed Safer Consumer Product Alternative Regulations offered improvements over prior proposed versions of these regulations. Specifically, we noted that the latest version included:

- The identification of chemical on the "list of lists" as "Candidate Chemical" of concern rather than a "Chemical of Concern";
- Establishing Priority Product/Chemical of Concern combinations using the Administrative Procedures Act rulemaking process; and
- Slightly narrower scope for the Alternative Analysis.

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These improvements are certainly a step in the right direction. We offer additional improvements and provide specific examples and recommendations below.

Additional Improvements to the Safer Consumer Product Regulations

1. Consistent Use of Language Would Reinforce DTSC Focus: Proposed §69501(b)(3) and (c) Should Use Same Language as Health and Safety Code (H&SC) §25257.1(b) and (c)

Two provisions of the Green Chemistry legislation identify limits of DTSC authority. The first is specified in H&SC §25257.1(b) where the DTSC is neither authorized “to supersede the regulatory authority of any other department or agency.” The next subsection H&SC §25257.1(c) 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.” These key sections clearly define the appropriate scope of DTSC’s proposed actions.

We are concerned that the proposed language in proposed §§69501(b) (3) and (c) use different language than the statute. These differences obscure the intent of the statute and are not reflective of the clarity exhibited by the statutory language. Section §69501(c) uses narrower language (“requirements”) than the statute (“regulatory authority”), while §69501(b) (3) does not explicitly include the prohibition of duplication or adoption of conflicting regulations. The effect is a potential expansion of DTSC authority beyond that permitted by the statute.

Recommendation: To address this ambiguity, we propose §69501(c) is modified as follows:

~~“Harmonization. Nothing in these regulations authorizes the Department to supersede the requirements—the regulatory authority of any another California State or federal regulatory program.”~~

In addition, WSPA suggests that new text be added to the regulation to explicitly acknowledge the statutory limitation on the authority of the DTSC that is identified at H&SC §25257.1(c) and to link this limitation to proposed §§ 69501(b) (3) (A) (1) and (2) as follows:

“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 chapter. Therefore, this chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or California State regulatory program(s), and/or applicable treaties or international agreements with the force of domestic law.”

We believe that these limitations would clearly apply to petroleum fuel and/or fuel additives because these products are already subject to broad and extensive regulations that evaluate and minimize potential health and environmental impacts. Moreover, most of these regulations are administered or enforced by a myriad of federal and state regulatory authorities, including the California Air Resources Board (ARB) and the U.S. Environmental Protection Agency. Hence, application of Green Chemistry regulations to transportation fuels would conflict with existing regulatory programs and is prohibited by statute. We feel that these same statutory strictures would also result in eliminating commercial and industrial oils from regulation under Green Chemistry.

2. The SCPA Regulatory Program Should Rely on Market Forces

The goal of the SCPA regulatory program is to promote “benign by design” products via incremental product improvements. One way to ensure that manufacturers initiate improvements consistent with this goal is to provide clear target design criteria to the manufacturers that identify “benign by design” product characteristics. By doing so, the DTSC can incentivize manufacturers to explore and incorporate “benign by design” improvements without direct DTSC involvement. The key to effectively utilizing market forces is to assure the regulations permit manufacturers to perceive an economic advantage in developing and improving products to meet the “benign by design” design criteria.

If this approach were taken, stakeholders would be benefitted by access to improvements to a greater number of products in a shorter time period and potentially at less cost than through the use of traditional involuntary command and control approaches.

Recommendation: WSPA suggests that the DTSC ensure that the regulations and implementing guidance provide clear target design criteria with accompanying methodology describing how alternatives will be assessed as to whether they meet the criteria.

3. An Effective and Properly Prioritized SCPA Program Should Focus on “Worst First”

The SCPA should focus on products truly warranting additional regulation in order to reduce potential hazards to human health and the environment more rapidly. Otherwise, “if everything is a concern, nothing is of special concern.”¹ Lack of prioritization will, instead, result in a waste of valuable time and resources while staff works on products posing less potential hazard.

Recommendation: The regulations should: 1) Emphasize an interest in protecting human health and the environment by focusing first on those products that may pose the greatest potential hazards, and 2) assign the highest priority to those products (i.e., “worst first” prioritization). Such an effort would allow DTSC to focus its limited resources on those products that actually present the greatest potential hazard to human health and the environment.

In the current version of the proposed regulations the criteria for selection of Priority Products at §69503.2 and §69503.3 are very broad. Consequently, they neither express a “worst-first” approach nor provide an effective market signal.² DTSC must clearly explain how these criteria were considered and how they may be applied in developing the proposed list of initial Priority Products. This clarity should improve understanding among all stakeholders if and how a “worst-first” approach is being implemented. Improved focus on priority products would send a market signal to manufacturers identifying what improvements are warranted.

¹ Comments by Dr. Berend to the DTSC Green Ribbon Science Panel 10/14/09 at p. 61 lines 17-18.

² If the regulations included a specific description of the product characteristics that would cause it to be listed as a Priority Product, then the regulations could act as an effective market signal to manufacturers identifying the specific improvements to their product that they ought to consider making to prevent it from being listed as a Priority Product.

Recommendation: Focus the proposed regulations to clearly emphasize the attention to priority products. Clarify this intent by crafting more specific criteria used in the prioritization.

WSPA agrees that existence of other regulatory programs at §69503.2(b) (2) is a key factor in prioritizing products. Considering this factor is consistent with a “worst-first” approach that focuses limited resources on products warranting additional regulation and is entirely consistent with H&SC §§25257.1(b) and (c), we support the use of this consideration in prioritizing products for direct regulation, tailoring/limiting the scope of selected regulatory response actions, and for identifying products not subject to SCPA regulation.

4. The Narrowed Alternative Analysis Threshold (AAT) Process is Unlikely to Significantly Enhance Administrative Efficiency

One objective of the SCPA is to identify products that warrant additional regulation and the appropriate regulatory actions to address potential harms posed by such products. The AAT is based upon a policy decision designed to further this objective by enhancing administrative efficiency in the identification of products not warranting additional regulation, including not going through the default detailed AA process.

Restricting the Alternatives Analysis Threshold process solely to “contaminants” may potentially subject many products to the default detailed AA process. Furthermore, using the Practical Quantitation Limit (PQL)³ as the sole basis to establish the AAT value (capping the AAT value at the PQL) further limits the administrative efficiency of the AAT process. Instead, it may be preferable for the AAT to be applicable to all COCs irrespective of their source and that a variety of relevant factors to be considered in deriving the specific AAT value for each Priority Product/COC combination.

Recommendation: WSPA recommends the DTSC use the previous version of the proposed regulation in which the AAT process was applicable to all COCs, regardless of source, and the broader number of factors that may be used to establish the AAT value. In the alternative, allow for narrowly scoped AAs focusing on specific potential hazards posed by the products as it will conserve resources of the DTSC and responsible entities. The Final Statement of Reasons and future AA guidance could be used by the DTSC to affirm the use of focused AA documents.

5. Economic Impact Analysis Requires Evaluation of Information Unavailable to Regulated Entities

Proposed §69505.6(a) (2) (C) requires the inclusion of an analysis of economic factors: “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.”

³ lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures

These items are based on data largely unavailable to manufacturers and other responsible entities. As a result, the economic analysis may be speculative, incomplete, or inaccurate, leading to potentially erroneous conclusions that could result in selecting inappropriate regulatory response actions. Furthermore, the inclusion of inaccurate or false information could create uncertainties or inconsistencies for those certifying documents as required by proposed §69501.3(c).

Recommendation: Eliminate analysis of the factors identified at §69505.6(a) (2) (C).

WSPA appreciates the continuing opportunity to provide input to the Agency. We look forward to the next version of the proposed regulations. Should you have any questions, feel free to contact me or Mike Wang of our staff (cell: 626-590-4905; mike@wspa.org).

Regards,



Cc: Ms. Debbie Rapahel (DRaphael@dtsc.ca.gov)
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Mr. Jeff Wong (JWong@dtsc.ca.gov)
Mr. Jeff Sickenger, KP



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February 28, 2013

Dear Ms. Von Burg:

Please accept this submission about the latest version of the proposed *Safer Consumer Production Regulations*, DTSC reference number R-2011-02.

Worksafe is pleased to submit our comments, as we have for earlier informal and formal drafts of these important regulations. We also have contributed to workshops, discussions and meetings about them, on our own and as a member of Californians for a Healthy and Green Economy (CHANGE).

Our input has focused on the occupational health/worker/workplace issues, while not ignoring the bigger picture and issues relevant to our coalition partners and other allies. It has been based on activities and conversations with those partners and allies in the labor and environmental movements, as well as public and occupational health professionals.

As explained in earlier submissions, Worksafe is a California-based independent non-profit dedicated to protecting people from job-related injuries, illnesses, and death. We advocate for protective worker health and safety laws and effective remedies for injured workers. In coalition with unions, workers, community, environmental and legal organizations, and scientists, we engage in campaigns to eliminate hazards and toxic chemicals from the workplace. We educate policymakers about the magnitude of workplace hazards and their impact on working people and communities, and propose public health-based solutions that focus on prevention. Many of our activities focus on low-wage immigrant workers and their experiences.

Our comments are divided into a list of changes that we are pleased to see (not always in their entirety), followed by our concerns and recommendations for further improvements. We also support the CHANGE coalition's

submission and have tried to not duplicate its feedback unless we wanted to emphasize the occupational health/workplace issues involved.

In both cases, we trust DTSC will give the comments and recommendations serious consideration. Should there not be another formal version of the regulations, we urge the Department to use guidelines and other supplementary materials to deal with as many of our concerns as possible, along with those of CHANGE and its members.

Finally, we want to reiterate our support for the Green Chemistry Initiative in general, and to recognize the importance of these regulations, as limited as they are. It is vital that the program get going. We know DTSC needs more resources to do this, and we will do our best to encourage and support efforts to get the department the means to implement this program, particularly through the Legislature.

Please let me know if you have any questions.

Sincerely

A handwritten signature in cursive script that reads "Dorothy Wigmore".

Dorothy Wigmore, M.S.
Occupational health specialist



Comments about the second formal California *Safer Consumer Product Regulations*

A. Many changes are improvements

We are glad to see that changes to the *Regulations* include:

- ✓ specifying the purpose is to “eliminate or reduce potential exposures to, or the level of potential adverse impacts posed”, in so far as the emphasis is on eliminating hazards and potential adverse effects (§ 69501);
- ✓ removing the limitation on application of the regulations “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” [§ 69501(b)(2)];
- ✓ changes to definitions that effectively clarify how workers are affected, such as:
 - including indoor air in “adverse air quality impacts”,
 - “the ability to reuse or recycle materials resulting from the treatment of solid waste and/or wastewater” in “adverse waste and end-of-life effects”,
 - the definition of “placed into the stream of commerce in California”,
 - the use of “potential” in a wide variety of situations, and
 - the attempt to define “reliable information”;
- ✓ adding the European Commission’s list of respiratory sensitizers to the list of so-called candidate chemicals [§ 69502.2(a)(1)(I)];
- ✓ adding “structurally or mechanistically similar chemicals for which there is a known toxicity profile” to criteria for additions to the “candidate chemicals” list [§ 69502.2(b)(1)(D)];
- ✓ removing the “availability of information” requirement for prioritizing additions to the “candidate chemicals” list [§ 69502.2(b)(3) -- lines 21 - 25 on page 30] and priority products list [lines 25 - 29, page 35];
- ✓ the addition of “workplace” presence of chemicals and products [§ 69503.3(b)(3)(B)] and the term “places of employment” in several sections [e.g., § 69501.1(a)(58)(A)2];

- ✓ the addition of “Material Safety Data Sheets” to required contents in an AA report [§ 69505.7(e)(4)] (although they will be known as Safety Data Sheets or SDSs under the upcoming Globally Harmonized System for the Classification and Labeling of Chemicals /GHS rules in the state’s Hazard Communication Standard, and elsewhere in the world);
- ✓ requiring the preliminary AA report to include information about which “relevant safeguards” in other regulatory programs were considered [§ 69505.7(g)(2)(B)];
- ✓ requiring responses to public comments about preliminary AA reports and how they are (not) addressed in the final version(s) [§ 69505.7(i)(1)]; and
- ✓ maintaining and explaining the “advancement of green chemistry and green engineering” [§ 69506.8].

B. More changes are needed

1. “Candidate chemicals” list

We are very unhappy with the unexpected change to the name of the initial list of toxic chemicals. They really are “chemicals of concern” or they would not be on the authoritative lists from other scientific bodies or government agencies. The name does not need to be changed, and should not be.

This obvious and unexpected sop to industry seriously reduces the list’s ability to drive marketplace changes. DTSC touted that effect as a fallback to the small number of chemical-product combinations that it can regulate. We heard regularly from Department representatives that the list would provide an incentive for businesses to re-design their products and processes, and that consumers in general would have information they could use to make informed choices about the products they use and purchase.

In particular, we argued that a list of “chemicals of concern” gives workers some leverage to question the use of toxic substances in their tasks, and encourages their employers to look for less or non-toxic alternative products or processes.

The new name will have an opposite effect, since it misleads the public, including workers and employers who purchase consumer products. It will be much more difficult to argue about the need to reduce the use of products containing chemicals on this list, and/or the chemicals themselves. It will be more difficult to push for better standards for these chemicals in workplaces and other environments. And it likely will lull a wide range of consumers -- workers and employers included -- into being less concerned about these chemicals of concern.

In fact, using the name “candidate chemical” is far more appropriate for chemicals that are candidates to be included in priority products.

Recommendations:

Revert to “chemicals of concern” for the name of the list. or use another phrase that conveys the proper nature of the list -- it’s about toxic chemicals whose use should be eliminated or greatly reduced.

Change the name for chemicals in priority products to candidate chemicals.

2. Prevention versus control

Preventing hazards is the innovative intent of AB 1879, consistent with good public health principles and practices. (The principles are summarized in the “prevention triangle” submitted in our October comments.) If a substance is inherently hazardous, that is sufficient reason to restrict its use. Otherwise, it is far too easy to use “containment”, relying on controls that still (may) allow exposure.

As we know in occupational and public health, this approach often fails. The public, and workers in particular, are left to reduce or limit the harm they face instead of expecting a manufacturer or employer to deal with the hazard at its source. They pay a price with adverse health effects, and their general environments also can be polluted.

These regulations rely far too much on assessing or getting information about exposures, as opposed to hazards. Restricting exposure with controls can be an improvement but it should not be a long-term goal. A containment or control approach also fails to drive the development and use of safer, less toxic chemicals, an overarching goal of the regulations and California's broader Green Chemistry Initiative.

For these reasons, CHANGE and Worksafe have consistently advocated that DTSC specifically consider engineered safety and health measures and administrative controls as *interim actions* -- not permanent solutions -- while inherently healthier/safer, less toxic alternatives are developed.

Recommendations:

In § 69506.6, when DTSC imposes engineered “safety measures” (see recommendations in sections 11 and 16 of this submission for related wording) or administrative controls, add a phrase to the effect that they are considered interim actions until a more sustainable solution is found. Also make clear that personal protective equipment is not an acceptable control for these purposes.

Add to § 69506.7(a) wording similar to that suggested by CHANGE (reflecting changes recommended in sections 11 and 16 of this submission):

While a solution to eliminate the hazard is found, as an interim action the Department may require a manufacturer to engineer health and safety measures that reduce or limit the harm from the chemical(s) of concern or replacement candidate chemical(s) in a selected alternative or the chemical(s) of concern in a priority product for which an alternative is not selected. These measures may include integrally containing or controlling access to and/or implement administrative controls. Personal protective equipment is not an acceptable control for these purposes.

3. Economic feasibility and costs associated with alternatives

We are glad to see that “public health and environmental costs” and some government agencies’ costs are now included in economic impacts that must be dealt with in the alternatives analysis process. However, some important externalized costs still are not covered. They include:

- ❑ the costs to government agencies other than those protecting the environment, particularly those dealing with people’s health and its consequences (e.g., those dealing with occupational health and safety and those covering medical and social expenses related to adverse public health effects);
- ❑ workers’ compensation costs (perhaps); and
- ❑ the costs to individuals and their families, who often bear most of the financial burden of work-related injuries, illnesses and deaths, and likely those related to environmental hazards.

See our previous comments for details about the consequences and recommendations. For specific details about what “public health costs” should include, see these studies and reports:

- ❑ the United Nations Environment Programme's [Global Chemicals Outlook](#) (e.g., Annex 3) (note that authors/contributors include Ken Geiser and Rachel Massey of UMass Lowell, who may be helpful resources for these definitions);
- ❑ recent papers by University of California Davis professor Paul J. Leigh (“[The Economic burden of occupational injury and illness in the United States](#)”, “[Workers' compensation benefits and shifting costs for occupational injury and illness](#)” and “[Numbers and costs of occupational injury and illness in low-wage occupations](#)”);
- ❑ Celeste Monforton and Liz Borkowski’s report using some of these studies ([Mom’s off work ‘cause she got hurt: The economic impact of workplace injuries and illnesses in the U.S.’s growing low-wage workforce](#)); and
- ❑ Ayres and colleagues’ 2012 paper, “[Costs of occupational asthma in the UK](#)”.

All have charts, tables and references that would be helpful.

Recommendation:

Ensure that “public health costs” in §69505.6(a)(2)(C) are defined or explained to include the costs incurred by individuals, health care/medical systems and insurance programs, government agencies that deal with the adverse public health effects of the chemical/product, and their consequences. If necessary, add to this section a phrase to ensure that the costs incurred by individuals and their families are evaluated, monetized and compared.

4. The definition of “reliable information”

The new definition of “reliable information” is helpful. However, the consequences of using it may require all kinds of resources at DTSC. (We are not arguing to remove the definition.)

If resources are not available, Department staff will not be able to determine if information exists that could be considered reliable and/or to properly evaluate information submitted in work plans and alternatives assessments. One solution is to rely on authoritative agencies (e.g., OEHHA) to vet information.

Furthermore, the definition should ensure that a single positive study is sufficient, provided it meets other criteria for reliable information. These sentinel studies are behind many of the “late lessons from early warnings” that led to the Green Chemistry Initiative. For a possible wording, see the [proposal](#) from Cal/OSHA to integrate the Globally Harmonized System (GHS) into California’s Hazardous Communication Standard (*Health hazard: A chemical, mixture of chemicals or a pathogen for which there is statistically significant evidence, based on at least one study conducted in accordance with established scientific principles, that acute or chronic health effects may occur in exposed employees.*)

Recommendations:

Use authoritative agencies (e.g., OEHHA) to determine if submitted or available information is “reliable”.

Ensure that one positive study can be used as reliable information, and that negative studies (especially those funded by industry in some way) get much less weight than positive ones.

5. The definition of “sensitive sub-populations”

We are disappointed to see that women and men of child-bearing age have not been added to the definition of “sensitive sub-populations”. This is an

increasingly-important issue as scientists learn about vulnerable windows that affect the ability to conceive and have a healthy pregnancy and children. Women and men do not always plan to conceive a child, nor do women know they are pregnant the instant it happens. Too many chemicals can have an effect on reproductive health, a foetus, and a child, at very low levels.

Lead is a classic example of a chemical that affects men and women's reproductive health, and their ability to conceive and have healthy children. Organic solvents and endocrine disruptors also have these effects, particularly in occupational settings [e.g., for a recent report, see T.A. Desrosiers, et al. (2012) "Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study", *Occupational and Environmental Medicine*, 69(8): 534 – 542].

Recommendation:

Add women and men of reproductive age to the definition of sensitive sub-populations.

6. Missing hazard traits

It is good that respiratory sensitizers in Annex VI of the EU's Regulation 1271/2008 are now on the list of "candidate chemicals". It would be better if respiratory irritants and astmagens also were there, as we recommended in our comments in October.

"Skin disorders" are so common in California workplaces, that they are one of five categories used to describe reported [non-fatal injuries](#). The issue is a long-standing problem in the state. For example, there is 1982 report from the Department of Industrial Relations, *Occupational skin disease in California (with special reference to 1977)*, and numerous studies in the literature (e.g., "[Latino farmworker perceptions of the risk factors for occupational skin disease](#)", published in 2006, and many from the 1980s).

For these reasons alone, chemicals classified as skin irritants and sensitizers also should be on the list. We argued for this addition in our comments about the first formal draft and refer DTSC to them again. In short, these hazard traits are already listed in Chapter 54. All kinds of chemicals have dermal effects, as noted in reports such as [The impact of REACH on occupational health with a focus on skin and respiratory diseases](#) and the [Proposed National Strategy for the Prevention of Dermatological Conditions](#). The effects can be devastating and many can be prevented.

We also support CHANGE's comments about the need to add neuro-developmental hazard traits, already on the OEHHA list from which DTSC draws for its initial list of hazard traits for problematic chemicals. These hazards are related to the need to name men and women of reproductive age in the definition of sensitive sub-populations.

Recommendations:

Add lists specific to asthmagens and respiratory irritants, using the lists recommended in October.

Include skin irritants and sensitizers in the “candidate chemicals list. At least use the European Union’s Annex VI as a source, if not others that we recommended in October.

Also add chemicals with neurodevelopmental hazard traits.

7. Cumulative effects

There are two places in the regulation where DTSC looks at adverse impacts that include a chemical’s “cumulative effects with other chemicals with the same or similar” hazards or endpoints.

It is unfortunate that the Department has not recognized that a chemical can have synergistic effects with hazards other than chemicals, or that cumulative effects may result when one chemical interacts with other chemicals that, on their own, do not have the same or similar traits or end points. For example, solvents and noise combine synergistically to increase hearing loss, while ultraviolet radiation in the presence of some chemicals increases the odds of skin cancer.

Recommendations:

After the phrase, add “or cumulative effects from combined exposure to the chemical and other hazards”. This applies to sections § 69502.2(b)(1)(A)3 (about adding to the “candidate chemicals” list) and § 69503.3(a)(1)(C) (adverse impacts and exposure factors for selection of priority products).

Clarify the meaning of “cumulative” to include synergistic effects.

8. Updating the initial chemical list

It is important to ensure that the list of “candidate chemicals” is kept up to date.

Recommendation:

Update the initial list of chemicals (best called the “chemicals of concern” list) at least every two years.

9. The product prioritization process

Is the Department starting its prioritization process with products? That is what seems to be described in § 69503.2.

We understood that an important premise of these regulations was that they would start with chemicals and then proceed to products. Doing the opposite could lead the Department to miss opportunities to catch emerging hazards before they become commonly used in a wide variety of products. (For example, 1-bromopropane initially had a niche use in electronics and now is widely used as a degreaser and solvent in many other sectors. NMP is supposed to be a less toxic substitute for methylene chloride, although it is a developmental toxicant.)

Recommendation:

Clarify that the product prioritization process starts with “candidate chemicals”.

10. Chemical information

Please see CHANGE’s comments about the need for a “no data, no market” approach, and the difficulties we expect DTSC to have getting reliable and available information about chemicals.

DTSC needs to be able to demand and get information from companies, wherever they are. Companies may refuse to do this (e.g., the experience of the Healthy Building Network in their [Pharos](#) database), making it appear that information about a chemical or product’s hazards, exposures, etc. is not available. The Department needs to be able to require companies to submit information, or penalize them if they don’t. (In the Pharos database, the authors try to find information from other sources and, in their ratings, effectively penalize those manufacturers who are not transparent with them, and the public.)

Recommendation:

Ensure that DTSC can get information that it needs from companies, wherever they are, about its market presence, customers, chemical-product combinations, etc., with penalties for non-compliance. This is relevant in several places in the regulation [e.g., § 69503.2(b)(C)].

11. Criteria for chemical-product combinations

Two criteria for chemical-product combinations seem problematic for those with occupational health concerns and workplace experience.

First, in § 69503.3(b)(4)(D)3, it is good to see schools included, although they are workplaces too. We would like to be sure that the “workers, customers, clients and members of the general public” do not all have to be in the same place at the same time.

Second, information about engineering and administrative controls may be useful to DTSC, especially since they are not long-term solutions that prevent adverse health and environmental effects. It also would be helpful for the Department to know how effective the controls really are, and to be sure that personal protective equipment is not the principal control method.

Recommendations:

Change the wording in § 69503.3(b)(4)(D)3 to read “... clients and/or members of the general public”.

In section § 69503.3(b)(4)(G), change the wording to read “Engineering and administrative controls that reduce exposure concerns associated with the product and its components, the specific type(s) of each, and their demonstrated effectiveness. Personal protective equipment is not an acceptable control for these purposes.”

12. Priority products criteria

The criteria for an initial priority products list is too stringent, as it likely excludes some important chemicals with occupational health concerns. The new requirement is that the chemicals must be on lists in both subsections (a)(1) and (a)(2) of section 69502.2. Unfortunately, there does not seem to be a lot of overlap between the two when it comes to workplaces and chemicals of concern to workers and occupational health practitioners.

Recommendation:

Re-word § 69503.6(a) to say if the chemical(s) is on the lists in subsection (a)(1) of section 69502.2, and not on those in subsection (a)(2), it can be listed if it is a chemical that has adverse effects on sensitive subpopulations, particularly workers.

13. Replacement chemicals

Replacement chemicals should not automatically be ones that are already in use in the same or similar products, as allowed in § 69505.2(b)(9)(F)2. History tells us that just because something is in a product as a “replacement” does not mean it has been tested appropriately, is less toxic than the original, etc. The long litany of regrettable substitutes was one of the reasons for the state’s Green Chemistry Initiative.

Recommendation:

Add language to ensure that if a replacement chemical is a “candidate chemical” and used in a similar/same product, that its hazard traits and endpoints must be less toxic than those of the chemical it is replacing.

14. Chemical removal intent notifications

Chemical removal intent notifications need to be better aligned with good occupational health and safety practices and regulations (e.g., the California Hazard Communications Standard). These include a promise to change information on Safety Data Sheets (currently called Material Safety Data Sheets or MSDSs) within three months, provide information to workers about the changes, and to pass along this information to Cal/OSHA (which is supposed to collect MSDSs) and the Hazard Evaluation System and Information Service ([HESIS](#)) in the Occupational Health Branch of the California Department of Public Health.

This will complement proposed [SB 193](#), introduced in February, 2013. It is designed to ensure that HESIS can get information from any manufacturer, supplier, etc. about their customers (i.e., whom and how much of a toxic substance is being shipped into California, and, if the substance is part of a mixture, the proportion of the toxic material in that mixture). HESIS is supposed to alert workers and their employers about hazards, and needs this kind of information to be able to carry out its mandate.

Recommendation:

Add language to ensure that notifications include a promise to:

- change SDS information within three months,
- notify and train workers about the changes, and
- provide the information to Cal/OSHA and HESIS.

15. Product information

Product information for consumers covers most of what is needed. We recommend two small additions.

Recommendations:

In § 69506.3(b)((4), the statement about disposal needs to include where to get information about how to dispose of the product or treat it as hazardous waste.

In § 69506.3(c)(2), change subsection (B), or add a (C), to the effect that the information must include a Safety Data Sheet.

16. Engineering controls

To complement the recommendation above (sections 2 and 11) about engineering controls, DTSC should clarify some small points in § 69506.6. “Safety” is not the same as “health” and personal protective equipment (PPE)

only limits harm and is inappropriate as a control measure in a green chemistry regulation.

Recommendations:

In subsection (a), re-word it to say .. “to engineer health and safety measures...”.

In subsection (b)(2), include “places of employment”.

Somewhere in this section, include a statement that personal protective equipment is not an acceptable engineering or administrative control.

17. Recycling and re-use issues

When there are requirements related to recycling and re-use of products [e.g., § 69506.7(c)(2)(H)], DTSC should be aware that there are efforts afoot in the state to improve the integrity of recycling processes. The goals are to ensure that there are fewer hazards for the workers who sort materials and better quality products can be produced when sorting is done to some extent before materials reach the recycling facility. The Department also should ensure that consultations about plans include workers and their representatives as stakeholders.

Recommendations:

In references to recycling and end-of-life management plans, ensure that plans consider the integrity of the recycled materials, not just the rate at which items are recycled.

In § 69506.7(c)(2)(L), add words to ensure workers are represented “ ... public, worker and other stakeholder ...”.

18. Regulatory responses and notifications

In regulatory response reports and notifications, DTSC would get much more “bang for the buck” if it co-ordinates with the state’s occupational health regulatory and policy entities, including Cal/OSHA and HESIS. (See the earlier remarks about HESIS.)

Recommendation:

In § 69506.10(a), add words to ensure that a copy of the notification goes to Cal/OSHA and HESIS.