

30-DAY NOTICE LIST OF PUBLIC COMMENTERS			
#	NAME OF ENTITY	DATE REC'D	LATE
1	Adhesive and Sealant Council	2/25/2013	
2	Agricultural Associations	2/28/2013	
3	Airlines for America & Boeing	2/28/2013	
4	Alliance of Automobile Manufacturers	2/28/2013	
5	American Apparel & Footware Association	2/28/2013	
6	American Chemistry Council	2/28/2013	
7	American Cleaning Institute	2/28/2013	
8	American Coatings Association	2/28/2013	
9	American Forest & Paper Association	2/28/2013	
10	American Forest & Paper Association	2/28/2013	
11	American Forest & Paper Association	2/20/2013	
12	American Wood Council	2/28/2013	
13	Applegate Review_ESPR	2/20/2013	
14	Ashford Review_ESPR	3/4/2013	
15	Association of Global Automakers	2/28/2013	
16	Association of Home Appliance Manufacturers	2/28/2013	
17	Automotive Aftermarket Industry Association	2/28/2013	
18	Battery Council International	2/28/2013	
19	Bay Area Clean Water Agencies	2/28/2013	
20	Bennett Review_ESPR	3/8/2013	
21	BizNGO	2/28/2013	
22	Boots Retail USA	2/27/2013	
23	California Chamber of Commerce	2/28/2013	
24	California Grocers Association	2/28/2013	
25	California Healthcare Institute	3/1/2013	<b>LATE</b>
26	California Industrial Hygiene Council	2/27/2013	
27	California Manufacturers & Technology Association	2/28/2013	
28	California New Car Dealers Association	2/28/2013	
29	California Product Stewardship Council	2/25/2013	
30	California Retailers Association	2/28/2013	
31	California Stormwater Quality Association	2/28/2013	
32	CHANGE (Californians for a Healthy and Green Economy)	2/28/2013	
33	Chemical Industry Council of California	2/28/2013	
34	Christensen Review_ESPR	3/4/2013	
35	Clean Water Action	2/28/2013	
36	Clorox Company	2/28/2013	<b>LATE</b>
37	Complex Durable Goods Coalition	2/28/2013	
38	Consumer Healthcare Products Association	2/28/2013	
39	Consumer Specialty Products Association	2/28/2013	



February 25, 2013

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives regulation Coordinator  
Regulation Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 958112-00806

**RE: Comments re DTSC's January 29<sup>th</sup> Draft Regulation for the Safer Consumer Products**

The Adhesive and Sealant Council (ASC) is a North American trade association representing 121 manufacturers of adhesives sealants and suppliers of raw materials to the industry. As director of government relations for ASC, I am writing to express our members' continuing concerns with the latest regulatory proposal for the implementation of The Green Chemistry Initiative legislation.

As we have noted in comments to earlier versions of the proposed regulation, ASC, our members and our industry support the concepts of green chemistry as well as the principles of product stewardship which together lead manufacturers to developing new technologies while always keeping in mind public health and environmental impacts. In reviewing the January 27<sup>th</sup> proposal, ASC recognizes that the Department has made modifications to the earlier proposals, but our industry still remains deeply concerned with many of the underlying precepts that remain in this proposal. It is still the belief of the Council that implementation of this regulation as proposed could lead to companies abandoning California markets or relocating manufacturing facilities to other states.

Throughout this regulatory process ASC and its members have been troubled by the DTSC's overly broad definition of consumer product. This continuing approach for defining consumer products will allow for few exceptions and results in almost any product that was bought, sold or leased in California (from the largest building structures to the smallest retail item) to be scrutinized. It is difficult to reconcile the complexity of this approach with the marginal improvement in health and environmental safety it is likely to advance.

For the regulation to be an effective and enforceable it should begin with a definition of consumer product that has focus and direction. A realistic approach would begin with a review of the California Air Resources Board's definition of consumer product as defined in their consumer rule (see <http://www.arb.ca.gov/consprod/regs/2008/3cp.htm>).

“Consumer Product” means a chemically formulated product used by household and institutional consumers including, but not limited to, detergents; cleaning compounds; polishes; floor finishes; cosmetics; personal care products; home, lawn, and garden products; disinfectants; sanitizers; aerosol paints; and automotive specialty products; but does not include other paint products, furniture coatings, or architectural coatings. As used in this article, the term “consumer product” shall also refer to aerosol adhesives, including aerosol adhesives used for consumer, industrial, and commercial uses.

This definition has been utilized by CARB for more than a decade and it provides a manageable scope of that regulation that continues to be lacking in the present draft language.

With regard to the Agency’s most recent proposal that would establish a list “Chemical Candidates” ASC recognizes the fact that the DTSC is proposing a significant reduction in the number of chemicals under consideration from earlier proposals. It is the Council’s understanding that the Chemical Candidates List would still represent at least 1200 chemicals. This approach remains seriously flawed unless the DTSC undertakes some sort of prioritization process that identifies a discrete subset of the highest priority of the 1200 to be considered. No other state, federal or international jurisdiction apart from California has sought to begin with 1200 or more actionable chemicals.

Given the expansiveness of the list, there may be a large number of chemicals that will not come under consideration by the DTSC process for a number of years yet in the interim formulated products containing those chemicals may be implicated as hazardous to consumers simply because of their original listing. DTSC should concentrate on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm and substances known to be persistent, bioaccumulative and toxic in the environment as designated by the US EPA and others

ASC acknowledges the positive step the DTSC took in dropping the proposed requirement that assessors undertaking Alternative Assessments (AA’s) be third party certified. Unfortunately the new proposal now requires a manufacturer to release their preliminary AA Reports for public notice and comment. It is likely these preliminary AA Reports would include trade secret information thus forcing manufacturers to offer redacted information. Public comments questioning this redacted material would have to be addressed by manufacturers in the Final AA creating further uncertainty in the mind of the public.

Another industry concern is the requirement that trade secret protection can only be claimed for a replacement chemistry when a manufacturer chooses to make a patent application on the new alternative. This approach conflates two very different intellectual property strategies (trade secrets v.s. patent law) and challenges a principle of intellectual property law which allows an entity to choose whether to seek trade secret protection or file a patent application.

Under federal statutory law and common state law, manufacturers may claim a trade secret on any non-publicly disclosed information that it derives economic advantage, as long as reasonable measures are taken to maintain the information as secret. There is no requirement under any current or statutory law that requires a manufacturer holding a trade secret to seek patent protection.

February 25, 2013

Page 3

Conversely a manufacturer, filing for patent protection on a new replacement chemistry, would waive trade secret protection upon publication of the patent application disclosing the trade secret in exchange for the possibility of obtaining a 20 year exclusive to its use upon issuance of the patent.

By forcing manufacturers to choose a patent application approach rather than utilizing a trade secret option, DTSC's proposal would likely have the unintended consequence of placing American and more particularly California companies, in the untenable position of having to disclose their most economically valuable trade secret formulations in a manner which ultimately would place those trade secrets in the hands of foreign competition.

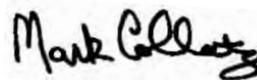
A continuing concern for ASC members with this latest proposal is that it does not specify a default concentration based on trigger that determines whether a manufacturer can qualify for an exemption from the Alternative Analysis requirement. Instead, DTSC will choose a threshold for designated Chemical of Concern (COC) in any Priority Product. Such an arbitrary approach will only further confuse formulators' understanding of what constitutes a COC. As an example, such an approach could result in rogue contaminants placing an otherwise benign product under scrutiny. There must be a fixed definition of what is de minimus and it must provide that "naturally occurring" contaminants are exempted under any definition.

In addition, leaving a default concentration open-ended for different chemicals and different products will add to the complexity for determining compliance with the regulation and leave manufacturers uncertain to whether they are ever in compliance with regulations.

ASC is supportive of proposal establishing as a "de minimus" level a concentration less than or equal to 0.1%

Again ASC and its members appreciate the opportunity to comment on the draft regulation and if there are any questions or need for further explanation of any of these points, please do not hesitate to contact me at 301/986-9700 ext. 112 or [mark.collatz@ascouncil.org](mailto:mark.collatz@ascouncil.org).

Respectfully Submitted,



Mark Collatz

Director of Government Relations

February 28, 2013

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
*Via Email to: [gcreqs@dtsc.ca.gov](mailto:gcreqs@dtsc.ca.gov)*

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

Dear Ms. Von Burg:

The undersigned organizations respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") revised proposed Safer Consumer Products Regulation ("regulation") of January 2013.

The statute authorizing the regulation defines "Consumer product", including exemptions for which the regulation cannot apply.

§25251(e) "Consumer product" means a product or **part** of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:"

...

§25251(e)(6) "A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide (7 United States Code Sections 136 and following)."

Based on this exemption, we believe the statute clearly intended to exclude any product which contains a pesticide as **part** of the product, such as seeds coated with insecticides or fungicides and all products containing or treated with chemicals regulated by the CA Department of Pesticide Regulations. We request your clarification that no aspect of a pesticide can be included in the regulation due to the statutory exemption.

Previous drafts of the regulation included language stating that the regulation does not apply to any statutory exemptions, as well as 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." In addition to exempting pesticides, the statute also exempts food (§25251(e)(4)). We believe the language recently struck from your regulation would have included fertilizers as an exempt product due to its use **solely for**

**the manufacture** of food. Without that exemption, we have concerns about the inclusion of fertilizers in the regulation as they are currently regulated under the Department of Food and Agriculture. We request that consideration be given for the existing regulation of fertilizers and that they not be included in the Safer Consumer Products Regulation.

We appreciate your consideration of our concerns. For further information or questions regarding the attached comments contact Crystal Jack at (916) 448-3826 or [cjack@kscsacramento.com](mailto:cjack@kscsacramento.com).

Sincerely,



Terry Gage  
California Agricultural Aircraft Association



Tad Bell  
California Association of Wheat Growers



Jan Townsend  
California Bean Shippers Association



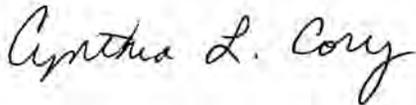
Joel Nelsen  
California Citrus Mutual



Earl Williams  
California Cotton Ginners Association  
California Cotton Growers Association



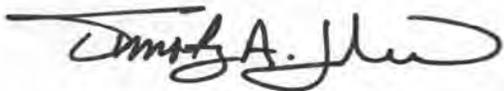
Chris Zanobini  
California Grain and Feed Association  
California Association of Nurseries and Garden Centers



Cynthia Cory  
California Farm Bureau Federation



California Pear Growers Association  
Debra Murdock



Tim Johnson  
California Rice Commission



California Seed Association  
Betsy Peterson



California State Floral Association  
Ann Quinn



Rick Tomlinson  
California Strawberry Commission



Mike Montna  
California Tomato Growers Association



Roger Isom  
Western Agricultural Processors Association



Matthew Allen  
Western Growers Association



Renee Pinel  
Western Plant Health Association

CC: The Honorable Matt Rodriguez, Secretary, California Environmental Protection Agency  
Miriam Ingenito, Deputy Secretary, California Environmental Protection Agency  
Kristin Stauffacher, Assistant Secretary, California Environmental Protection Agency  
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  
Karen Ross, Secretary, California Department of Food and Agriculture  
Sandra Schubert, Undersecretary, California Department of Food and Agriculture  
Jim Houston, Deputy Secretary, California Department of Food and Agriculture



February 28, 2013

**Submitted Via Email:**

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

**RE: Comments of Airlines for America and The Boeing Company on the Revised Proposed Safer Consumer Products Regulations; DTSC Reference #R-2011-02; OAL Notice File #Z-2012-0717-04**

To Whom It May Concern:

Airlines for America (“A4A”)<sup>1</sup> and The Boeing Company<sup>2</sup> appreciate this opportunity to submit comments on the Department of Toxic Substances Control (“DTSC”)’s Revised Proposed Safer Consumer Products Regulations, dated January 29, 2013 (“Revised Proposal”). A4A, its members, and Boeing appreciate DTSC’s efforts to respond to comments it received on the 2012 Proposed SCP Regulations (the “2012 SCP Proposal”). In our view, however, several of the key flaws in the 2012 SCP Proposal that we identified in our prior comments remain and others have been exacerbated by the revisions. In particular, we are concerned that neither an exemption defining aircraft out of the definition of “consumer product” in section 69501.1, nor an explicit statement that the sale of transportation services are not included in the definition of “consumer product” has been made. We therefore incorporate our full 2012 SCP Comments by reference (included in Attachment 1) and respectfully request that DTSC consider each argument and specific revision outlined therein as applied to the Revised Proposal. In addition, we kindly request your consideration of the new comments below.

Before presenting our comments on the content of the Revised Proposal, however, we emphasize our serious procedural concerns. The Department has provided notice and

---

<sup>1</sup> A4A is the principal trade and service organization of the U.S. airline industry. Its member airlines and their affiliates transport more than 90 percent of all U.S. airline passenger and cargo traffic. The members of A4A are: Alaska Airlines, Inc., American Airlines, Inc., Atlas Air, Inc., Delta Air Lines, Inc., Federal Express Corporation, Hawaiian Airlines, JetBlue Airways Corp., Southwest Airlines Co., United Continental Holdings, Inc., UPS Airlines., and US Airways, Inc. Air Canada is an associate member.

<sup>2</sup> The Boeing Company is the world's leading aerospace company and the largest manufacturer of commercial jetliners and military aircraft combined. Additionally, Boeing designs and manufactures rotorcraft, electronic and defense systems, missiles, satellites, launch vehicles and advanced information and communication systems. The company also provides numerous military and commercial airline support services.

opportunity to comment pursuant to Government Code section 11346.8(c); however, under any reasonable reading, the changes set out in the Revised Proposal are neither “nonsubstantial or solely grammatical in nature,” or “sufficiently related to the original text that the public was adequately placed on notice that the change[s] that could result from the originally proposed regulatory action.”

To the contrary, the Revised Proposal departs significantly from the 2012 SCP Proposal in scope, process and regulatory burden. A non-exhaustive list of examples includes: revisions to the definition of “Manufacture” and “Manufacturer” (which affect the scope of responsible entities under the Regulations);<sup>3</sup> introduction of “Assemblers” as an additional category of responsible entities;<sup>4</sup> a significant adjustment to how Alternatives Analysis Thresholds are defined;<sup>5</sup> and wholesale removal of certified assessors from the alternatives analysis process.<sup>6</sup>

In this context, perhaps the most significant departure from the 2012 Proposed SCP Regulations is the new requirement that responsible entities, rather than DTSC, must receive and respond to public comments on initial Alternatives Assessment documents.<sup>7</sup> This represents an un signaled change that would shift core governmental responsibilities and their attendant financial and administrative burdens to private parties, effecting a fundamental change in the structure of the proposed regulatory scheme.<sup>8</sup> This change is inconsistent with fundamental Administrative Procedure Act (“APA”) and administrative due process requirements.<sup>9</sup> The Revised Proposal is also impermissibly vague with regard to the how the proposed process would work and how responsible entities would be expected to respond to public comments, and what criteria would govern the legal sufficiency of the same.

---

<sup>3</sup> See proposed §§ 69501.1(a)(43)-(44).

<sup>4</sup> See proposed §§ 69501.1(a)(15)-(16).

<sup>5</sup> See proposed § 69501.1(a)(12).

<sup>6</sup> See *e.g.*, stricken language in proposed §69505.1(e).

<sup>7</sup> See *e.g.* §§ 69505.1(d)(1)-(2) and 69505.7(i)(1). Under proposed section 69505.7(i)(1), DTSC would require Final AA Reports and final Abridged AA Reports to include a summary of the public comments submitted under section 69505.1(d)(2) and a description as to how the comments are addressed in the report or an explanation of why they are not explained in the report.

<sup>8</sup> We understand modern budgeting pressures may animate this attempt to redistribute significant financial and administrative burdens of implementing the Green Chemistry Law (California Health & Safety Code sections 25251 to 25257.1) from DTSC to the private sector. However, if the Department believes it cannot incur the financial and administrative burdens of implementing this regulatory scheme, the solution is to curtail the regulatory scheme. If there is any gap between legislative aspirations and financial reality, it is incumbent upon elected officials to address that gap. That gap cannot be filled by unlawfully shifting core responsibilities of agencies (and thus imposing what amounts to a tax) on the private sector.

<sup>9</sup> California Government Code § 11346.9(a)(3) requires an agency to respond to comments related to a proposed action. DTSC cannot amend California Administrative Procedures Act requirements to delegate this requirement to regulated entities by regulation. The Alternatives Analysis process in the Revised Proposal would require the responsible entity to propose the requirements that would apply to its products and business. See *e.g.*, proposed § 69505.4(b)(4) (requiring a responsible entity to specify in the draft and final Abridged AA Report the milestones and dates for implementation of proposed regulatory responses).



Accordingly, California Government Code section 11346.4 applies and we respectfully request that DTSC observe the applicable procedural requirements and re-release the Revised Proposal (or an Updated Revised Proposal) with an accompanying Statement of Reasons<sup>10</sup> for a full, 45-day public notice and comment proceeding, including a public hearing.

## 1. Federal Law Clearly Preempts Regulation of Aviation Safety and Operations

Our 2012 SCP Comments explain in detail why state regulation related to aviation operations and aviation safety is preempted under federal law. There is ample case law, including appellate and U.S. Supreme Court precedent, establishing that the Federal Aviation Administration Authorization Act (“FAA Act”) and its implementing regulations create a “uniform and exclusive system of federal regulation” of aviation safety that preempts state and local regulation.<sup>11</sup> Further, the Airline Deregulation Act (“ADA”) expressly prohibits states from enacting or enforcing any law related to a “price, route, or service” of an air carrier.

Accordingly, we reiterate our request that the Department, acknowledge in the final SCP regulations and the rulemaking record that the State is precluded from regulating aviation under the SCP regulations, including regulation of products needed to maintain, service, or repair aircraft and related equipment as “priority products.” Such an acknowledgement is not only consistent with the California Constitution; the statutory limitation placed on DTSC’s authority to regulate consumer products under section 25257.1(b) requires it. Article 3.5 of the California Constitution states that an agency may not declare a legislatively enacted statute unenforceable on the basis of preemption unless there are appellate or higher level court decisions supporting same. This provision is meant to prevent administrative agencies from ignoring or invalidating the express will of the California legislature. But that is not the case here. In this case, there are extensive appellate and Supreme Court decisions supporting preemption. With regard to development of its own regulations, an agency must and should consider the extensive body of appellate and U.S. Supreme Court precedent establishing aviation preemption in its rulemaking process and specifically recognize preemption in its regulations as appropriate.<sup>12</sup>

---

<sup>10</sup> The lack of a Statement of Reasons to accompany the Revised Proposal has made it difficult to discern DTSC’s intentions, particularly as related to modified definitions. For example, in the 2012 SCP Proposal, repair and refurbishment was explicitly excluded from the definition of manufacturing; in the Revised Proposal, it is unclear whether repair and refurbishment would now be back in scope under the new “assemble” and “assembler” definitions. See section 5 for more related to this question.

<sup>11</sup> *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); see also *American Airlines v. Department of Transp.*, 202 F.3d 788, 801 (5th Cir. 2000) (aviation regulation is an area where “[f]ederal control is intensive and exclusive”) (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 3030 (1944)).

<sup>12</sup> See FN 11 and our 2012 SCP comments. Failure to consider preemption would likely result in deficiencies related to an agency’s legal authority to regulate in a preempted area and may result in regulations that are inconsistent with other law. Failure to consider preemption could also waste state resources by proposing and/or enacting regulations that are unenforceable from the start due to preemption.

More importantly, in section 25257.1(b) of the enabling legislation for the SCP regulations, state lawmakers explicitly provided that the law did “not authorize DTSC to *supersede* the regulatory *authority* of any other department or agency.”<sup>13</sup> In any field in which a Federal agency exercises plenary and exclusive jurisdiction to regulate (such as aviation), any attempt to regulate in that field by a state agency (even if intended only to supplement Federal regulation) would supersede the Federal agency’s authority.<sup>14</sup> Accordingly, an explicit statement consistent with the overwhelming, comprehensive and unequivocal court rulings at all levels of our judicial system that federal law preempts states from regulating in the field of aviation<sup>15</sup> is necessary to comply with section 25257.1(b).<sup>16</sup>

A. The SCP Regulations Must Consider Federal Preemption Explicitly

At a minimum, any regulatory scheme purporting to implement Article 14 of Division 20, Chapter 6.5 the California Health & Safety Code faithfully *must* give effect to section 25257.1(b) by ensuring the Department will not exercise authority within fields preempted under federal law.<sup>17</sup> To reflect the statutory instruction more clearly, we suggest the following revision (underlined text added; ~~strikeout~~ text deleted) to Revised Proposed SCP Regulation section 69501(c):

Harmonization. Nothing in these regulations authorizes the Department to supersede the regulatory authority requirements of another California State or federal department or agency regulatory program, or to promulgate rules that are preempted under federal law.

In addition, we request that DTSC revise the following sections as indicated:

---

<sup>13</sup> See California Health & Safety Code § 25257.1(b) (emphasis added).

<sup>14</sup> “The FAA preempts the entire field of aviation safety ... [t]he FAA regulations promulgated pursuant to it establish complete and thorough safety standards for air travel, which are *not subject to supplementation by, or variation among, state laws.*” See *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9<sup>th</sup> Cir. 2007) (emphasis added). In addition, the ADA expressly prohibits states from enacting or enforcing any law “related to a price, route, or service of an air carrier.” 49 U.S.C. § 41713. “[I]t makes no difference whether the state law is consistent or inconsistent with federal regulation.” See *Rowe v. N.H. Motor Transportation Ass’n*, 128 Sup. Ct. 989, 995 (U.S. 2008). See also *Wisconsin Department of Industry, Labor & Human Relations v. Gould, Inc.*, 475 U.S. 282, 288-89 (1986) (holding that states may generally not regulate activity that the National Labor Relations Act (“NLRA”) regulates, and this rule prevents states not only from setting forth standards of conduct inconsistent with the substantive requirements of the NLRA but also from providing their own regulatory or judicial remedies for conduct prohibited or arguably prohibited by the Act).

<sup>15</sup> Again, see our 2012 SCP Comments.

<sup>16</sup> As explained by the California Supreme Court in *Reese v. Kizer*, “[b]y limiting the implementation of a statute as directed by the Legislature, an agency neither ‘declares it unenforceable’ nor ‘refuses to enforce it.’ Indeed, far from thwarting the Legislature’s mandate, such action precisely fulfills it.” *Reese v. Kizer*, 46 Cal.3d 996, 1002 (1988).

<sup>17</sup> *Id.*

### **Proposed Section 69503.2**

(b)(2) Other Regulatory Programs. The Department shall next consider the scope of the other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements (A) have been ruled to preempt regulation of the product and/or field by an appellate or higher level court; or (B) address, and provide adequate protections with respect to the same potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product.

### **Proposed Section 69506(a)**

(a) Need for and Authority to Promulgate Regulatory Response. The Department shall identify and require implementation of one or more regulatory responses for Priority Products and/or selected alternative products when the Department determines such regulatory responses are necessary to protect public health and/or the environment. In selecting regulatory responses, the Department shall determine whether its authority to promulgate such a regulatory response has been preempted by federal law and seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.

## **2. The SCP Regulations Must Be Revised to Reflect the Limitation on DTSC's Authority to Regulate Consumer Products Under California Health & Safety Code § 25257.1(c)**

In California Health & Safety Code section 25257.1(c), the Legislature explicitly limited its grant of authority to regulate consumer products by providing “[t]he department *shall not duplicate* or adopt conflicting regulations for product categories already regulated ... *consistent with the purposes of this article.*” See California Health & Safety Code § 25257.1(c) (emphasis added).<sup>18</sup>

In revised section 69501(b) of the Revised SCP Proposal is the Department’s attempt to implement this limitation on its regulatory authority.<sup>19</sup> However, far from articulating a

---

<sup>18</sup> In contrast to section 25257.1(a), which is expressly phrased to preserve and extend the Department’s authority to regulate, both sections 25257.1(b) and (c) are phrased as explicit limitations on the Department’s authority: “This article does not authorize the department to . . .” in the case of subsection (a) and “The department shall not duplicate or adopt conflicting regulations . . .” in the case of subsection (b).

<sup>19</sup> Under revised section 69501(b), the SCP regulations will not apply if other regulations (including federal or state, and international requirements with the force of domestic law) already exist that (1) address the exact same potential adverse impacts, potential exposure pathways, and potential adverse waste and end-of-life effects that DTSC would have used as the basis for regulation and those regulations, and (2) those regulations “[p]rovide a level of public health and environmental protection that is equivalent to or

limitation on the Department's authority, revised section 69501(b) asserts authority to enact regulations that not only duplicate, but second-guess regulations enacted to protect public health. For example, where use of a product could potentially impact waters of the U.S., the discharge must be permitted under a valid permit from the California Water Resources Control Board implementing the requirements of the federal Clean Water Act. Under a proper interpretation of Health & Safety Code section 25257.1(b), the Department is prohibited from reconsidering the protectiveness of the Water Board's regulatory scheme. Under the interpretation of section 25257.1(b) reflected in the Revised Proposal (revised section 69501(b)), however, the Department is free to act where, in its view, its regulations would provide increased protection against public health and the environmental impacts than the Water Board's regulations. In short, where the Legislature clearly intended section 25257.1(b) to limit the Department's regulatory authority, the Department interprets it as a basis for arrogating a kind of "super-regulatory" authority. This certainly contradicts the Legislature's intent to limit the Department's authority and must be amended accordingly.

Revised section 69501(b) also is problematic because it ignores another legislative limitation on the Department's regulatory authority, California Health & Safety Code section 25257.1(b), which states Article 14 "does not authorize the department to supersede the regulatory authority of any other department or agency." That limitation is appropriately implemented in revised section 69501(c). Presumably, if DTSC were to exercise its claimed right to regulate a product more stringently than existing regulations targeting the same product and same adverse impacts, it would be superseding the authority of the other regulatory department or agency. While states typically are in a position where they may enact regulation that is more stringent than federal requirements, in this case, DTSC is limited by its enabling statute to not use the SCP regulations to regulate products that are already regulated under other programs.

Accordingly, we respectfully request that DTSC remove sub-section 69501(b)(2)(A)(2) from the Revised Proposal. Similarly, we request that DTSC revise section 69503.2(b)(2) by striking the last full sentence of that provision as follows:

~~Other Regulatory Programs. The Department shall next consider . . . that are under consideration as a basis for the product-chemical combination being listed as a Priority Product. If a product is regulated by another entity with respect to the same potential adverse impact and potential exposure pathways, and potential adverse waste and end-of-life effects, the Department may list such a product-chemical combination as a Priority Product only if it determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing.~~

Also, DTSC must include the evaluation of functional acceptability,<sup>20</sup> technical feasibility, and economic feasibility within the Priority Product identification and prioritization process. The

---

greater than the protection that would potentially be provided if the product were listed as a Priority Product."

<sup>20</sup> Please note requested modification to "functionally acceptable" definition in section 4 of these comments.



revised section 69503.2 makes this evaluation discretionary. Since determination of “functionally acceptable” includes a review of applicable legal requirements, this should be a required element of the identification and prioritization process. Therefore, section 69503.2(b) should be revised to read:

Identification and Prioritization Process. The Department may identify and list as a Priority Product one or more product-chemical combinations that it determines to be of high priority. The Department’s decision to identify and list a product chemical combination as a Priority Product shall be based on an evaluation of the product chemical combination to determine its associated potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects by considering the factors described in paragraphs (1), ~~and (2), and (3)~~ for which information is reasonably available. ~~The Department may additionally, in its discretion, consider paragraph (3).~~

In addition, section 96503.2(b)(3) should be revised to read:

(3) Safer Alternatives. When deciding whether to list a product-chemical combination as a Priority Product, the Department ~~may~~ shall also consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

### **3. Deficiencies in the Definitions of “Import” and “Importer” Need to be Addressed**

We first wish to acknowledge the addition of the final sentence to the definition of “importer.” We consider this to be responsive to our 2012 SCP Comments and we thank you for this change.

#### **A. Definition of “Import” must be revised**

As explained in our 2012 SCP comments, we are concerned that without clarification, operators of commercial aircraft would be considered “importers” of the aircraft under the SCP regulations even if the aircraft cross U.S. borders only incidental to, or for the purpose of, providing transportation services. As set out in detail in our 2012 SCP comments, California is preempted from regulating aircraft operations and cannot achieve an equivalent result by purporting to regulate “importation” of products.<sup>21</sup> We suggest the following language be added to address this issue:

---

<sup>21</sup> In any event, we note that aircraft, spare parts, regular equipment and aircraft stores are exempt from customs duty, inspection fees or similar national or local duties and charges under international law, specifically Article 24 of the Chicago Convention on International Civil Aviation of 1944. In addition, the United States has entered into over 100 “open skies” agreements with other countries, which generally exempt from import restrictions aircraft, their regular equipment, ground equipment, fuel, lubricants, consumable technical supplies, spare parts (including engines), aircraft stores (including but not limited to such items of food, beverages and liquor, tobacco, and other products destined for sale to or use by passengers in limited quantities during flight), and other items intended for or used solely in connection with the operation or servicing of aircraft engaged in international air transportation. See Model Open

§ 69501.1(a)(38): “Import” ... Aircraft (or any aircraft part of component), vessels, vehicles, and other equipment are not “imported” if they cross borders incidental to, or for the purpose of, providing transportation services. ...

If the above language is not included in the final regulation as requested above, DTSC should at least explain in the Final Statement of Reasons that the operation of aircraft into or out of the United States in connection with provision of air transportation services would not constitute the “import” of such aircraft, nor would it constitute “import” of any part or component thereof.

B. Definitions of “Import” and “Importer” should be modified to avoid assertion of authority to regulate activity beyond California borders

The definition for the term, “import,” provided in the Revised Proposal implicitly asserts that DTSC has the authority to regulate imports that enter the U.S. through points other than California even if the actual products have not reached California. See Revised Proposal at section 69501.1(38) (providing in relevant part: “‘Import’ means to bring, or arrange to bring, a consumer product *into the United States* for purposes of placing the product into the stream of commerce in California...” (emphasis added)). This definition is not appropriate given that it prompts DTSC to regulate conduct occurring wholly outside the state. The import definition should be revised to remove the “for purposes of” language since it is not the intent of the importer that establishes a link to California, but the actual placement of the product into the stream of commerce in the state. See below for suggested revisions in bold text:

[Proposed § 69501(38):] “Import” means to bring, or arrange to bring, a product into the United States ~~for purposes of~~ and placing the product into the stream of commerce in California. “Import” includes reimporting a product manufactured or processed, in whole or in part, in the United States. Aircraft (or any aircraft part of component), vessels, vehicles, and other equipment are not “imported” if they cross borders incidental to, or for the purpose of, providing transportation services.

**4. “Functionally Acceptable” Definition Must Include Additional Compliance Considerations**

In addition to legal requirements applicable to the sale of a product, some highly regulated products are also required to comply with performance standards in order to be legally used or certified for use. This needs to be reflected in the definition of functionally acceptable in the SCP Regulations. In particular, we request the following modification:

- (35) “Functionally acceptable” means that an alternative product meets all of the following requirements:
- (A) The product complies with all applicable legal requirements;

---

Skies Agreement (available here: <http://www.state.gov/e/eb/rls/othr/ata/114866.htm>). This reflects the understanding under international law that the aircraft, related parts, equipment, etc. are not treated as imported products.



(B) The product meets mandatory safety and performance standards required for regulatory approval or certification under other California state or federal regulatory programs; and

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

## 5. Clarification Requested Related to Status of Repair and Maintenance

### A. Definitions of “Manufacture”/“Manufacturer”; “Assemble”/“Assembler”

In the 2012 SCP Proposal, the definition for manufacturer included specific exclusions for repair and refurbishment of an existing consumer product; installation of standardized components to an existing consumer product; or making non-material alternations to an existing consumer product. In the Revised Proposal, these exclusions are stricken, but a new responsible entity (assembler) is added and defined. It appears that the simplification of the definition of “manufacture” still keeps repair and refurbishment out of the scope of manufacturing. We respectfully request DTSC’s confirmation of this reading, which is consistent with the Initial Statement of Reasons (“ISOR”),<sup>22</sup> as well as confirmation that the new “Assemble”/“Assembler” definitions do not bring repair and maintenance back into scope.<sup>23</sup>

### B. Intended Scope of “Manufacturer” Definition

The definition of “manufacturer” includes “any person that controls . . . or has the capacity to specify the use of chemicals in such a product.” This would appear to apply to FAA, which dictates the use of chemicals in certain applications. DTSC, EPA and other agencies exercising authority to regulate chemicals in products also may be encompassed within this broad definition of “manufacturer.”

## 6. Additional, General Comments

### A. Clarification of “Adverse Public Health Impacts” Required to Exclude Use of Proposition 65 Thresholds

“Adverse public health impacts” in section 69501.1(a)(6) of the Revised Proposed SCP Regulations are defined to include:

---

<sup>22</sup> The ISOR accompanying the 2012 SCP Proposal discusses the intent of the exclusion of repair, refurbishment, replacement parts, and alterations from the definition of “manufacture” as follows: “Existing products, especially durable goods, may need to have replacement parts available for service, repair and maintenance. By allowing these three exclusions, repair and maintenance of existing products can continue without the involvement of this regulatory program.” See ISOR at pp. 28-29.

<sup>23</sup> It does not appear that the “assemble” definition includes repair or refurbishment, as the text reads: “Assemble” means to fit, join, put, or otherwise bring together components to *create* a consumer product.” Since repair and refurbishment do not create consumer products, we read this definition to exclude repair and refurbishment. We kindly request your confirmation of this reading.

[A]ny of the toxicological effects on public health specified in article 2 or article 3 of Chapter 54, or exceedance of an enforceable California or federal regulatory standard relating to the protection of public health. Public health includes occupational health.

Through this comment, we request confirmation from DTSC that Proposition 65 thresholds are not suitable for use in determining a potential “exceedance of an enforceable CA regulatory standard.” The reason why Proposition 65 No Significant Risk Levels (“NSRLs”) and No Observable Effect Levels (“NOELs”) do not qualify as enforceable CA regulatory standards is that exposures above these levels is allowed, so long as a warning is provided. As a practical matter, it would also be very difficult to determine what the NSRL or NOEL is for a given Proposition 65 listed chemical (the majority of listed chemicals are not assigned a threshold), and the thresholds that are specified are stated not as concentration limits, but as micrograms of exposure per day that differ based on the size, age, and gender of the person. It would also be very difficult to determine (and for parties or scientists to agree on) whether a product resulted in exposure to a listed chemical above a NSRL or NOEL.<sup>24</sup> Finally, Proposition 65 is its own law, with its own enforcement mechanism for exposures from products in California.

**B. Listing of Candidate Chemicals on the Basis of their Identification as Priority Chemicals under the California Environmental Contaminant Biomonitoring Program Should Not be Allowed**

In proposed section 69502.2, a chemical could be listed as a Candidate Chemical under the regulations if it exhibits a hazard trait or toxicological endpoint and is identified as a Priority Chemical under the California Biomonitoring Program. The Biomonitoring Priority Chemical category should not be the basis for a Candidate Chemical listing, since these chemicals are identified for inclusion in the biomonitoring program in order to study *whether they are present in the bodies of Californians*; their identification as priorities for testing under the Biomonitoring Program is not necessarily an indication that the chemicals are known to be harmful. Furthermore, the criteria for selecting the priority chemicals for biomonitoring is very loosely defined in the biomonitoring statute and is not subject to the APA process.

**7. Conclusion**

A4A, its members, and Boeing take environmental protection seriously and we have a strong record of advancing environmental protection within our operations and throughout our respective supply chains. We generally support the goals of this regulatory initiative, however, there are still significant changes that need to be made to bring the proposed SCP regulations within the scope of the authorizing statute. As detailed in these comments and our 2012 SCP comments, DTSC may not ignore the extensive body of appellate and higher court decisions ruling that state regulation of aviation is preempted. It is also essential that DTSC consider and address the procedural infirmities that remain in the Revised SCP Proposal.

---

<sup>24</sup> In fact, determining whether or not a product caused a knowing exposure to a Proposition 65 listed chemical above a NSRL or NOEL is sufficiently complex that most defendants in Proposition 65 cases elect to settle rather than being faced with the legal and technical battle regarding whether exposure was at a level that required a Proposition 65 warning.



We respectfully request that DTSC recognize the unique character of the aviation sector and the preemption that applies to state requirements that attempt to regulate in this field. We also respectfully request that the Department incorporate our comments and suggested revisions regarding procedure, safety and economic considerations, and suggested clarifications to certain definitions in the proposed regulation.

Thank you for your consideration.

Sincerely yours,

Timothy A. Pohle  
Sr. Managing Director  
Environmental Affairs  
Airlines for America

Michael A. Beasley  
Sr. Environmental Specialist  
Enterprise EHS Strategy Policy Analysis  
The Boeing Company



## **Attachment 1** **(10-11-2012 Comments)**

October 11, 2012

**Submitted Via Email:**

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

**RE: Comments on Proposed Safer Consumer Products Regulations (Proposed New Chapter 55, division 4.5 of Title 22, California Code of Regulations)**

**Department Reference Number: R-2011-02**

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

To Whom It May Concern:

Airlines for America (“A4A”) and The Boeing Company appreciate this opportunity to submit comments on the Department of Toxic Substances Control (“DTSC”)’s proposed Safer Consumer Products Regulations (“proposed regulations”). A4A is the principal trade and service organization of the U.S. airline industry.<sup>1</sup> Its member airlines and their affiliates transport more than 90 percent of all U.S. airline passenger and cargo traffic.

The Boeing Company is the world's leading aerospace company and the largest manufacturer of commercial jetliners and military aircraft combined. Additionally, Boeing designs and manufactures rotorcraft, electronic and defense systems, missiles, satellites, launch vehicles and advanced information and communication systems. The company also provides numerous military and commercial airline support services.

A4A, its members, and Boeing take environmental protection seriously and we have a strong record of advancing environmental protection within our operations and throughout our respective supply chains. Our achievement has largely been the result of a relentless

---

<sup>1</sup> The members of A4A are: Alaska Airlines, Inc., American Airlines, Inc., Atlas Air, Inc., Delta Air Lines, Inc., Federal Express Corporation, Hawaiian Airlines, JetBlue Airways Corp., Southwest Airlines Co., United Airlines, Inc., United Parcel Service Co., and US Airways, Inc. Air Canada is an associate member.

# **Attachment 1**

**(10-11-2012 Comments)**

commitment to innovation and efficiency improvement, a commitment that extends to the green chemistry arena. Accordingly, we generally support the goals of this regulatory initiative. Like all regulatory schemes, however, the proposed regulations must be structured to mesh with the existing legal structure governing aviation. The defining characteristic of our industry is that safety is our core mission and cannot be compromised. To help ensure the safety of air transportation, the Federal Aviation Administration (“FAA”) was granted exclusive authority to specify the requirements under which U.S. aircraft and aircraft components are approved, aircraft maintenance is performed, and aircraft are operated. Aircraft operators are required by law to operate under these strict controls and attempts by states to regulate aircraft operations have consistently been struck down by the courts under the doctrine of federal preemption.<sup>2</sup>

It also is critical to understand the importance of aviation to the California economy and the nation as a whole. The FAA reports that commercial aviation is ultimately responsible for 4.9 to 5.2 percent of U.S. gross domestic product (“GDP”) and helps generate \$1.2 to \$1.3 trillion in annual economic activity, \$370 to \$405 billion in annual personal earnings and 9.7 to 10.5 million jobs.<sup>3</sup> Aviation is even more important to the California economy:

- In 2009, aviation drove 4.8% of California’s GDP and accounted for about 1.1 million jobs, about 5.5% of total employment in the state.<sup>4</sup>
- “[In 2008, a]cross all states, a total value of \$562.1 billion in goods was transported by air. California ranked highest with \$101.4 billion [or, 18% of the national total].”<sup>5</sup>
- “[In 2008, t]he value of domestic air freight from California accounts for about one-fifth of the value all domestic shipments, or \$39 billion.”<sup>6</sup>
- According to U.S. Department of Commerce, nearly half of all exports from California are shipped by air. Together, California imports and exports shipped by air were valued at over \$160 billion in 2011 (about \$440 million per day).<sup>7</sup>
- Within the State of California, Boeing is the largest manufacturer with about 21,000 employees.

---

<sup>2</sup> Courts have consistently held the Federal Aviation Act of 1958 creates a “uniform and exclusive system of federal regulation” of aircraft that preempts state and local regulation. *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); see also *American Airlines v. Department of Transp.*, 202 F.3d 788, 801 (5th Cir. 2000) (aviation regulation is an area where “[f]ederal control is intensive and exclusive”) (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 3030 (1944)). This pervasive federal regulatory scheme extends not only to aircraft in flight, but also to aircraft-related operations on the ground. In addition, the Airline Deregulation Act (“ADA”) precludes states from “enact[ing] or enforce[ing] a law, regulation, or other provision having the force and effect of law related to a price, route or service.” 49 U.S.C. § 41713(b)(1).

<sup>3</sup> FAA, *The Economic Impact of Civil Aviation on the U.S. Economy* (August 2011), available at: [http://www.faa.gov/air\\_traffic/publications/media/FAA\\_Economic\\_Impact\\_Rpt\\_2011.pdf](http://www.faa.gov/air_traffic/publications/media/FAA_Economic_Impact_Rpt_2011.pdf).

<sup>4</sup> *Id.* at p. 8.

<sup>5</sup> *Id.* at p. 40.

<sup>6</sup> *Id.*

<sup>7</sup> Percentages are based on value of shipments. See U.S. Dept. of Commerce, International Trade Administration State Import Data (<http://tse.export.gov/stateimports/TSIREports.aspx?DATA=>) and State Export Data (<http://tse.export.gov/TSE/TSEReports.aspx?DATA=SED>).



## **Attachment 1** **(10-11-2012 Comments)**

- Boeing has about 4,100 suppliers/vendors, supporting an estimated 200,000 direct and indirect jobs. The goods and services purchased from these suppliers/vendors are worth more than \$6.8 billion to the California economy.
- Boeing also has more than 56,000 retirees in the state and contributed more than \$11.3 million to California charities.<sup>8</sup>

We understand that the purpose of the present regulatory proposal is to establish a structure for future regulation. It is difficult to assess the ultimate impact of such a scheme, for example, before the chemicals of concern and priority products are determined. However, ensuring that essential considerations are built into the structure of the regulation from the beginning is vital to the long-term viability of this regulation. Most fundamentally, this means recognizing safety is the aviation industry's overriding imperative<sup>9</sup> and the limits of the State's authority under federal law.

### **I. Executive Summary**

As discussed in greater detail below, the proposed regulations are preempted as applied to aviation. Courts have long held that the Federal Aviation Administration Authorization Act ("FAA Act") and its implementing regulations create a "uniform and exclusive system of federal regulation" of aviation safety that preempts state and local regulation.<sup>10</sup> Further, the Airline Deregulation Act ("ADA") expressly prohibits states from enacting or enforcing any law related to a "price, route, or service" of an air carrier.

We therefore request that DTSC, consistent with its authorizing legislation<sup>11</sup> and its stated intent to avoid "duplicat[ion of] or conflict with existing federal law"<sup>12</sup>: (1) acknowledge

---

<sup>8</sup> Based on 2011 annual data.

<sup>9</sup> For example, General Electric recently discovered that their decision to use a new, lower lead coating on certain jet engines caused cracks on the engine shafts. *See Cracks Spur Board to Urge Check of Dreamliner Engines*, N.Y. Times, Sept. 14, 2012. Reports indicate that the coatings were intended to keep moisture off the threads of the engine shaft, however, the lower-lead coating had actually sealed in moisture, which weakened the steel when it came under pressure. <http://www.nytimes.com/2012/09/15/business/national-transportation-safety-board-urges-frequent-inspections-of-ge-engines.html> As a result, several 787s were removed from service and/or had their engines replaced until the cracking could be corrected, potentially affecting rates, routes, and services.

<sup>10</sup> *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); *see also American Airlines v. Department of Transp.*, 202 F.3d 788, 801 (5th Cir. 2000) (aviation regulation is an area where "[f]ederal control is intensive and exclusive") (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 3030 (1944)).

<sup>11</sup> California Health & Safety Code § 25257.1(b) ("This article does not authorize the Department to supersede the regulatory authority of any other department or agency.")

in the final regulations, or in the rulemaking record, that the State is precluded from regulating aviation; (2) acknowledge that the State cannot identify products used to maintain, service, or repair aircraft and related equipment as “priority products”; and, (3) revise specified definitions and operative provisions in the proposed regulations accordingly, as set forth herein.

**II. As Reinforced by its Authorizing Legislation, DTSC is Preempted from Regulating Aviation.**

DTSC has stated that it does not intend to promulgate regulations that “duplicate or conflict with federal law,”<sup>13</sup> a statement which is entirely consistent with California Health & Safety Code section 25257.1(b). This section specifies that the statutory article “does not authorize the department to supersede the regulatory authority of any other department or agency.” To act within the authority conferred under the California Green Chemistry legislation and consistent with federal law, it is critical to understand the preemptive effect of federal law. It is particularly important with respect to the aviation industry.

**A. The FAA Act preempts the entire field of aviation safety.<sup>14</sup>**

The FAA Act provides that “[t]he United States Government has exclusive sovereignty of airspace of the United States.”<sup>15</sup> The principal objectives of the FAA Act are to promote safety

---

<sup>12</sup> Initial Statement of Reasons (“ISOR”) for the California Green Chemistry Proposed Safer Consumer Product Alternative Regulations (R-2010-05) at p. 10.

<sup>13</sup> ISOR at p. 10.

<sup>14</sup> Article VI of the United States Constitution provides that the laws of the United States “shall be the supreme law of the land . . . anything in the constitution or laws of any state to the contrary notwithstanding.” Federal law may supersede state law in several different ways. Congress may preempt state law through express statutory terms or “express preemption.” *Jones v. Rath Packing Company*, 430 U.S. 519, 525 (1977). Alternatively, Congressional intent to preempt state law in a particular field may be inferred from a scheme of federal regulation “so pervasive as to make reasonable the inference that Congress left no room for the State to supplement it,” and where the state law touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. *Pacific Gas and Electric v. State Energy Resources Conservation & Development Commission*, 461 U.S. 190,203-204 (1983). This is known as field preemption. In areas where Congress has not completely displaced state regulation, federal law may nonetheless preempt state law to the extent it conflicts with federal law, either because compliance with both federal law and state regulations is “a physical impossibility” (*Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)) or because the state law stands “as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is known as conflict preemption. In addition to preemption, the Commerce Clause of the U.S. Constitution places limits on the amount of regulatory control that DTSC may exert over commerce that takes place wholly outside the state. See *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 88-89 (1987); see also *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). To the extent that the proposed regulations had the practical effect of controlling conduct beyond the boundaries of the State (e.g., the design, manufacture, or operation of aircraft out of state and/or the purchase and use of chemicals in out-of-state operations for aircraft that may operate in California), these could unduly burden interstate commerce.

<sup>15</sup> 49 U.S.C. § 40103(a).



## Attachment 1 (10-11-2012 Comments)

and efficiency and the development of air commerce.<sup>16</sup> To achieve the statutory purposes of the FAA Act, Congress provided extensive and plenary authority to the FAA to implement these objectives.<sup>17</sup> The FAA has exercised this authority by promulgating regulations that broadly regulate aircraft and passenger safety.<sup>18</sup> This extensive body of federal regulation leaves no room for states to establish or impose aircraft or passenger safety requirements different than or in addition to the federal requirements. In *Montalvo v. Spirit Airlines*, the Ninth Circuit Court of Appeals held, “[T]he FAA preempts the entire field of aviation safety through implied field preemption. The FAA and regulations promulgated pursuant to it establish complete and thorough safety standards for air travel, which are **not subject to supplementation by**, or variation among, state laws.”<sup>19</sup>

In *City of Burbank v. Lockheed Air Terminal*, the Supreme Court ruled that the FAA Act preempted local regulations that intruded upon the free flow of aircraft on the ground and in the air.<sup>20</sup> The Court concluded that under the FAA Act, “the delicate balance between safety and efficiency . . . and the protection of persons on the ground” imposed by federal aviation law “requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the Federal Aviation Act are to be fulfilled.”<sup>21</sup> The pervasive nature of this scheme of federal regulation led the Court to conclude that Congress had intended to fully preempt the field of aircraft operations. According to the Court:

Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands.<sup>22</sup>

---

<sup>16</sup> 49 U.S.C. § 40101 *et seq.*

<sup>17</sup> *See, e.g.*, 49 U.S.C. §§ 40103, 44502, and 44721.

<sup>18</sup> *See e.g.*, 14 C.F.R. Parts 21 (certification procedures for products and parts), 25 (airworthiness standards: transport category airplanes), 33 (airworthiness standards: aircraft engines), 39 (airworthiness directives), 43 (maintenance, preventative maintenance, rebuilding, and alteration), 61 (certification: pilots, flight instructors, and ground instructors), 63 (certification: flight crewmembers other than pilots), 65 (certification: airmen other than flight crewmembers), 91 (general operating and flight rules), 119 (certification: air carriers and commercial operators), 121 (operating requirements: domestic, flag, and supplemental operations), 145 (repair stations).

<sup>19</sup> *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007) (emphasis added).

<sup>20</sup> *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 633-34 (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 303 (1944) (Jackson, J., concurring)).

Courts have consistently adopted this preemption model to invalidate or limit state laws regulating aircraft operation, including laws that were not specifically directed at aviation, but which nonetheless regulated aircraft flights indirectly.<sup>23</sup>

FAA oversees every aspect of aircraft design, engineering, and maintenance, approves aircraft design and requires certification aircraft meet approved design and establishes stringent mandates governing ongoing maintenance and modification of aircraft. FAA regulations establish detailed requirements applicable to virtually every part and product used on or in the maintenance of aircraft that can take the form of performance standards applicable to parts and products used on aircraft.<sup>24</sup> Requirements in FAA regulations can also specify or limit the use of certain chemicals.<sup>25</sup> The point is that FAA has plainly preempted the field and DTSC is precluded from issuing “supplementing” regulations; DTSC retains no authority to act in this sphere, even if the FAA has not acted to regulate a specific chemical or product.

Preemption applies in the aviation context even where the FAA has not specifically addressed the issue targeted under state law. For example, in *Montalvo*, the court held that plaintiffs could not maintain negligence claims against the airlines for their alleged failure to warn passengers of the risks of developing deep vein thrombosis, because, even though FAA regulations do not address such risks, federal law preempts the entire field of aviation safety. Similarly, DTSC is preempted from regulating aviation safety under the proposed regulations, related to reducing consumer exposure to chemicals from products, even if federal requirements do not relate to the precise issues covered in the regulations. In the present context, preemption of State authority to regulate the use of certain chemicals or products used in aircraft or aircraft maintenance does not depend on the presence of federal regulations that specifically address chemicals or products.<sup>26</sup>

---

<sup>23</sup> *E.g.*, *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007); *U.S. Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1326 (10th Cir.2010); *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 795 (6th Cir.2005); *Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 367-68 (3d Cir.1999); *French v. Pan Am Express, Inc.*, 869 F.2d 1, 5 (1st Cir.1989).

<sup>24</sup> *E.g.*, 14 CFR 25.735(b)(2) (requiring “[f]luid lost from a brake hydraulic system following failure . . . is insufficient to cause or support a hazardous fire on the ground or in flight”); 14 CFR 25.733(e) (requiring “wheels must be inflated with dry nitrogen or other gases shown to be inert so the gas mixture in the tire does not contain oxygen in excess of 5 percent by volume”); 14 CFR Part 25, Appendix F (detailing fire resistance standards applicable to a wide variety of aircraft parts, including interior ceiling and wall panels, floor covering, textiles, seat cushions, padding, decorative and non-decorative coated fabrics, leather, trays, galley furnishings, partitions, galley structure, large cabinet walls, structural flooring, electrical conduit, air ducting, joint and edge covering, clear plastic windows and signs, materials used in the construction of stowage compartments, etc.)

<sup>25</sup> *E.g.*, 76 Fed. Reg. 77367-69 (requiring use of “alodined rub strips”).

<sup>26</sup> Even in the tort context, an area of law traditionally within the police powers of the states, courts have recognized that the FAA Act preempts state standards of care relating to aviation safety. *E.g.*, *Abdulla*, 181 F.3d at 371 (finding that even when there is no specific federal provision or regulation governing air safety, the general standard of care in FAA Act regulations prohibiting the “careless or reckless” operation of an aircraft preempts “any state or territorial standards of care relating to aviation safety”) (emphasis in original); *Curtin v. Port Authority of New York*, 183 F. Supp. 2d 664, 668-671 (S.D.N.Y. 2002) (finding that the standard of care in a negligence action relating to aviation safety is a matter of federal, not state, law



## **Attachment 1** **(10-11-2012 Comments)**

### **B. The ADA expressly preempts any state regulation that significantly impacts airline rates, routes, or services.**

In addition to implied field preemption under the FAA Act, the ADA expressly prohibits states from enacting or enforcing any law “related to a price, route, or service of an air carrier.”<sup>27</sup> The U.S. Supreme Court has interpreted the term “related to” broadly to preempt all state laws that have “a connection with or reference to” airline prices, routes, or services.<sup>28</sup> In *Morales v. Trans World Airlines, Inc.*, the Supreme Court found that a state’s enforcement of fare advertising guidelines was preempted as applied to airline fare advertising because the obligations imposed by the guidelines severely burdened the airlines’ ability to place restrictions on lower priced seats and to advertise lower fares.<sup>29</sup> The *Morales* decision made clear that a state law need not expressly address the airline industry or be specifically designed to affect it; as long as the law has a connection with airline prices, routes or services, preemption of the law is mandated under the ADA.<sup>30</sup>

In *Rowe v. N.H. Motor Transportation Association*, the Supreme Court recently reaffirmed *Morales* and its broad interpretation of ADA preemption.<sup>31</sup> The state law at issue sought to compel tobacco retailers to use a “delivery service” that provided certain assurances about the recipients of the tobacco purchases. The Supreme Court held in *Rowe* that: (1) state laws “having a connection with, or reference to carrier rates, routes, or services are pre-empted”; (2) “such pre-emption may occur even if a state law’s effect on rates, routes or services is only indirect”; (3) “it makes no difference whether a state law is consistent or inconsistent with federal regulation”; and (4) “pre-emption occurs at least where state laws have a ‘significant impact’ related to Congress’ deregulatory and pre-emption-related objectives.”<sup>32</sup>

---

given that FAA Act regulations set out a "general standard of care" for the aviation industry supplemented by "an array of specific safety standards").

<sup>27</sup> 49 U.S.C. § 41713(b)(1).

<sup>28</sup> *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992).

<sup>29</sup> *Id.* at 388-90.

<sup>30</sup> *Id.* at 386.

<sup>31</sup> *Rowe v. N.H. Motor Transp. Ass’n*, 128 S. Ct. 989 (U.S. 2008).

<sup>32</sup> *Id.* at 995 (internal quotation marks omitted).

**III. Consistent with its Authorizing Legislation, DTSC May Not Regulate Aviation as Contemplated by the Proposed Regulations.**

Given the “intensive and exclusive” federal control noted above, DTSC cannot apply the proposed regulations to aviation because federal law preempts the entire field of aviation safety.<sup>33</sup>

**A. Preemption applies to aircraft and operation of aircraft.**

To the extent that the proposed regulations could regulate aircraft owned or operated by the airlines or sale by airlines of air transportation services as “consumer products,” they would be plainly preempted. In particular, the proposed regulations could be interpreted as authorizing the imposition (in certain circumstances specified in § 69506.5) of restrictions on the settings in which a product may be sold or used, the form in which a product may be sold, who may purchase or use a product, and “any other use restriction” that reduces the amount of chemicals of concern in the product or reduces the ability of the product to cause an exposure.

Any restrictions on chemicals or materials in aircraft used by airlines to transport passengers would require airlines to cease routing aircraft containing these chemicals into the state, a result that would clearly have a significant impact on rates, routes and services, as well as aircraft operations. As such, the ADA would preempt the proposed regulation due to its direct relation to airline prices, routes or services<sup>34</sup> and under the FAA Act due to its impermissible encroachment into or supplementation of FAA’s regulation of aircraft operations and safety.

**B. Preemption applies to aircraft parts and components and aircraft maintenance.**

The FAA, exercising its exclusive jurisdiction over aircraft safety, certifies aircraft and aircraft components. In order to operate a U.S. registered aircraft in any airspace, FAA requires that the aircraft maintain an Airworthiness Certificate.<sup>35</sup> As one part of maintaining certification, an aircraft must comply with all applicable Airworthiness Directives (“ADs”) that FAA adopts over the aircraft’s service life.<sup>36</sup> ADs are rules issued by FAA that direct actions necessary to ensure that aircraft remain at or above their certified level of safety. The ADs prescribe specific inspections, repairs, modifications, maintenance, and/or operating procedures.<sup>37</sup> Airworthiness Directives, including referenced manufacturer Service Bulletins or

---

<sup>33</sup> In contrast to conflict preemption, which applies only to the extent that a state law conflicts with federal law or stands in the way of effectuating the purpose of the federal law, field preemption applies more broadly based on the inference that Congress intended to occupy the entire field at the exclusion of state regulation in the same area.

<sup>34</sup> In the present context, air transportation is a service, not a product.

<sup>35</sup> To obtain and maintain an airworthiness certificate, the operator must ensure that the configuration of the aircraft, including all related products or articles, are consistent with the FAA-approved specifications. See FAA Order No. 8130.2G, sections 200(a) and 4002(a) (Aug. 31, 2010).

<sup>36</sup> See *id.* at section 4002(a)(9).

<sup>37</sup> See FAA database of Current Airworthiness Directives by Make, available at [http://rgl.faa.gov/Regulatory\\_and\\_Guidance\\_Library/rgAD.nsf/Frameset?OpenPage](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAD.nsf/Frameset?OpenPage).



## **Attachment 1** **(10-11-2012 Comments)**

Instructions for Continued Airworthiness (“ICAs”), are explicit regarding the actions to be performed and materials to be used.<sup>38</sup> ADs address the full range of aircraft parts and components, from aircraft engines and skins to aircraft furnishings, insulation, and coffee makers.<sup>39</sup>

To the extent the proposed regulations would impede the use of products necessary or mandated for aircraft maintenance and safety, the regulations would also be preempted under the ADA as an impermissible state law relating to prices, routes or services.<sup>40</sup> The U.S. Supreme Court has concluded that where a state law has a “significant impact” on airline prices, routes or services, it is preempted under the ADA, even if the law is not specifically designed to affect the airline industry and has only an indirect effect on prices, routes or services.<sup>41</sup>

The airlines must be able to maintain access to spare parts, supplies, and other materials that support the safe flight and operation of aircraft. Under FAA regulations, airlines are required to have these items available at all points along their service route as necessary for the proper servicing, maintenance, and preventative maintenance of airplanes and auxiliary equipment.<sup>42</sup> Interruptions to airlines’ access to, use of, or price paid for service and maintenance products resulting from state regulation would impact the airlines’ ability to offer required service in California. Hence, any regulation which may impair the airlines’ ability to procure materials needed to perform required service, or which has the effect of driving costs of said items up, is expressly preempted by the ADA.<sup>43</sup>

Given federal preemption in the field of aviation safety, preemption of state regulations affecting routes, rates and services, and the clear limitation on the Department’s rulemaking authority under Section 25257.1(b), we respectfully request that DTSC:

- (1) Provide a categorical exemption for aviation:

---

<sup>38</sup> *Id.* An ICA is a manual or set of manuals that a manufacturer must provide along with an aircraft, aircraft part, or other associated product. ICAs must include servicing information with instructions covering topics including, but not limited to, servicing parts, task capacities, types of fluid to be used, applicable pressures for the various systems, access panels for inspection and servicing, lubrication points, and types of lubricants to be used.

<sup>39</sup> See FAA database of Current Airworthiness Directives.

<sup>40</sup> *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992).

<sup>41</sup> *Rowe at 364; Morales at 390.*

<sup>42</sup> See *e.g.*, 14 CFR §121.105.

<sup>43</sup> Regulation that prohibits or makes it more challenging to perform non-essential aircraft maintenance in California also has the effect of moving these operations, and associated jobs, out of state.

**Attachment 1**  
**(10-11-2012 Comments)**

- a. Exclude “federally certified products” from the definition of consumer product by adding the following language:

§ 69501.1(a)(22)(D) “Consumer product” or “Product” does not mean a “federally certified product.”

And,

§ 69501.1(a)(XX) “Federally certified product” means:

- i. A product manufactured in accordance with a design certified or approved by the Federal Aviation Administration or the Department of Defense;
  - ii. A product that is used as a replacement part or component of a product identified in (a); or,
  - iii. A product identified in a federally certified program or procedure for the repair or maintenance of a product identified in (a) or (b).
- b. Add new language to the final regulation recognizing the limitations on DTSC’s authority to impose requirements related to aviation safety. Specifically, section 69501 should be revised as follows:

§ 69501. Purpose and Applicability.

...

(b)(1) Except as provided in paragraphs (2) ~~and~~, (3), and (4), this chapter applies to all consumer products placed into the stream of commerce in California.

... (4) this chapter does not apply to any consumer product that is required to be certified or approved for such use by the Federal Aviation Administration or the Department of Defense.

- c. Include language in the Final Statement of Reasons (“FSOR”) acknowledging Supreme Court and Ninth Circuit Court of Appeals precedent on federal preemption of the field of aviation safety.<sup>44</sup>
- d. Include language in the FSOR acknowledging that the ADA expressly preempts state laws that relate to airline rates, routes, or services.<sup>45</sup>
- (2) Clarify that the Regulations Cannot Apply to Operation of Aircraft or the Sale of Air Transportation Services.

In the absence of a categorical exemption applicable to aviation, DTSC must at least confirm that air transportation services and aircraft used to provide same are not “consumer products” within the scope of the Safer Consumer Products Regulations, by adding the following language to section 69501.1:

---

<sup>44</sup> See e.g., *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007).

<sup>45</sup> See 49 U.S.C. § 41713(b)(1).



## **Attachment 1** **(10-11-2012 Comments)**

§ 69501.1(a)(22)(X) “Consumer product” or “Product” does not include (i) the sale of transportation services, such as transportation by air, vessel, vehicle, or rail; or the aircraft, vessel, vehicle, or train used by a service provider to provide such transportation.

In the absence of a categorical exemption applicable to aviation, DTSC also must clarify that aircraft operators would not be considered “importers” of aircraft based on their operation and movement of aircraft across borders for the purpose of providing transportation services, and that aircraft operators would not be considered “importers” of products (e.g., replacement parts or maintenance supplies for aircraft and associated equipment) for use in its own workplaces when the operator does not sell or distribute these products to “consumers.” Specifically, we respectfully request that DTSC Revise Section 69501.1(a)(35), as follows:

§ 69501.1(a)(35) “Import” means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce. “Import” includes reimporting a consumer product manufactured or processed, in whole or in part, in the United States. Aircraft (or any aircraft part or component), vessels, vehicles, and other equipment are not “imported” if they cross borders incidental to, or for the purpose of, providing transportation services. ...

If aircraft were considered to be within the scope of consumer products, the change above is necessary. Otherwise, nearly every aircraft operator would be an “importer” and hence, responsible party with regard to the aircraft in its fleet, simply by virtue of crossing U.S. borders in connection with provision of air transportation services. If the above language is not included in the final regulation as requested above, DTSC should at least explain in the FSOR that the operation of aircraft into or out of the United States would not constitute the “import” of such aircraft, nor would it constitute “import” of any part or component thereof.

Similarly, we respectfully request that DTSC include the following sentence at the end of Section 69501.1(a)(35):

A person does not become an importer for purposes of these regulations, by importing products only for use in its own workplaces, and not to sell or distribute to consumers.

As noted previously, FAA requires airlines to have certain parts and supplies in stock at each repair facility and available for use at any airport for unscheduled maintenance activities. If aviation were regulated under the proposed regulations, the revision shown above is necessary; otherwise, an airline would become an importer, and hence a responsible party, with respect to products which it is mandated by law to keep in stock for use by its employees or contractors in servicing the aircraft.

- (3) DTSC Must Require Consideration of the Preemptive Effect of Federal Law in the Determination of Priority Products.<sup>46</sup>

Specifically, sections 69503.2(a)(3) and 69501.1 should be revised as follows:

§ 69503.2(a)(3) Other Regulatory Programs. The Department shall consider the scope of other California and federal laws, and international agreements with the force of domestic law, under which the product or the Chemical(s) of Concern in the product is/are regulated, and the extent to which these other regulatory programs (A) preempt the regulation of the product; (B) impose specifications or certification requirements on the product; (C) are subject to requirements related to classified information and information subject to limitations on the basis of national security; and/or, (D) address, and provide adequate protections with respect to the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product. The Department shall not identify any “federally certified product” as a “priority product.”

§ 69501.1(a)(XX) “Federally Certified Product” means:

- a) A product manufactured in accordance with a design certified or approved by the Federal Aviation Administration or the Department of Defense;
- b) A product that is used as a replacement part or component of a product identified in (a); or,
- c) A product identified in a federally certified program or procedure for the repair or maintenance of a product identified in (a) or (b).

#### **IV. Additional Clarifications Needed in the Regulations**

Irrespective of DTSC’s views on federal preemption, the following additional issues need to be resolved regarding functional acceptability, public safety, and the definitions for the terms “manufacture,” “retailer,” “functionally acceptable” and “technically and economically feasible” alternatives.

##### **A. DTSC should revise proposed Section 69501.1(a)(40)<sup>47</sup>-(41) to clarify that aircraft operators would not be considered “manufacturers” of aircraft based on their**

---

<sup>46</sup> The proposed regulation does not take account of field preemption or express preemption. Proposed section 69503.2(a)(3) requires DTSC to consider only the extent to which federal requirements “address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.” This proposed language does not consider that under both field and express preemption, state action may be preempted even if federal regulation does not address the same issues or impacts that are targeted by the state regulation. See sections II (A) and (B), above, and FN 14.

<sup>47</sup> Proposed section 69501.1(a)(40) defines “manufacture” to mean make, produce, or assemble. The section goes on to explain that “manufacture” does not include (A) repair or refurbishment of an existing consumer product, (B) installation of standardized components to an existing consumer product, or, (C) making non-material alterations to an existing consumer product, *unless* the action results in the addition, or increased concentration, or a Chemical of Concern, or replacement of a Chemical of Concern, in a product. (Emphasis added.)



## **Attachment 1** **(10-11-2012 Comments)**

**repair or installation of standardized components on aircraft (even if such action resulted in the addition/replenishment or increased concentration of a chemical of concern).**<sup>48</sup>

Specifically, we respectfully request that DTSC remove the qualifying language from the definition of “manufacture” in section 69501.1(a)(40), as follows:

§ 69501.1(a)(40) “Manufacture” means to make, produce, or assemble. Manufacture does not include any of the following actions, ~~unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:~~

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

The Initial Statement of Reasons (“ISOR”) accompanying the proposed regulation discusses the intent of the exclusion of repair, refurbishment, replacement parts, and alterations from the definition of “manufacture” as follows: “Existing products, especially durable goods, may need to have replacement parts available for service, repair and maintenance. By allowing these three exclusions, repair and maintenance of existing products can continue without the involvement of this regulatory program.” We agree with the sentiment of this provision.<sup>49</sup>

However, the addition of language that would make repair, refurbishment, installation of replacement parts, or non-material alterations fall into the “manufacture” category if they “result[ed] in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern” is extremely problematic. This language could effectively render the exclusions without effect. For example, under this modified definition, an aircraft operator’s use of a maintenance product containing a chemical of concern to perform mandatory maintenance could potentially render the operator a “manufacturer” of aircraft. This result is inconsistent with DTSC’s stated intent in the ISOR.

**B. DTSC should revise proposed Section 69501.1(a)(55) to clarify that “retailer” does not include a person who purchases products (e.g., replacement parts or maintenance supplies) for use in its own workplaces and who does not sell or distribute these products to “consumers.”**

---

<sup>48</sup> The FAA certifies aircraft and mandates specific repair and preventative aircraft maintenance procedures. Operators do not have a choice regarding whether to do aircraft maintenance or repairs, nor do they have a choice regarding the materials with which these procedures are performed. Hence, it does not make sense to classify operators as “manufacturers” based on performance of required duties, particularly since they do not have the freedom to modify protocols for existing aircraft, nor do they have the ability to adopt alternative aircraft designs.

<sup>49</sup> ISOR at 28-29.

Specifically, we respectfully request that DTSC revise section 69501.1(a)(55), as follows:

§ 69501.1(a)(56) “Retailer” means a person to whom a consumer product is delivered or sold for purposes of sale or distribution by the person to a consumer. “Retailer” does not include a person to whom a product is delivered or sold for purposes of use by the person or one of their employees or contractors, if the product will not be sold or distributed to customers.

As referenced above, aircraft operators are mandated to keep specified service, repair, and maintenance products on hand for use by their repair technicians. If there is not a provision to address this, airlines would be considered “retailers” for all of the products they are required to stock in order to meet federal requirements.

**C. DTSC should revise proposed Sections 69501.1(a)(31), 69505.4(a)(2)(B)(3), and 69506(a) to clarify the meaning of “functionally acceptable” and include consideration of functional acceptability in the Alternatives Analysis and Regulatory Response Sections.**

Specifically, we respectfully request that DTSC revise sections 69501.1(a)(31), 69505.4(a)(2)(B)(3), and 69506(a) as follows:

§ 69501.1(a)(31) “Functionally acceptable” means that an alternative product meets ~~both~~ all of the following requirements:

- (A) The product complies with all applicable legal requirements;
- (B) ~~The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace~~  
The product is compliant with all applicable safety standards and regulatory approval or certification requirements in the relevant industry;
- (C) The product meets other product criteria applicable to the specific nature of the product, including but not limited to: durability; and functional performance; and
- (D) The product would not create significant administrative or other burdens on the Department, the responsible entities, the product end-users, or the public including difficulty in regulatory enforcement.

§ 69505.4(a)(2)(B)(3) A determination of whether a functionally acceptable and “technically and economically feasible alternative” exists.

§ 69506(a) The Department shall identify and require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are functionally acceptable and technically and economically feasible.

**D. DTSC should revise proposed Section 69501.1(59) to clarify the meaning of “technically and economically feasible alternative.”**

Specifically, we respectfully request that DTSC revise section 69501.1(59) as follows:



## **Attachment 1** **(10-11-2012 Comments)**

(59) “Technically and economically feasible alternative” means an alternative product or chemical for which:

- (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; ~~and~~
- (B) The manufacturer’s operating margin is not significantly reduced; and
- (C) There is not an associated material increase in consumer or business costs.

### **E. DTSC should revise proposed Section 69506.6(d)(2)(A) to include consideration of safety in the analysis of product sales prohibitions.**

Specifically, we respectfully request that DTSC revise Section 69506.6(d)(2)(A) as follows:

§ 69506.6(d)(2)(A) The overall beneficial public safety, health, economic, societal, and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and ...

The reason for this modification is that we believe that before the DTSC decides to ban or otherwise restrict a product that the DTSC should consider the purpose the product services and the potential broader impacts that would be caused by regulating the product. For example, restrictions could result in certain businesses needing to relocate outside of the State in order to conduct needed maintenance or a product may serve a broader safety or societal benefit that should be considered before deciding to restrict a product for which a safer alternative does not exist.

## **V. Economic Impacts**

### **A. Regulatory action by DTSC, such as listing a Priority Product, requires DTSC to comply with California Administrative Procedure Act requirements.**

The California Administrative Procedure Act (“APA”) requires that any agency proposing to adopt, amend, or repeal any administration assess the potential for adverse economic impacts on California business enterprises and individuals. The current proposal largely avoids the issue of economic impacts based on DTSC’s assertion that these impacts cannot be quantified until the initial list of Priority Products is released.<sup>50</sup> If this is the case, we ask that

---

<sup>50</sup> See e.g., ISOR at p. 4 (“DTSC has determined that until the initial list of Priority Products is released that it cannot quantify the number of jobs that may be created or eliminated”) and Attachment to the Economic and Fiscal Impact Statement (Std. Form 399) (“The ‘Economic Analysis of California’s Green

DTSC commit to revisiting the economic impact issues when taking subsequent action, including but not limited to listing Priority Products.

Waiting until the alternatives assessment or regulatory response phases to consider economic aspects of the regulation is not acceptable. The listing of a Priority Product is a form of rulemaking, and as such, DTSC will be operating under APA rulemaking requirements.<sup>51</sup> The APA specifies that:

[A]ssessing the potential for adverse economic impact shall require agencies... to adhere to the following requirements ...

(1) The proposed adoption, amendment, or repeal of a regulation shall be based on adequate information concerning the need for, and *consequences of, proposed governmental action.*

(2) The state agency, prior to submitting a proposal to adopt, amend, or repeal a regulation to the office, shall consider the proposal's impact on business, with consideration of industries affected including the ability of California businesses to compete with businesses in other states. For purposes of evaluating the impact on the ability of California businesses to compete with businesses in other states, *an agency shall consider, but not be limited to, information supplied by interested parties.*<sup>52</sup>

We respectfully request DTSC's acknowledgement that it will comply with APA requirements (including, but not limited to analysis of economic impacts)<sup>53</sup> when identifying Chemicals of Concern, Priority Products, Alternatives Analysis Thresholds, and Regulatory Responses.

We also request that in DTSC's consideration of economic feasibility, the Department look broadly, not just at manufacturers of Priority Products, but also on economic impacts felt by other businesses and individuals. Many businesses, including A4A member airlines and Boeing, would be significantly impacted if prices of products used or sold by the business

---

Chemistry Regulations for Safer Consumer Products' does not include an estimate of the costs of the SCP regulations....it is not possible to estimate the costs to businesses and individuals until implementation is under way").

<sup>51</sup> Every "regulation" is subject to the rulemaking procedures of the APA unless expressly exempted by statute. California Government Code § 11346. California Government Code section 11342.600 defines "regulation" as "every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure."

<sup>52</sup> California Government Code §11346.3(a)(1)-(2) (emphasis added).

<sup>53</sup> While it appears in some respect that DTSC intends to follow notice and comment procedures for each stage of implementation, it is less clear whether DTSC intends to meet all applicable APA requirements. For example, there are several statements in the ISOR which seem to indicate that rather than responding to all comments submitted as part of the Priority Products rulemaking, DTSC will look for latitude to determine which comments warrant a response. See *e.g.* ISOR at 103 and 158. Under the APA, on the other hand, an agency is required to address each comment received, so long as it is directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action. See CA Govt. Code § 11346.9(a)(3).



**Attachment 1**  
**(10-11-2012 Comments)**

increased or if product relied upon by a business were no longer distributed in California. This request is consistent with the proposed changes to section 69501.1(59) shown in section IV(D), above.

**VI. Conclusion**

For the reasons outlined above, the proposed regulations are preempted to the extent they would: (1) overlap with aviation safety (a field occupied at the federal level by the FAA); and/or, (2) regulate airline prices, routes, or services (directly or indirectly). We respectfully request that DTSC recognize the unique character of the aviation sector and reflect that recognition appropriately in the final regulations and rulemaking record. We also respectfully

request that DTSC consider our comments regarding safety and economic considerations, and suggested clarifications to certain definitions in the proposed regulation.

Thank you for your consideration.

Sincerely yours,

Timothy A. Pohle  
Sr. Managing Director  
Environmental Affairs  
Airlines for America

Michael A. Beasley  
Sr. Environmental Specialist  
Enterprise EHS Strategy Policy Analysis  
The Boeing Company



February 28, 2013

VIA EMAIL  
gcregs@dtsc.ca.gov

VIA MAIL  
Krycia Von Burg, Regulations Coordinator  
Regulations Section  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Comments on the January 29, 2013 Revised Text of Proposed  
Safer Consumer Products Regulations

Dear Ms. Von Burg:

On behalf of the Alliance of Automobile Manufacturers (“Alliance”), I am pleased to submit the following comments in response to the latest draft of the Department of Toxic Substances Control’s (“Department” or “DTSC”) proposed Safer Consumer Products Regulations released on January 29, 2013 (the “January 2013 Proposal”).

While we continue to have serious concerns about the structure of this regulatory scheme that may render compliance infeasible, we highlight in this letter the three remaining issues that are of greatest concern to us:

- (1) Using clear terms to describe the product or component that will be subject to the extensive data and analysis requirements this regulation will require of industry;
- (2) Clearly distinguish and exclude replacement parts for products no longer being manufactured; and
- (3) Clearly specify, as the statute requires, that no products will be subject to duplicative regulation.

The Alliance is a trade association of 12 car and light truck manufacturers, consisting of BMW Group, Chrysler Group LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda North America, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars North America, Toyota Motor North America, Inc., Volkswagen Group of America, and Volvo Cars of North America. As indicated in prior letters, the Alliance appreciates the complexity of the task at hand, and the efforts put forth to date in preparing the January 2013 Proposal. The Alliance embraces the goals and vision for safer consumer products embodied in California's Green Chemistry Statute (the "Statute").

Revisions reflected in the January 2013 Proposal show the Department has considered and incorporated some of the comments previously submitted by the Alliance and other impacted industry groups. The Alliance appreciates several revisions in the January 2013 Proposal, particularly the introduction of the concept of "assemblers" in the regulatory scheme.

However, the Alliance remains concerned the proposed regulations create an unworkable regulatory scheme for complex durable goods. Moreover, the January 2013 Proposal does not adequately address the Statute's restriction against duplicative regulations for products already covered by other regulatory programs. Many of our issues with the proposed regulatory scheme, as revised by the January 2013 Proposal, remain unresolved. Since the Alliance has exhaustively covered those in our previous comment letters and submissions, we will not repeat those concerns herein. Instead, the Alliance hereby incorporates by reference its previously submitted comments relating to the draft texts for the proposed regulations. Since the Department has in its possession the large volume of letters and CD-ROM attachments previously submitted by the Alliance, we do not reattach them to this letter. The Alliance also incorporates by reference the comments submitted by the Complex Durable Products Coalition.

The Alliance continues to advocate for revisions that will render the Green Chemistry Regulations more effective, efficient and expedient, while maximizing the public health and environmental benefits achieved by the Statute. To help achieve the Statute's goals, increase compliance among regulated groups and clarify various definitions and provisions addressing the list of Priority Products, the Alliance suggests the following edits:

## **I. SUGGESTED CLARIFYING REVISIONS TO TEXT OF PROPOSED REGULATIONS**

It is apparent from the January 2013 Proposal that the Department has considered comments made by the Alliance and other concerned industry groups. In particular, we appreciate the addition of the concept of "assembler" into the proposal. The Department's "Summary of Significant Changes" states:

The definition of "manufacture" [has] been revised to explicitly state that "manufacture does not include acts that meet the definition of "assemble". "Assemble" is defined to mean "fit, join, put, or otherwise bring together components to create a consumer product". "Assembler" is defined as someone who "assembles a product containing a component that is a product subject to the

requirements” of the regulations (i.e., a component that is listed as a Priority Product). In the event that the manufacturer and importer of the Priority Product component do not comply with applicable requirements, assemblers who use that component have the same option as do retailers – they can comply with the requirements themselves, or cease ordering the Priority Product component.

In keeping with the Department’s intent, we believe the following clarifying changes in the Definitions in Section 69501.1 and to the Products Priority List in Section 69503.5 will improve overall compliance and will help the Department best achieve the Statute’s goals. The Alliance provides the suggested edits below, with additions shown in underline and deletions shown in ~~strikeout~~.

- **§69501.1 – (23)(A) “Component”** – “Component” means a uniquely identifiable homogeneous material, part, or piece assembly, or subassembly that is a necessary or intended element of a an assembled consumer product.
- **§69501.1 – (38) “Import”** – “Import” means to bring, or arrange to bring, a product into the United States for purposes of placing the product into the stream of commerce in California. “Import” includes reimporting a product manufactured or processed, in whole or in part, in the United States. “Import” does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States. “Import” does not include complex durable good assemblers.

Moreover, in the event that an assembler has the duty to comply, we remain greatly concerned with the ability of complex durable good assemblers to comply with the proposal due to the sheer scope of the chemicals and components within our products as explained in our prior comments incorporated by reference in this letter. The following changes would significantly alleviate this concern.

- **§69503.5 – Priority Products List** – . . . (c) Complex Durable Products. (1) For a complex durable product, the Department may not list as Priority Products more than ~~ten~~ three (403) components contained in that product in a three-year period.

## II. REPLACEMENT PARTS MUST BE EXCLUDED

The January 2013 Proposal properly excludes from the data gathering, hazard studies, lifecycle analysis etc. in the alternatives analysis (AA) requirements any replacement parts that are in existing inventories and have already been manufactured. We support this treatment of existing replacement part inventories. However, replacement parts produced after that date to maintain, service and/or repair the historic product as-built should also be treated in this way. Similar laws with goals to replace harmful substances with less harmful substances have examined this issue and have opted not to include replacement parts. (*See, e.g., European Union*

End-of-Life Vehicle Directive, Canada Consumer Product Safety Act, and California's motor vehicle brake pads standards, CAL. HEALTH AND SAFETY CODE §25250.50 *et seq.*)

While replacement parts *can* be redesigned for vehicles no longer in production, the technical, economic, regulatory and logistical barriers make such redesign infeasible, if not impossible, in most cases. Our previous submissions provided technical evidence of the multitude of barriers to such redesign, and we have discussed this issue with the Department. For ease of reference, a short summary of this issue is attached (Attachment A). We urge DTSC to make the following essential revision to the January 2013 Proposal.

- **§69501.1(a)(43) – “Manufacture”** – “Manufacture” means to make or produce. “Manufacture” does not include:
  - (A) acts that meet the definition of “assemble;” or
  - (B) repair or refurbishment of an existing consumer product; or
  - (C) installation of components to an existing consumer product; or
  - (D) making non-material alterations to an existing consumer product.
- **§69501.1(a)(24)(B) – “Consumer product” or “Product”** – “Consumer product” or “Product” does not mean a product that ceased to be manufactured prior to the date the product is listed as a Priority Product or a replacement part used to repair, refurbish or maintain existing consumer products.

### III. CONCERNS OVER DUPLICATIVE REGULATION

Additionally, the Alliance remains concerned about the January 2013 Proposal's duplication with other existing regulations, as prohibited by the Statute. Section 25257.1 of the Statute provides that “[t]he 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.” CAL. HEALTH AND SAFETY CODE §25257.1. The proposed definition of “consumer product” is very broad and more inclusive than the same term in other federal and California statutes and regulations, including federal Consumer Product Safety standards and California's air emission standards. *See* 15 U.S.C. §2052, CAL. HEALTH AND SAFETY CODE §41712. However, Section 25257.1 limits the Department's authority to include any product category that is already regulated by other agencies, such as automobiles which have an entire federal agency devoted to the regulation of their safety, and whose emissions are regulated by both the U.S. Environmental Protection Agency and the California Air Resources Board. For these reasons, we urge DTSC to replace subsection (b)(3)(A) of Section 69501 with the following language:

§69501(b)(3)(A)

This chapter does not apply to a consumer product regulated by one or more federal and/or California state regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that address the same adverse public health and environmental impacts that would otherwise be the basis for the product being listed as a Priority Product.

In addition, Section 69503.2 violates the statutory requirement for an exemption where there would be a conflict with, or duplication of existing laws and regulations. This should not be a judgment call of DTSC; the existence of other laws that conflict with or duplicate should, in itself, be sufficient to exempt those products.

**IV. CONCLUSION**

Even with the changes suggested above, concerns remain that the proposed regulations create an unnecessarily burdensome regulatory scheme as described in our previously submitted comments. Throughout the regulatory development process, the Alliance has consistently advocated for revisions that will render Green Chemistry Regulations more effective, efficient and expedient, while maximizing the potential for environmental benefits envisioned by the Statute.

As always, thank you for your time and consideration of our comments. If you have any questions, please feel free to contact me at [frio@autoalliance.org](mailto:frio@autoalliance.org) or (202) 326-5551.

Sincerely,

A handwritten signature in blue ink that reads "Filipa Rio".

Filipa Rio  
Senior Manager, Environmental Affairs

**Attachment A: The Issue of Replacement (Maintenance, Service and/or Repair) Parts**

The January 2013 Proposal properly excludes from the data gathering, hazard studies, lifecycle analysis etc. in the alternatives analysis (AA) requirements, replacement parts that are in existing inventories and have already been manufactured up until the time DTSC lists priority products. The Alliance supports this treatment of existing replacement part inventories. However, it is critical that replacement parts produced after that date to maintain, service and/or repair the historic product as-built should also be treated in this way.

DTSC's rationale for not excluding the making of ongoing replacement parts is that automakers and/or suppliers will find a way to build historic parts using a safer substitute discovered as part of the AA process.

While we appreciate the notion that a redesign of replacement parts for vehicles no longer in production may be possible, the technical and/or economical infeasibility due to declining production, economies of scale, and consumer expectations would greatly increase their cost and potentially affect their availability. If the parts at issue are critical for safety or emissions control, their unavailability could result in the denial of vehicle registration -- a perverse environmental and equal justice consequence.

The use of replacement parts is an integral piece of the automotive service industry. Automobile manufacturers are responsible for manufacturing and stocking these parts for the automobiles that they supply to the public. In many cases, vehicle warranties address availability of parts as a specific and binding issue. Consumers purchase cars with the expectation that they will be able to repair or replace any necessary components over the lifetime of the vehicle.

Each major OEM carries over 250,000 active service parts, with roughly 20,000 new service parts added yearly (~3,000 for each new vehicle introduction). The design and validation (testing) of these parts is frozen at least a year in advance of production intent. To go back and redesign and validate a post model part for the small volume service demand (generally 1% to 5% of the production volume) resulting from a material change would be cost prohibitive. The basic economic business model for replacement parts is that manufacturers put a marginal supply of parts in stock during the production time of a running series. They do not produce replacement parts for the total lifetime of the vehicle due to the high costs of warehousing. Thus, to the extent that customers need spare parts beyond what is initially stocked, there is a reproduction-on-demand market whereby suppliers use the "original" tools, materials, production processes and engineering specifications to continue to ensure that vehicles already purchased by consumers can continue to be maintained and in service, as consumers bring their cars in for repair.

If the current replacement parts supply market is required to comply with these regulations, the targeted replacement parts may need to be redeveloped. The development of a new replacement part would involve development of alternative/substitute materials, design/engineering changes, new suppliers, new releases, new durability tests, part number

changes and far higher costs due to all these factors and declining volumes needed. This is not only infeasible and impractical, but in many instances may be impossible.

Both states and the European End of Life Vehicle (ELV) Directive have recognized these issues and opted to exempt replacement parts.

For the reasons stated above, the Alliance urges DTSC to reconsider inclusion of the following language in the next iteration of the draft regulations.

**§69501.1(a)**

**(43) – “Manufacture”** – “Manufacture” means to make or produce.  
“Manufacture” does not include:

- (E) acts that meet the definition of “assemble;” or
- (F) repair or refurbishment of an existing consumer product; or
- (G) installation of components to an existing consumer product; or
- (H) making non-material alterations to an existing consumer product.

**(24)(B) “Consumer product” or “Product”** – “Consumer product” or “Product” does not mean a product that ceased to be manufactured prior to the date the product is listed as a Priority Product or a replacement part used to repair, refurbish or maintain existing consumer products.

To recap and summarize:

- Replacement parts for older vehicle models often cannot be used interchangeably with parts manufactured for newer models.
- Imposing regulatory requirements on replacement parts manufactured to maintain, service and/or repair vehicles built (before a regulatory response date) will be cost prohibitive, especially if/when production is limited.
- To redesign or reengineer a part plus validate the durability, reliability, safety, and feasibility for a vehicle no longer in production would be cost prohibitive.
- Without such replacement parts, many automobiles will not be able to be repaired, and a major consumer investment will be lost.
- Automotive safety may be jeopardized as this rule, if unchanged, may stimulate others to develop “workarounds” and/or counterfeit parts.

- Repair shops and companies that manufacture and replacement parts will be significantly disadvantaged by the loss in revenue and stock value and/or the increased costs to comply with the regulations for parts designed before a regulatory response date existed.
- To subject replacement parts, other than those already in stock, to the alternative assessment process will be costly, time consuming and with limited regulatory benefit.

For all of the above reasons, again, we urge DTSC to exclude all replacement parts (maintenance, service and/or repair) built to repair a vehicle as produced prior to a regulatory response date, irrespective of the replacement parts' manufacture date.



**we wear<sup>SM</sup> our mission**

February 28, 2013

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

**RE: Public Notice and Comment Period – Safer Consumer Products Regulations; Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04 (Released January 29, 2013)**

Dear Ms. Von Burg:

On behalf of the American Apparel & Footwear Association (AAFA), I am submitting the following comments in response to the request for public comments by the California Department of Toxic Substances Control (DTSC) on the revised text of the Safer Consumer Products proposed revised regulations as identified in the file number referenced above.

AAFA is the national trade association representing apparel, footwear, and other sewn products companies, and their suppliers, which compete in the global market. Our membership consists of 380 American companies which represent one of the largest consumer segments in the United States. Of these companies, more than 50 are headquartered in California and represent thousands of jobs in the state. Most others, although not headquartered in California, retain employees in California in retail, distribution, design, and other roles.

Thank you for this opportunity to submit comments. Upon review of this latest draft of the Proposed Regulations, there are three main areas of concern for which we have suggested improvements. They are:

- The use of practical quantitation limits (PQLs).
- The lack of prioritization based on potential for exposure and harm.
- Timeframes to find alternatives are unrealistic.

1601 North Kent Street  
Suite 1200  
Arlington, VA 22209

(703) 524-1864  
(800) 520-2262  
(703) 522-6741 fax  
[www.wewear.org](http://www.wewear.org)

### **1) The Use of Practical Quantitation Limits**

The Proposed Regulations as currently written appear to set the threshold for the requirement to perform an alternatives analysis at the detection level for intentionally added chemicals and at the Practical Quantitation Limit (PQL) for contaminants. If adopted, this provision would lead to a large amount of meaningless paperwork searching for the infinitesimal, which, in turn, would then trigger burdensome work analyzing alternatives without any corresponding benefit to the environment or public health. We are concerned that this quest for the most minute concentrations that instruments can measure is not only impractical, but will inevitably divert resources of both industry and the Department from higher value work that can and will make significant and measurable reductions toxics and innovations in lower impact materials.

We understand previous drafts had proposed a de minimis of 0.1% for most chemicals, and 0.01% for chemicals of higher risk. We urge the Department to return to this earlier proposal.

### **2) Lack of Prioritization**

The Proposed Regulations decline to propose a prioritization of higher risk chemicals in consumer products. We believe this is a critical flaw. The Proposed Regulations create a large, complex, data-intensive collection and assessment system, with hundreds and even thousands of individual requirements. And yet, the draft text does not recognize that not all of these are equally important and must be prioritized. All projects have limitations on budget, staff, and schedule, and resources are not unlimited and must be given focus and prioritized.

California Health and Safety Code 25252 (a) states: “the regulations adopted pursuant to this section shall establish an identification and prioritization process that includes, but is not limited to, all of the following considerations:

1. The volume of the chemical in commerce in this state.
2. The potential for exposure to the chemical in a consumer product.
3. Potential effects on sensitive subpopulations, including infants and children.”

While the problem the Department is attempting to tackle is huge, the Department must give “priority” to certain chemicals in consumer products. “Priority” means something will be given or merit attention before competing alternatives, and that it will be given precedence in terms of date and time. The statute mentioned above provides a simple scheme to prioritize based on volume, potential for exposure and potential effects on sensitive subpopulations. The Proposed Regulations can build on this to provide some direction to industry on what to tackle first.

When everything is a priority, nothing is. We urge the Department follow the statutory direction and to give meaningful priority to those chemicals in consumer products which have the greatest risk of exposure and potential for harm.

### **3) Experience Shows the Timeframes to Find Alternatives are Unrealistic**

The alternative assessments required by the Proposed Regulations will prove to be extraordinarily complex and very time consuming. Numerous brands have taken great care in their own business to carefully evaluate the characteristics of chemicals utilized in its products, and to evaluate alternatives where appropriate. Based upon this experience we are certain that some alternatives assessments (AAs) can be done in the 180 days proposed, however some AAs will take far longer than 180 days to identify the range of potential alternatives required in the Preliminary AA Report. For complex materials with multiple chemical inputs, it will take far longer than the 18 to 30 months provided to complete the Final AA Report.

Without the adequate time to perform quality AAs, product performance could suffer or unintended consequences could result. These unintended consequences could result in significant negative impact in other areas such as increased water use, increased CO2 emission, increased energy inputs, replacement of one hazardous chemical with another hazardous chemical.

We urge the Department to consider a variable timeframe for companies to find alternatives. The timeframe adopted should allow for quick substitutions when they are achievable but also allow for cases where alternatives will require coordination of chemical research, performance testing of reformulated products, and even the possibilities that production facilities may need to be modified to accommodate differences in manufacturing. Unrealistic timelines could impact employment and competitiveness of products.

Furthermore, in situations in which an AA is needed by more than one brand or manufacturer for the same or similar scenario, it would be beneficial for all parties involved if the regulation allowed for a joint analysis to perform one submission instead of multiple submissions. Doing so could save resources and provide the opportunity of cost sharing for companies challenged with the task.

We respectfully request that you re-examine the above three issues before the Proposed Regulations move closer to completion to ensure that they achieve their intended goals.

Additionally, while we acknowledge and appreciate the Department's efforts to incorporate stakeholder input into the revised regulations, we were disappointed to discover several of the points of contention on which we have previously commented were not addressed in the revised regulations. We wish to stress our association's support for the broad goals of the Safer Consumer Product Alternatives Regulations to develop tools to assist companies in their ongoing efforts to ensure they make and market safe consumer products, and to ensure consumers are aware of and have confidence in these efforts. However, we feel regulations can be effective only when they are transparent, predictable and clear. To make this possible, clarity is still needed in several sections of the regulations. For the Department's reference, we have attached as an addendum the most recent comments submitted by AAFA which outline these specific sections.

Thank you for your time and consideration in this matter. Please do not hesitate to contact AAFA if we can be of any help to you. Please feel free to contact me or Marie D'Avignon of my staff at 703-797-9038 or by e-mail at [mdavignon@wewear.org](mailto:mdavignon@wewear.org) if you have any questions or would like additional information.

Sincerely,



Kevin M. Burke  
President & CEO



**we wear™ safety**

October 11, 2012

Deborah Raphael  
Director  
Department of Toxic Substances Control  
1001 "I" Street  
P.O. Box 806  
Sacramento, CA 95812-0806

**RE: Safer Consumer Products Proposed Regulations; Public Notice and Comment Period; Office of Administrative Law Notice File Number: Z-2012-0717-04 (July 27, 2012)**

Dear Director Raphael,

On behalf of the American Apparel & Footwear Association (AAFA), I am submitting the following comments in response to the request for public comments by the California Department of Toxic Substances Control (DTSC) on the Safer Consumer Products proposed regulations as identified in the file number referenced above.

AAFA is the national trade association representing apparel, footwear, and other sewn products companies, and their suppliers, which compete in the global market. Our membership consists of 380 American companies which represent one of the largest consumer segments in the United States. Of these companies, 59 are headquartered in California and represent thousands of jobs in the state. Most others, although not headquartered in California, retain employees in California in retail, distribution, design, and other roles.

Thank you for this opportunity to submit comments. As we have noted in previous comments, we wish to stress our association's support for the broad goals of the Safer Consumer Product Alternatives Regulations to develop tools to assist companies in their ongoing efforts to ensure they make and market safe consumer products, and to ensure consumers are aware of and have confidence in these efforts. However, AAFA and its members feel regulations can be effective only when they are transparent, predictable and clear. Our comments today will underline this notion while addressing specific segments of the proposed regulations.

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

Section (a) (4) under this heading, allows for the Department to request manufacturers or importers to generate new information and provide it to the Department<sup>1</sup>. Our concern with this requirement is the lack of specificity and details of what kind, how much, and how often this "new information" might be requested.

<sup>1</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 18, (July 2012).

1601 North Kent Street  
Suite 1200  
Arlington, VA 22209

(703) 524-1864  
(800) 520-2262  
(703) 522-6741 fax  
[www.wewear.org](http://www.wewear.org)

At some point, there must be a limit to how much information the Department can request for manufacturers and expect them to still be able to run a functioning operation.

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

This section of the regulations deals extensively with how COCs will be identified through these regulations<sup>2</sup>. Specifically it outlines the mechanism by which the initial list of a certain number of COCs will be codified with the completion of the regulatory rulemaking process. In sum, chemicals that display a hazard trait and are on one of 22 separate lists of chemicals would automatically be included as COCs. In short, once the regulations are finalized, approximately 3,000 chemicals, according to documents released by DTSC, will be added as COCs. This is of concern to our industry for two reasons:

- 1) This change to the regulation has the effect of shortening the timeline for implementation of the regulation. Previous drafts of the regulation have called for the official process of generating a list of COCs to begin immediately upon completion of the regulations with an initial list of COCs due 6 months after the regulations have been finalized. This process significantly decreases the amount of time the business community would have to prepare compliance mechanisms for the regulations. It is important to note that for many industries, the apparel and footwear industry being one of them, supply chains can stretch as long as a full calendar year. In theory that means even if a company makes an immediate change to a product, it may be as long as year until the changes are reflected on the store shelf. In previous regulations like the Consumer Product Safety Improvement Act<sup>3</sup> (CPSIA), short and unreasonable timelines for implementation have led to enormous confusion and costs throughout our industry before the Consumer Product Safety Commission (CPSC) ultimately had to step in to extend deadlines anyway. It is essential to the success of regulations that there is enough time built into them to allow companies to adequately prepare compliance mechanisms and avoid mass confusion in the various consumer product industries.
- 2) We are concerned with the idea of the initial list of COCs being automatically adopted upon the finalization of the regulations. In previous drafts of these regulations, DTSC would release an initial list of COCs that would be open for public comment upon finalization of the regulations. This would be the same process when any chemicals were under consideration for inclusion in the COC list. Although we do note the provision for a 45-day comment period for any revisions to the list as outlined in section § 69502.3 (c) (1)<sup>4</sup>, the current regulations do not allow for a dedicated public comment period for this initial list of over 3,000 chemicals.

As a final thought on the COCs, it would be very helpful if the list of COCs to be added immediately upon finalization of the current regulations, would be included in the regulations as a single appendix. Ideally, this list would be cross referenced with various other chemical management regulations such as REACH and TSCA, so industry would be able to see where there may be overlaps and redundancies. This would provide much needed clarity for companies and will also help companies which have comments or concerns to comment on the proposed COCs of which we are currently aware.

---

<sup>2</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Pages 21-24, (July 2012).

<sup>3</sup> United States Consumer Product Safety Commission, The Consumer Product Safety Improvement Act of 2008: Public Law 110-314, (August 14, 2008).

<sup>4</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 24, (July 2012).

## **§ 69503.2 – Priority Products Prioritization Factors**

We appreciate the approach DTSC has taken with regard to prioritizing products, rather than requiring every manufacturer with a COC in a product to perform an Alternatives Analysis (AA). However, we still have concerns with the product prioritization process.

The proposed regulations are fairly clear in what information will be used in determining whether a product should be included in the Priority Product (PP) list. We see that the priority determination will be based essentially on an evaluation of the COCs potential adverse impacts and exposures<sup>5</sup>. However, we are concerned that while the regulations are complete in what information will be used, it does not give insight into the process by which the information will be used. In this regard, the process lacks transparency and predictability, both of which are necessary for our industry to adequately prepare and understand the regulations.

With regard to measuring exposure as it relates to the product prioritization, we are pleased to see the department has included the concept of “intended use” of a product. We understand the department needs to look at total exposure potential when evaluating products. However, intended use should play a significant role in that evaluation process as the intended use is by and large the use for which the product will be utilized. Not giving weight to the intended use of a product when evaluating potential exposures has the unfortunate effect of punishing manufacturers for the consumers misusing their product, something over which the manufacturers have no control.

## **§ 69503.4 – Priority Products List**

The promise of one or more public workshops to provide opportunity for oral comment on products being considered for the proposed PP list<sup>6</sup> is a welcome step towards transparency in the process and we applaud DTSC for this initiative.

At the same time, the proposed regulations require the initial PP list be released for public comment by DTSC no more than 180 days after the regulations are finalized. Initial drafts of these regulations put that same deadline at 24 months after the finalization of the regulations. As was previously mentioned in these comments, allowing adequate time for implementation of the regulations is essential to avoid rampant confusion within the industry and ensure a smooth transition. This is especially true in relation to the PP list, as manufacturing a product contained on the PP list is the trigger to initiate a compliance process for manufacturers. Once a PP list is finalized, it automatically starts the clock on preliminary alternatives assessments. Therefore, it is essential there be adequate time built into this step of the process to allow companies time to put in place compliance mechanisms.

## **§ 69503.5 – Alternatives Analysis Threshold Exemption**

While we are pleased that the department has included an Alternatives Analysis Threshold Exemption<sup>7</sup>, similar to what was previously known as a *de minimis* exemption, the concerns surrounding the practical use of the *de minimis* exemption remain in this new context.

As previous comments and past experience have shown, set threshold levels are not one-size-fits-all and attempting to approach it in this way undermines the outcome of such initiatives. Levels should be set on

---

<sup>5</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 25-27, (July 2012).

<sup>6</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 30, (July 2012).

<sup>7</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 31-32, (July 2012).

a case-by-case basis, as conducting evaluations based on potential COC exposure for each product and determining an individual threshold level based on that evaluation only strengthens the legitimacy of the levels and provides a sounder scientific basis for the levels.

Section 69503.5 (c) of the proposed regulations alludes to a process which is based on this notion of setting levels on an individual chemical basis<sup>8</sup>, but we ask that DTSC better define the process that will be used for setting levels. For example, section 69503.5 (e) allows DTSC to lower or raise a previously established AA threshold based on new, or newly considered, information<sup>9</sup>. Yet, there is no indication of what kind of new information would constitute a change in threshold levels.

#### **§ 69503.6 – Alternatives Analysis Threshold Exemption Notifications**

We strongly believe that the Alternatives Analysis Threshold Exemption notification process is unwarranted and undermines the reason behind having AA threshold levels in the regulations. Under the current regulations, a company must petition DTSC to accept that COCs in their product fall below the assigned threshold levels in order to avoid the AA process.<sup>10</sup> The main purpose of the threshold level is to establish a concentration under which the chemical poses no appreciable risk. Having to undertake a tedious process of submitting the required notifications when COCs exist in amounts under the approved threshold level amounts to a burdensome requirement with no appreciable gain to consumer safety or chemical innovation.

Furthermore, standardized analytical testing methods for detecting COCs in certain products may not exist. In the absence of established testing methods, the 60-day time period allotted by DTSC for AA threshold exemption notification is generally insufficient time to develop testing methods and be able to notify DTSC of the results.

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

The proposed regulations state a person may petition DTSC to add to or remove from the Chemicals of Concern list one or more chemicals, or to add the entirety of an existing chemicals list to the lists specified in section 69502.2 (a).<sup>11</sup> While we agree that private individuals should be able to petition the DTSC regarding COCs or PPs, the proposed regulations do not require the person be a California resident. As the regulations are in fact for the state of California, it seems odd that private citizens from outside the state would be able to petition for the DTSC to evaluate chemicals and products. We would recommend limiting the petitioning process to citizens of California and organizations with a presence in California.

#### **§ 69504.1 – Merits Review of Petitions**

We believe that the petitioning process described in Article 4 should provide an opportunity for all stakeholders, including industry, to comment and be notified of decisions. Earlier sections of the proposed regulations state additions to the COC list and PP list will be subject to a public comment period. This being established, this section of the regulations is unclear as to whether chemicals and products that are reviewed and accepted by DTSC will be included outright on the lists, or if they will be put on proposed lists which are subsequently open to public comment. We would strongly urge DTSC to

---

<sup>8</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 31, (July 2012).

<sup>9</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 32, (July 2012).

<sup>10</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 32 -33, (July 2012).

<sup>11</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 34, (July 2012).

embrace the latter of the two options. If chemicals and products whose petitions are accepted by DTSC are placed on the COC and PP lists outright, it completely excludes industry and other stakeholders from the opportunity to comment on the regulations.

**§ 69505.1 – Alternatives Analysis: General Provisions, § 69505.3 – Alternatives Analysis: First Stage, and § 69505.4 – Alternatives Analysis: Second Stage**

We have several concerns related to the two-stage AA procedures outlined in Article 5 of the proposed regulations.<sup>12</sup> The basic purpose behind the AA seems to be to provide manufacturers a pathway toward reformulation when a PP contains a priority chemical. We appreciate the need to outline a regimented process and the fact that DTSC will be providing further guidance on completing AAs prior to the first PP list being published, however the process that has been created will be extremely expensive for companies who need to complete an AA. One approach to alleviate that burden would be to cut down on the number of AAs that must be completed. We have three suggestions to accomplish this goal.

1. Currently the regulations require companies to submit an AA if they are responsible for a product which is named to the final PP list, even if all the COCs from the priority product are removed. A simpler approach would be to enable manufacturers who choose to remove a chemical to simply send a chemical removal notification to DTSC which includes the effective date of the change. Such a system would also give DTSC a simpler workload so they can easily understand and trace industry reactions to the publication of various lists.
2. Another option to reduce the amount of AAs being conducted is to allow companies to collaborate. AAs for assembled products center on the components of the product which contain the COCs. If a number of companies within the industry share common components, for example zippers, it would greatly reduce the number of AAs to be completed, if the companies could submit a joint AA. The proposed regulations make it difficult to determine whether or not this kind of cooperation would be acceptable. We ask that the process be made clearer going forward.
3. Finally, it would be helpful if the use of third party chemical management certifications could be incorporated into the AA process. A number of companies already use these certifications to help with various chemical management regulations. A clear explanation of how these certifications may be used in the regulations may not help reduce the number of AAs which must be conducted, but it would certainly make the process much easier and less resource intensive.

We appreciate that the regulations no longer require the use of a third party to do the AAs, as was the case in previous regulations. However, the regulations still require the use of a certified assessor for all AAs completed two years after the effective date of the regulations be performed by a certified assessor as outlined in Article 8.<sup>13</sup> This is an unnecessary expense for our members to incur. Regardless of whether they hire an outside certified assessor, which amounts to a third party assessor, or if they have one of their staff certified to do the AAs, it represents a superfluous and burdensome expense.

Most of the companies in our industry have very qualified personnel already in their employ and may be more than capable already to perform the AA. The argument gains credence, especially when one considers that ultimately it is the responsible entity that is responsible for the content of the AA and complying with the regulations, not the certified assessor. Forcing companies to use a certified assessor needlessly cedes power from those responsible for compliance to those with no stake in it. Companies are ultimately responsible for their AAs and compliance. Therefore, it should be left up to each individual

---

<sup>12</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 36-52, (July 2012).

<sup>13</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 37 and 65-66, (July 2012).

company to decide whether or not it is necessary to enlist an outside assessor or to have their own personnel certified in order comply with the regulations.

### **§ 69505.2 – Analysis of Priority Products and Alternatives**

We are appreciative of DTSC for showing flexibility and an openness to cooperate with the inclusion of section 69505.2 (c) which allows companies to utilize an AA process which differs from the process previously outlined within the regulations.<sup>14</sup> This type of flexibility allows companies to streamline some of the compliance requirements with internal procedures they may already have in place. It reduces the burden, and could prevent companies from being forced to recreate the wheel internally, so-to-speak.

### **§ 69507.6 – Department Procedures for Requests for Review**

The regulations are clear on which of the decisions from DTSC qualify for the formal dispute resolution procedure and the informal dispute resolution procedure. Our main concern lies with the formal dispute resolution procedure. Under no circumstances do we support a procedure in which DTSC can deny a review of a dispute.<sup>15</sup> This is the main protection built into the regulations for industry. The allowance for DTSC to simply deny a request undermines the entire principle of the safeguard. We request that a more robust system be put in place that does not allow DTSC to deny requests for dispute resolution.

### **§ 69508 – Qualifications and Certification for Assessors and § 69508.1 – Qualifications for Accreditation Bodies**

We have already outlined our serious misgivings with the requirement of a certified assessor for AAs and the corresponding accreditation program for organizations. However, if such a program must exist, we want to stress that it should not preclude those organizations with which industry already has relationships. It is common for our members to already use testing labs for various services including product safety compliance. These organizations often are already equipped with their own labs to do the testing required under this regulation. It would seem that they are a natural fit to serve as accrediting bodies so their employees can become certified and conduct the AA's for their already existing clientele.

### **§ 69510 – Assertion of a Claim of Trade Secret Protection**

We remain deeply concerned about the inadequate provisions laid out in these regulations to protect trade secret information. We acknowledge there are several provisions that permit companies to claim information is of a sensitive nature and must be kept confidential. Yet those same provisions also require the public filing of redacted information, even when the non-redacted portions would end up divulging confidential information through context. Moreover, making the redacted copy available at the discretion of DTSC is inconsistent with Sections 69501.5 (b) (6) of these regulations.

The trade secret provisions in Article 10<sup>16</sup> contain troubling requirements for companies to justify why they believe information is confidential. For example, filing a request for trade secret protection requires companies to speculate as to how much the information would be worth to competitors, and how readily competitors would be able to replicate the information on their own. It would be very difficult for companies to attempt to quantify this type of information for themselves, let alone a competitor who may have very different internal mechanisms and cost structures. Therefore, we feel the process by which

---

<sup>14</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 39-40, (July 2012).

<sup>15</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 64-65, (July 2012).

<sup>16</sup> Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 75-77, (July 2012).

companies apply for trade secret protection should be reexamined with an eye for keeping information requirements within the realm of what can be reasonably expected for companies to know.

Some of the questions in the trade secret protection provision appear to attempt to establish a dollar figure for the information. This is an ultimately unwieldy strategy, as the value of this information is often in name recognition and product reputation in addition to dollar amounts. Furthermore, information that can be quantified materially is at serious risk of being taken out of context. For example if a dollar amount is assigned to a piece of information, how is that assigned worth? Companies vary in size and revenue structures, and information valued at X dollars can be worth drastically different things to different companies. Nowhere in Article 10, which deals with trade secret information, is there any attempt to capture information which would put a dollar value into context. It is our recommendation that questions of this nature be completely excluded from the trade secret protection process.

### **General Comments**

Our industry's main concern within this field is the growing patchwork quilt of chemical management regulations we are seeing across the United States. We understand and fully support a state's prerogative to enact legislation it deems will protect its citizens in absence of federal action. However, we would be remiss if we did not make regulators aware of the difficult position in which this places business. It is our hope that regulators continue to look at different ways to work with other states to streamline the regulatory requirements for products as much as possible.

Thank you for your time and consideration in this matter. Please do not hesitate to contact AAFA if we can be of any help to you. Please feel free to contact me or Marie D'Avignon of my staff at 703-797-9038 or by e-mail at [mdavignon@wewear.org](mailto:mdavignon@wewear.org) if you have any questions or would like additional information.

Sincerely,



Kevin M. Burke  
President & CEO



February 28, 2013

Ms. Krysia Von Burg  
Department of Toxic Substances Control  
Regulations Section  
P.O. Box 806  
Sacramento, California 95812-0806  
Via E-mail: [gcregs@dtsc.ca.gov](mailto: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 American Chemistry Council (ACC) respectfully submits the attached comments on the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Products Regulation Post-Hearing Changes of January 2013.

ACC and its member companies believe that consumers deserve to have confidence that the products they buy are safe for their intended uses. ACC members invest significant resources in product and environmental stewardship and share a common commitment to advancing the safe and secure management of chemical products and processes. We believe that health, safety, and environmental protection policies are most effective when they incorporate risk-based priorities and decision-making processes. It is in this spirit that we offer our comments on the proposed regulation.

For the last five years ACC has actively and constructively engaged DTSC on the California Green Chemistry Initiative. We are an active member of the Green Chemistry Alliance (GCA) and support GCA's comments on the proposed regulation. ACC and our GCA partners believe that DTSC should foster a meaningful, practical, and legally defensible regulatory environment. While DTSC has made changes that minimally improve the "workability" of the proposed procedures, we are disappointed that the proposed regulations fall short of achieving the critical test of clarity, necessity, authority, and consistency required by California administrative law. At best the proposed regulation will produce only marginal improvement in human health and environmental safety, but at great expense and lost opportunities for businesses nationwide.

We appreciate certain aspects of the proposed regulation, but on balance we believe DTSC has developed a proposed regulation that creates uncertainty, goes beyond what is necessary to meet the intent and purpose of the authorizing statute, and, in several instances, goes beyond the



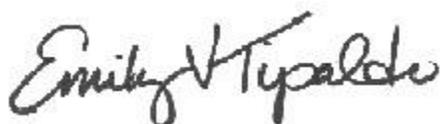
authority provided in the statute. We are very concerned that the approach will stifle innovation and competition by creating an unpredictable and burdensome regulatory environment for consumer product manufacturers and all parties in their supply chains.

Compliance will be extremely difficult given the uncertainty of meaning and intent of much of the regulation. Ironically, DTSC is proposing such a regulation at a time when Governor Brown is looking for ways to “search out and strip away any accumulated burdens or unreasonable regulations that stand in the way of investment and job creation” in order to put more than two million Californians back to work.<sup>1</sup> DTSC clearly neither considered nor appreciated the difficulty of compliance with and enforcement of these regulations and their far reaching impacts on competitiveness. Perhaps the only certain choice any party in a product supply chain facing an alternatives assessment required by the regulation is to exit the California market. Yet even that decision comes with its own reporting and compliance burdens.

DTSC revised and issued for public review and comment the *Initial Statement of Reasons* prior to publishing the revised regulatory proposal. DTSC has offered no insight as to why a number of changes were made, and failed to address the constructive feedback and analysis offered by ACC, GCA, and other industry stakeholders. ACC’s comments provided October 11, 2012, are referenced in the following comments to highlight issues that were not addressed by DTSC (see attachment). We look forward to DTSC’s response to all comments.

In summary, ACC appreciates that DTSC has engaged all stakeholders throughout the regulation development process. However, we are disappointed that DTSC has ignored many of the substantive comments and suggestions that GCA members have provided and has chosen instead to release a proposed regulation that fails critical tests of clarity, necessity, consistency, and authority mandated by California law. As drafted, the proposed regulation has significant consequences for businesses and their employees within and beyond the borders of California. We hope that our comments and questions will encourage DTSC to re-consider some of the choices it has made in developing the proposed regulation and that DTSC will modify and significantly improve the final regulation.

Sincerely,



Emily V. Tivaldo  
Manager, Regulatory and Technical Affairs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA ([mrodriguez@calepa.ca.gov](mailto:mrodriguez@calepa.ca.gov))  
Miriam Ingenito, Deputy Secretary, CalEPA ([mingenito@calepa.ca.gov](mailto:mingenito@calepa.ca.gov))

---

<sup>1</sup> Edmund G. Brown, Jr., State of the State Address, January 31, 2013, <http://gov.ca.gov/news.php?id=16897>.



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

Nancy McFadden, Cabinet Secretary, Office of the Governor

([nancy.mcfadden@gov.ca.gov](mailto:nancy.mcfadden@gov.ca.gov))

Mike Rossi, Senior Business & Economic Advisor, Office of the Governor

([mike.rossi@gov.ca.gov](mailto:mike.rossi@gov.ca.gov))

Cliff Rechtschaffen, Senior Advisor, Office of the Governor

([cliff.rechtschaffen@gov.ca.gov](mailto:cliff.rechtschaffen@gov.ca.gov))

Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

([martha.guzman-aceves@gov.ca.gov](mailto:martha.guzman-aceves@gov.ca.gov))

James Jones, Acting Assistant Administrator, U.S. EPA ([jones.jim@epa.gov](mailto:jones.jim@epa.gov))



## ACC COMMENTS ON THE PROPOSED REGULATIONS – POST-HEARING CHANGES SAFER CONSUMER PRODUCTS (R-2011-02) January 29, 2013

### **The exemption for bulk chemicals should be restored.**

ACC urges DTSC to exempt both bulk chemicals and products manufactured in or transported through California solely for use outside of California from the Safer Consumer Products Regulation. The goal and intent of the California Green Chemistry Initiative is to provide better, safer options to California consumers, in terms of the products they use on a daily basis. The focus of the Safer Consumer Products Regulation therefore should be the “Chemicals of Concern” (COC) in “Priority Products,” not on bulk chemical manufacturing and transportation. It is unclear why DTSC has included bulk chemicals within the scope of the regulation. As a practical matter, neither manufacturers nor DTSC have the capacity to include the entire universe of manufacturing materials (may be referred to as a “chemical” or a “product”) in a regulation aimed at final consumer products. As noted in our comments dated October 11, 2012, the bulk chemical exemption should be restored.

Furthermore, ACC requests DTSC clarify why the applicability of the proposed rule has been revised to address products 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, and any consumer products manufactured or stored in or transported through California solely for use outside the State. Currently, these factors are merely “adverse impact and exposure factors” considered in the product-chemical combination prioritization process. Federal statutes, such as the Occupational Safety and Health Act, the Hazardous Materials Transportation Act, the Federal Hazardous Substances Act, and the Controlled Substances Act, already regulate the manufacture and transport of chemical products.

### **The definition of “import” requires further clarity.**

The proposed definition of “import” is unclear. The proposal states that “‘import’ does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States.”<sup>1</sup> This particular statement appears to contradict the intended scope of the provision. ACC believes DTSC may be referring to an individual placing a personal order for a product manufactured outside of the U.S., but not for commercial resale. ACC requests clarification of “import” as defined in the proposed regulations.

### **The revised definition of “reliable information” should include a weight-of-evidence approach.**

Although marginally improved from previous definitions of “reliable information,” the latest definition does not guarantee reliance on quality science through a weight-of-evidence (WoE) approach. As noted in our comments dated October 11, 2012, without a WoE approach a single study, regardless of its quality and irrespective of other available relevant data could be used to conclude that a chemical possesses “suggestive evidence” of a specific hazard.<sup>2</sup> WoE means a

---

<sup>1</sup> §69501.1(a)(38).

<sup>2</sup> OEHHA Green Chemistry Hazard Traits for California’s Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).

systematic evaluation that assesses the adequacy, strength, and consistency of the scientific information utilized for identifying Candidate Chemicals and the process for prioritizing consumer products containing Chemicals of Concern. WoE also facilitates identifying potential alternatives to Priority Products in order to determine how best to limit exposures to, or the level of adverse impacts posed by, the Chemical(s) of Concern in the Priority Product.

In carrying out a WoE evaluation, the Department should determine whether a consistent and biologically plausible scientific understanding of significant adverse effects emerges from a comprehensive evaluation of relevant scientific studies, including null findings, taking into account the following:

- The scientific quality of each study and the relevance, reliability, sensitivity, and specificity of each test method;
- Whether study results demonstrate similar adverse effects across species, strains, and routes of exposures;
- Clear evidence of a dose-response relationship;
- A scientifically plausible relationship between mode or mechanism of action, the adverse effect of concern, and data on absorption, distribution, metabolism and excretion;
- Comparison to toxicity exhibited by structurally related compounds using a scientifically valid method; and,
- The extent to which scientific evidence does, or does not, support a causal link between specific exposure to the chemical and evidence of the adverse effect of concern in humans or in other relevant species.

ACC urges DTSC to include a WoE approach in the regulation, as it is critical to agency decision making, particularly with regard to prioritizing Candidate Chemicals and products. It would reinforce DTSC's commitment to science-based decision making.

**DTSC should not rely upon European lists still under development as the basis of candidate chemical listing.**

The July 27, 2012, proposed rule offered a 2000 report prepared by a consultant for the European Commission entitled *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, as a basis for what was then termed the "Chemicals of Concern" list. Given that this was intended as a preliminary list that was subsequently modified, DTSC correctly removed that resource as a listing trigger in the present proposal.

DTSC has replaced that trigger, however, with a reference to "[c]hemicals included as endocrine disruptors identified in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation 1907/2006."<sup>3</sup> As DTSC is aware, this is a list that has yet to be populated by European authorities. An initial list could be released in 2014, and is expected to be modified over time as new information and analysis becomes available.

---

<sup>3</sup> §69502.2(a)(1)(C).

As such, the use of this list as a trigger for Candidate Chemical listing in California represents a “dynamic incorporation,” a practice that raises due process and non-delegation concerns. Professor Dorf of Cornell calls dynamic incorporation “a prima facie threat to the democracy of the incorporating polity because it takes decisions out of the hands of the people's representatives in that polity and delegates them to persons and bodies that are accountable only to a different polity, if at all.”<sup>4</sup>

California courts have long regarded dynamic incorporation as constitutionally flawed. As the court in *Brock v. Superior Court* noted:

*It is, of course, perfectly valid to adopt existing statutes, rules or regulations of Congress or another state, by reference; but the attempt to make future regulations of another jurisdiction part of the state law is generally held to be an unconstitutional delegation of legislative power.*<sup>5</sup>

For this reason, the California Court of Appeals has observed that “[w]hile existing statutes may be incorporated by reference, prospective incorporation has never been approved by a California court.”<sup>6</sup> DTSC should strike references to the candidate list.

**DTSC’s approach to regulating intentionally added chemicals and contaminants should be revised.**

The proposed rule lacks a threshold for intentionally added COCs, based on the risk posed by the COC in the product. Manufacturers must measure the contaminants in the Priority Product, down to the Practical Quantitation Limit (PQL). The “practical quantitation limit” is defined as the “lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.”<sup>7</sup> Essentially, DTSC is stating that intentionally added chemicals are subject to alternatives assessment if they are present in the priority product at any concentration, whereas contaminants are subject to reporting if they can be detected in the product. This is a meaningless distinction and effectively treats intentionally added chemicals identical to contaminants.

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 present in products at such low levels as to be barely observable, and has no bearing on whether these barely detectable materials could migrate from the product and if so whether such migration results in any detectable exposure for users of the product.

---

<sup>4</sup> Dorf, Michael C., "Dynamic Incorporation of Foreign Law" (2008). Cornell Law Faculty Publications. Paper 114. <http://scholarship.law.cornell.edu/facpub/114>.

<sup>5</sup> *Brock v. Superior Court*, 9 Cal.2d 291, 297 [71 P.2d 209, 114 A.L.R. 127] (1937).

<sup>6</sup> *PEOPLE v. KRUGER*, 48 Cal.App.3d Supp. 15 (1975).

<sup>7</sup> §69501.1(a)(52).

A better approach would be to set numerical thresholds for intentionally added chemicals that are harmonized with those applied by federal and international agencies. As noted previously, in our comments dated October 11, 2012, harmonization with numerical thresholds set by federal and international bodies would be consistent with the enacting statute.<sup>8</sup> The federal Occupational Safety and Health Administration (OSHA), the Globally Harmonized System for Classification and Labeling (GHS), and the European Union's REACH standard apply a risk-based *de minimis* threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens, and reproductive toxins. Provided the manufacturer has done its due diligence to remove contaminants from the product, contaminants should be exempt from reporting.

Further, DTSC should treat intentionally added chemicals and contaminants in a manner that incentivizes efforts to limit them. Washington State has adopted such an approach in implementing its *Children's Safe Product Act*, Chapter (70.240 RCW). Washington allows product manufacturers the option of not reporting contaminants if they have in place a "manufacturing program to minimize contaminants in their products" and "use due diligence to ensure the effectiveness of the program."<sup>9</sup> Washington encourages manufacturers to use process improvements, contract specifications, testing and auditing to reduce the presence of contaminants in final products, while recognizing that "intentionally added chemicals...offer the best opportunity for substitution with a safer alternative and should be where we focus most of our attention."<sup>10</sup>

**DTSC's approach to prioritizing product-chemical combinations is overly subjective and is missing key scientific elements.**

Prioritization is central to any benefits that will be derived from the regulation. DTSC must employ a rigorous scientific process for selecting product/COC combinations. Despite suggestions made by industry groups for a more quantitative prioritization approach that draws on sound scientific principles such as Canada's program (where 500 high priority chemicals have already been assessed and risk management action taken where appropriate), DTSC instead has proposed a non-quantitative product-chemical prioritization process. This so-called "narrative standard," in ACC's view, is not scientifically defensible for identifying high priorities, and its use may not make meaningful improvements to public health and the environment in California.

In addition, ACC recommends that DTSC add a critical "route of exposure" descriptor to §69503.3(b)(3)E. Currently the provision mentions only "frequency, extent, level and duration." The route of exposure is a critical consideration in determining the potential for adverse impacts.

Unfortunately, the proposed rule has weakened the prioritization process to the point where virtually any ingredient in any product could arguably be selected as the Priority Product.

---

<sup>8</sup> ACC Comments on the Proposed Safer Consumer Products Regulation, October 11, 2012, p. 20.

<sup>9</sup> Washington Department of Ecology, *Children's Safe Product Act Reporting Rule* – WAC 173-334. December 3, 2012.

<sup>10</sup> Washington Department of Ecology, *Children's Safe Product Act Reporting Rule*, May 4, 2011.

**The use of the term “potential” could weaken DTSC’s focus.**

The term “potential,” which had been largely dropped in the July 2012 proposal (e.g. potential adverse effects, potential exposures, etc.), has been returned to virtually every definition, prioritization criterion and consideration. This could overwhelm DTSC with all manner of hypothetical scenarios. Although, this change is somewhat mitigated by the addition of a definition for potential (“...that the phenomenon described is reasonably foreseeable based on reliable information”).<sup>11</sup> DTSC should focus on expected and probable health and environmental concerns, not every imaginable possibility. Furthermore, ACC recommends that the definition of the term “potential” include the concept of likelihood, e.g. “...that the phenomenon described is likely and reasonably foreseeable based on reliable information.”

**Key Principles must reflect the fact that presence does not equal harm.**

A vital phrase has been eliminated from the Key Principles. This phrase, “...in quantities that would contribute to or cause adverse...impacts,” demonstrates the potential for exposure to the chemical in the product to occur at a magnitude, frequency, and duration that raises a concern for potential health and/or environmental effects to arise.<sup>12</sup> This is a critically important part of the Principles and ACC recommends that it be reinstated.

The exposure factors in §69503.3(b) are broad, yet relevant to the prioritization process. The focus of the exposure criteria, however, often seems to be on “presence,” “contact” and “occurrence,” which do not equate to exposure. This suggests an entirely qualitative evaluation, which could result in opinions and perceptions driving the process. Indeed, this approach suggests the potential for arbitrary decisions rather than a deliberative scientific effort to identify high priorities with real and significant threats to human health and the environment. Qualitative information, while helpful in indicating existence, occurrence, contact or presence, cannot make up the sole factors in determining whether a situation creates an exposure with the potential for adverse impacts. Presence does not equate to harm or to risk, and quantitative information demonstrating the potential for exposures to occur at levels of toxicological concern must be a primary driving factor in priority setting decisions.

ACC recommends that the underlined phrase be reinstated in the Principles, §69503.2(a)(2), “[t]here 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.”

**ACC supports use of an APA rulemaking process to update the Priority Products List.**

ACC supports the provision that updates and revises the Priority Products List through a rulemaking process pursuant to the Administrative Procedure Act. We are hopeful the rulemaking process will permit all stakeholders to provide a range of data and information to DTSC, which will enable DTSC to make objective and economically sound Priority Product decisions. ACC is concerned that the absence of quantitative, objective decision-making criteria

---

<sup>11</sup> §69501.1(a)(51)(A).

<sup>12</sup> Text of Proposed Regulations, July 2012, Division 4.5, Title 22, California Code of Regulations, Chapter 55., Safer Consumer Products, §69503.2(b)(2).

for prioritization, including how to assess economic impacts, could result in further uncertainty and additional burdens on industry during the rulemaking process.

**The proposed regulation should allow manufacturers the option of demonstrating the safety of a Priority Product.**

ACC is concerned that the proposed regulation relies on chemical elimination rather than safe use (e.g., see discussion above on the PQL provision and in proposed “Removal/Replacement Notification in Lieu of Alternatives Analysis”). This bias will in turn promote unwarranted product de-selection by the value chain. As noted in our comments dated October 11, 2012, we firmly believe the approach described in the proposed regulation stands in sharp contrast to the statutory requirement that DTSC’s regulations must “...determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern...”<sup>13</sup> Throughout the proposed rule, DTSC should recognize the importance and benefit of incremental improvements as the program commences. Based on a manufacturer’s demonstration of safe use for particular chemicals in a particular product, limiting exposure or reducing the level of hazard posed should be sufficient for compliance.

The proposed regulation, however, is not clear as to when, if at all, manufacturers may demonstrate the safety of a product/COC combination. Furthermore, the rule does not allow manufacturers to make a “safety case,” and instead compels the Alternatives Analysis (AA) process. ACC strongly recommends that DTSC revise the proposed rule to enable manufacturers to demonstrate the safety of specific product/chemical combinations. The mere presence of an identified Candidate Chemical or COC should not be presumed to indicate potential harm. If manufacturers can demonstrate the safety of their product, the product should not be required to complete the AA process.

**DTSC must change its proposed regulation to protect confidential chemical identities consistent with California trade secret law.**

The proposed regulation fails to adequately protect confidential chemical identity, which is critical to companies’ ability to innovate and develop new and improved products and formulations – including “greener” ones. Although the revised proposal attempts to expand protection to confidential chemical identity by allowing trade secret protection when a patent application is pending for a chemical or its use in a product, the proposal actually confuses two distinct types of intellectual property protections (patents and trade secrets), and threatens to erode existing federal and California statutory trade secret law protections.

Broadly speaking, intellectual property rights relate to legal protection for ideas. A copyright protects works of authorship (not relevant to a chemical identity). A trademark distinguishes the goods of one party from those of others, and a service mark does that for services (not relevant to a chemical identity). A patent is a limited duration property right relating to an invention in exchange for public disclosure of the invention (potentially relevant to a chemical identity). These intellectual property protections are all federal rights.

---

<sup>13</sup> California Health and Safety Code Section 25253.

A trade secret is a formula, pattern, or device which is used in business and which provides an opportunity to obtain an advantage over competitors who do not know or use it. A chemical identity may be a trade secret. A key aspect is that the subject must remain a secret, and must not be readily ascertainable. If it is disclosed publicly, it is lost. State law generally governs trade secrets.

Under the California Uniform Trade Secrets Act (CUTSA), modeled after the Uniform Trade Secrets Act (UTSA), a trade secret is information, including a formula, pattern, compilation, program, device, method, technique or process that:

- (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.<sup>14</sup>

Patents are inadequate to protect confidential chemical identities. A trade secret chemical identity may not qualify for a patent. To be patentable, an invention must meet strict requirements for novelty and utility, plus it cannot be obvious to relevant experts. A chemical identity or its use in a mixture may not meet those requirements. To be patented, an invention must be an advance upon the prior art. Novelty and non-obviousness are measured against the prior art. For a trade secret, however, the prior art is irrelevant. A trade secret need only provide economic value from not being generally known to or readily ascertainable by competitors. For example, the identity of a new chemical may be a logical development from previous chemicals that were known to experts, and therefore not patentable. It may be a trade secret, however, if it provides an actual or potential economic advantage over others.

A patent freezes technology, but a trade secret builds on it. A patent covers technology as it exists at the time the patent application is filed. Subsequent incremental improvements are not covered by the patent. Even if a chemical identity or its presence in a formula for a mixture is covered by a patent, improvements to the chemical structure or formula through additional research and development may qualify as trade secrets.

A patent may not provide adequate protection because it is difficult to enforce. Both patents and trade secrets seek to prevent competitors from using the information (at least without authorization). A trade secret does this by keeping the information from competitors through secrecy. A patent does this by disclosing the information to competitors but giving a right to sue them for unauthorized use.

A patent may not protect against foreign competitors. A patent is good only in the country for which it is granted. A U.S. patent, for example, would not prevent foreign competitors from using the patented information to their own advantage.

---

<sup>14</sup> Cal. Civ. Code 3426.1(d).

Requiring disclosure of trade secret product formulations without imposing an affirmative obligation on the receiving party not to disclose the trade secret to any third party automatically triggers the loss of trade secret protection. The only way trade secret information can be disclosed without forfeiting its trade secret status and its competitive economic advantage is under a confidentiality agreement or to a government agency under a statute guaranteeing confidentiality. Absent such a requirement, DTSC's proposed disclosure requirements would risk valuable trade secrets to foreign and domestic competitors.

ACC strongly recommends that DTSC conform its proposed regulations to the CUTSA and protect confidential chemical identities from disclosure as trade secrets.

**DTSC should resolve other issues raised in ACC's October 11, 2012, comments but not addressed in detail here.**

ACC is also concerned about a number of provisions that were not addressed in the post-hearing changes proposed rule, for which we commented on in our October 11, 2012, submission. The following points summarize key issues that have yet to be resolved:

- **Products otherwise regulated by federal law should be excluded.**

Two areas of the proposed regulation appear to duplicate other regulatory programs and further reinforce the inconsistency with the enacting statute. Section 69501 does not exempt food contact materials from the scope of the regulation, and thus duplicates the Federal Food, Drug and Cosmetic Act. At a minimum, it is not clear what additional level of health or environmental protection California would confer to food contact materials beyond the extensive and costly federal governmental reviews conducted by highly trained scientific staff with years of experience.

Similarly, the proposed addition of "workers" as a potentially sensitive subpopulation appears to duplicate the existing authority of Cal/OSHA to protect workers from unreasonable exposures to chemicals. California State Plan, §19 OSHA (1970), approved May 1, 1973, and certified August 19, 1977. At a minimum, DTSC should explain how the inclusion of workers as a potentially sensitive subpopulation does not duplicate CalOSHA's authority.

- **DTSC should clarify its authority to require information generation.**

ACC believes the Department should follow the three-step sequential, tiered process for collecting information set forth in §69501.4(a)(1)(A)-(D). ACC agrees that DTSC should begin its information collection by reviewing information in the public domain that is readily available in a useable format, as laid out in §69501.4(a)(1)(A), followed by reviewing information in the public domain that is available by subscription, and then by requesting additional, existing data from chemical manufacturers or importers. However, as set forth above ACC finds DTSC's requirement to "generate new information"... "necessary to implement this chapter" in §69501.4(a)(1)(D) beyond the scope of the cited authorizing statute.

- **DTSC should clarify the process for evaluation of aggregate and cumulative effects.**

The proposed rule fails to mention what framework DTSC will use, as well as what framework(s) responsible entities may use, during the alternatives assessment process to evaluate aggregate and cumulative risk.<sup>15</sup> ACC urges DTSC to specify what process will be used to determine when an aggregate and cumulative risk assessment is necessary, and, what framework will be used to do so. Specifically, DTSC should clarify whether it is referring to both an assessment of human health aggregate and cumulative risks, and, environmental aggregate and cumulative risks.

- **DTSC should address its intention to respond to public comments.**

Transparency in DTSC's processes is crucial, and therefore, DTSC should clarify the role of the Department in responding to public comments.<sup>16</sup> The success of DTSC's regulation depends in large part on the degree to which the compliance and decision making processes are transparent. DTSC should respond to any and all substantive public comments.

- **DTSC should have provided a revised Initial Statement of Reasons (ISOR) with the current proposed rule.**

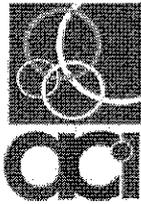
DTSC has undertaken an action that appears to be contrary to the spirit and perhaps letter of California administrative procedure law. In order for the population affected by the proposed regulatory action to be best informed and therefore able to "be heard on the merits" in comments on regulations, the proposed regulations are supposed to be accompanied by an explanatory document, the ISOR. Without understanding the rhyme and reason behind all aspects of the proposed regulation, it would be difficult for the affected public to provide informed comments to be considered by the agency. DTSC did not heed the request in ACC's comments on the revision of the ISOR, dated January 22, 2013, asking that "no regulatory proposal for Safer Consumer Product Alternatives be presented for comment and review without a final ISOR upon which all affected entities can comment in tandem."<sup>17</sup>

---

<sup>15</sup> §69503.3(a)(1)(B)-(C).

<sup>16</sup> See, e.g., §69502.3(d).

<sup>17</sup> ACC Comments on the Revised Initial Statement of Reasons, Proposed Safer Consumer Products Regulation, January 22, 2013, p. 2.



american cleaning institute®  
for better living

February 28, 2013

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

**Re: Revised Text of Proposed Safer Consumer Products (SCP) Regulations**

Dear Ms. Von Burg:

The American Cleaning Institute (ACI)<sup>1</sup> appreciates this opportunity to provide comments on the revised text of the *Proposed Safer Consumer Products Regulations* released for public comment on January 29, 2013 by the California Department of Toxic Substances Control (DTSC or the Department). We were pleased with a number of the revisions the Department has made to the proposed regulation and believe they will improve the Department's ability to implement the regulation. However there are still many challenges that were not addressed and a number of additional changes that will hinder the Department in its goal to foster the development of safer products in implementing AB1879. We would like to take this opportunity to articulate those improvements and remaining challenges below.

**Improvements to the Proposed Regulation**

We believe the new definition which makes the distinction between an *intentionally added ingredient* and a *contaminant* was a critical conceptual element that was added to the revised regulation (§69501.1(a)(26)). This distinction will allow DTSC to focus the Alternatives Analysis (AA) process on the most relevant aspects of product design and development.

We agree that the Priority Products list should be established and updated through rulemaking pursuant to the Administrative Procedure Act (§69503.5(a)(2)).

Likewise, we agree that the Initial Priority Products List should focus on Candidate Chemicals that meet one or more of the criteria of Section 69502.2(a)(1) and Section 69502.2(a)(2) (§69503.6(a)). By focusing the Department's resources on a robust subset of chemicals (~230)

---

<sup>1</sup>ACI is the trade association representing the \$30 billion U.S. cleaning products market, with about \$3 billion associated with business in the State of California. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy.

that is not so broad as to dilute its importance, the desired effects of sending important signals to the market and adding a measure of predictability to the process will be achieved.

Similarly, we agree with the added clarifying language that will prevent the Department from duplicating the work of other Federal or California State regulators. This not only will reduce confusion for the regulated community but it will result in more effective utilization of resources by DTSC (§69503.2(b)(2)). However, the Department should not be permitted to override the decision of another agency if the Department does not agree with the level of protection that the agency has deemed appropriate for the purposes of the statutes it is implementing.

We agree with the Department's decision to eliminate the Certified Assessors component of the proposed regulation (formerly §69508). This was a highly bureaucratic and burdensome aspect of the regulation which promised little added value for the process.

Finally, we believe the replacement of the "Chemical of Concern" terminology with the "Candidate Chemical" designation provides added certainty and clarity to the regulation without diminishing its impact.

### **Unfavorable Changes**

Despite our enthusiasm for the distinction between *intentionally added ingredients* and *contaminants* we are greatly concerned and dismayed at the proposal to set the AA Threshold for contaminants at the practical quantitation limit (PQL; §69501.1(a)(12)). There are several flaws to this approach. First, such a threshold is completely arbitrary. We have articulated in the past that we believe the AA Threshold should be set at a risk-based safety level. There is precedent for this approach in the Safe Harbor limits under Proposition 65. At a minimum, no Alternatives Analysis should be required for a product having a contaminant present at a level below the Prop. 65 Safe Harbor limit for labeling. Second, the AA Threshold Notification process would require the manufacturer to conduct the analytical method development and establish the PQL. This is an extraordinarily burdensome requirement especially for most firms that will not have an analytical lab with such capability. Moreover, this will be burdensome and confusing for the Department receiving varying laboratory testing protocols from a variety of manufacturers. Finally, the notion of conducting an Alternatives Analysis on a contaminant is nonsensical – contaminants by their definition are unnecessary, so an Alternatives Analysis is not required. While it is conceivable in the case where the source of the contaminant is a feedstock material that one could conduct an AA on the feedstock, it is not clear that such an approach is permitted by the statute. The Department would have to declare the feedstock a Chemical of Concern and require the AA on that material. While it may be appropriate for contaminants in products to be evaluated for their safety and for manufacturers to be encouraged (if not required) to reduce or eliminate their presence, the Safer Consumer Product regulations are not an appropriate vehicle for such action. These regulations should be strictly focused on intentionally added ingredients which are determined to be Chemicals of Concern in Priority Products.

Regarding the identification of Chemicals of Concern, we continue to object to the "List of Lists" approach that the Department has repeatedly proposed (and that we have repeatedly criticized). The approach represents an abdication by the Department of its responsibility under the statute to identify and prioritize Chemicals of Concern. Moreover, not all of the lists the

Department has specified are appropriate for this exercise because, as has been noted in the past, either the developer of the list or the process by which that list has been developed does not afford due process for those who will be regulated under this regulation. To that point, the revised regulations includes two additional Candidate Chemical lists – Category 1 respiratory sensitizers from the European Union’s Classification, Labeling and Packaging (CLP) regulation, and the Clean Water Act 303(d) list for California. We do not believe the addition of these two lists improves the regulation and, in fact, there are elements of the two lists that would detract from the scientific basis for the regulations. Regarding the CLP regulation, there was an initial list of respiratory sensitizers included when that regulation was promulgated however additional chemicals are added based on self-classification by chemical manufacturers and users. We are already seeing different, contradicting classifications for the same chemical and there is no independent body monitoring or confirming these classifications. So they will not be harmonized in the future. For sensitizers in particular, there are few definitive objective tests to support such a classification so conclusions are reached based on limited science. Predictive animal models for respiratory allergy in humans do not exist. Therefore, the available clinical studies are the only basis for classification of respiratory sensitizers. When respiratory sensitizers are ranked based on human data, it relies on human exposure information considering magnitude and frequency of exposure and severity of response among exposed individuals during the actual use of the marketed available products. A recent publication examined whether a sub-categorization of protein and/or chemical respiratory allergens was realistic and/or feasible.<sup>2</sup> The conclusion drawn was that, on the basis of the currently available information, potency categorization for respiratory sensitizers was premature and could potentially be misleading. Given uncertainties associated with classifying respiratory sensitizers, we recommend that the EU CLP regulation be deleted from the regulation as a source for identifying potential respiratory sensitizers.

Regarding the 303(d) list, there are a number of pollutants listed that are not relevant to consumer products. For example, algae, debris, electrical conductivity, acid mine drainage, oxygen, pH, scum, temperature, and trash, just to name a few. In addition, there are a number of pesticides included on the list that would be exempted from this regulation. There are very few additional chemicals that would be captured by including the 303(d) list but having these additional pollutants among the Candidate Chemicals detracts from the stature of the regulation.

### **Additional Concerns**

We continue to be concerned with the Trade Secret Protection provisions of the regulation (§69509). We are disappointed with DTSC’s continued reluctance to forcefully protect trade secrets and intellectual property. The approach is self-defeating and inhibits the introduction of new, safer products to the market place. We note two particular changes. The recognition that a company may be bound by non-disclosure agreements and prevented from releasing information publicly is very pragmatic and should be retained in the regulations (§69509(c)(1)). However, a later revision permitting the protection of potentially confidential chemical identity information only in the case when a patent is pending is ill-conceived and should be revisited. For the SCP regulations to succeed, innovators will need to feel assured that their investments in intellectual property are not going to be given away by DTSC in order for them to participate in the process.

---

<sup>2</sup>Basketter D.A., Kimber I. (2011) Assessing the potency of respiratory allergens: Uncertainties and challenges. *Regul. Toxicol. Pharmacol.*, 61, 365-372.

Though we are pleased that the cumbersome Certified Assessor process has been removed from the revised regulations, we are concerned with the alternative that has been inserted; namely, the public comment process for Alternative Assessments. In particular, we are concerned about a manufacturer's obligations to respond to public comments under Section 69505.1(d). Most companies will not have experience responding to public comments and the process could devolve, especially if competitors are commenting on each other's submissions. The Department should monitor the commenting process closely and permit wide latitude for the author in responding to comments so as not to unnecessarily delay the process.

Finally, the success of the Safer Consumer Product regulations rests on the willingness of manufacturers to engage in the process and conduct these public Alternative Analyses (rather than abandon the market place). Some initial early successes will be vital as the Department builds internal expertise and hones administrative efficiency. To that end, we think it would be useful for DTSC to incorporate a safe harbor process whereby early adopters of the AA process seeking to solve complex product design challenges could work within the spirit of the SCP regulations but avoid the crushing bureaucratic burdens that will stifle the ability to bring a new safer innovative product to the market. Regrettably, the process of identifying safer alternatives and bringing them to market in California is likely to get caught up in legal wrangling and administrative challenges in the absence of an early effort by the DTSC to provide some safe harbor for companies looking to improve the sustainability of their products while meeting the expectations of their shareholders.

\* \* \* \* \*

ACI would like to express, once again, its appreciation in being able to comment on the revised Safer Consumer Product regulations. We offer more detailed comments on the specific text revisions in the following attachment.

If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at [pdeleo@cleaninginstitute.org](mailto:pdeleo@cleaninginstitute.org).

Sincerely,



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

Cc: The Honorable Matt Rodriguez, Secretary, CalEPA ([MRodriguez@calepa.ca.gov](mailto:MRodriguez@calepa.ca.gov))  
Miriam Ingenito, Deputy Secretary, CalEPA ([mingenito@calepa.ca.gov](mailto:mingenito@calepa.ca.gov))  
Kristin Stauffacher, Assistant Secretary, CalEPA ([kstauffacher@calepa.ca.gov](mailto:kstauffacher@calepa.ca.gov))  
Nancy McFadden, Cabinet Secretary, Office of the Governor ([Nancy.McFadden@gov.ca.gov](mailto:Nancy.McFadden@gov.ca.gov))  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor ([Mike.Rossi@gov.ca.gov](mailto:Mike.Rossi@gov.ca.gov))  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor ([Cliff.Rechtschaffen@gov.ca.gov](mailto:Cliff.Rechtschaffen@gov.ca.gov))  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor ([Martha.Gusman-Aceves@gov.ca.gov](mailto:Martha.Gusman-Aceves@gov.ca.gov))

## ATTACHMENT 1 – SPECIFIC COMMENTS

### Article 1. General

#### Section 69501 – Purpose and Applicability

- (a) Safer Consumer Product Regulations. We note the use of the word “potential” beginning in this section in reference to *potential* exposures or *potential* adverse impacts. The word *potential* has been used throughout the revised text without justification and lowers the threshold the Department might use in making decisions. DTSC should not be using speculative criteria in its decision-making. The additions of *potential* throughout the revised text should be removed.
- (c) Harmonization – we concur with the addition of the text in this section.

#### Section 69501.1 – Definitions

- (a)(2) Adverse air quality impacts – the added text “indoor or outdoor” should be deleted; it is unnecessary.
- (a)(12) Alternatives Analysis Threshold – This definition should be deleted entirely. First, Alternatives Analyses should not be required for contaminants in products. The Department should reconsider how contaminants might be handled. Second, the threshold for contaminants in products should be a risk-based safety standard; the use of the Practical Quantitation Limit is entirely arbitrary.
- (a)(26) We concur with the addition of the definitions for *contaminant*, *intentionally added ingredient*, *processing agent* and *recycled material*.
- (a)(29) Economically feasible – the notion of economic feasibility should take into consideration the analysis, development and commercialization costs in bringing a new product to market. The manufacturer should realize economic benefits for their investments in bringing a new product to market.
- (51)(A) Potential – the definition and use of the term throughout the revised text should be struck from the regulation as it is speculative and arbitrary.
- (57) Reliable information – we note improvements in this definition with the addition of subparagraphs (A) – (C) which should be retained.

### Article 2. Process for Identifying Candidate Chemicals

- We concur with the change in terminology to “Candidate Chemicals”

#### Section 69502.2 – Candidate Chemicals Identification

- (a)(1)(I) – For reasons stated above, we believe the EU CLP Category 1 Respiratory Sensitizers should not be included in the revised regulation.
- (a)(2)(D) – For reasons stated above, we believe the Clean Water Act 303(d) list for California should not be included in the revised regulation.

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

#### Section 69503.2 – Product-Chemical Identification and Prioritization Factors

- (b)(2) Other Regulatory Programs – we concur with the added text clarifying that the Department should avoid regulatory duplication.

#### Section 69503.3 – Adverse Impact and Exposure Factors

- (a)(3) – We concur with the use of information associated with structurally or mechanistically similar chemicals with a known toxicity profile to the extent that it reduces the requirements for Information Gathering specified in §69501.4.
- (b)(4)(B) – We strongly disagree with the application of the SCP regulations to product manufactured, stored or transported through California solely for use outside of California. Aside from being unnecessary and prohibited by the statute it will only further burden those manufacturers whose products are intended for sale solely outside of the state.

#### Section 69503.5 – Priority Product List

- In selecting Priority Products, the Department should use a standardized product nomenclature system. We note that the Initial Statement of Reasons (ISOR) made reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing the Priority Product Work Plan (formerly Section 69503.3(f), now Section 69503.4). We agree that the GS1 GPC is an appropriate source for describing products and that Priority Products should be identified at the Brick Level. Priority Product categories should be described at the Class Level for the purposes of the Department’s Priority Product Work Plan.
- (a)(2) – We concur with the text that specifies that the Priority Product list shall be established and updated through rulemaking pursuant to the Administrative Procedure Act.

#### Section 69503.6 – Initial Priority Products List

- (a) Scope of Candidate Chemicals – we concur with the approach of developing the initial list of Priority Products based Candidate Chemicals that meet one or more of the criteria under Section 69502.2(a)(1) and Section 69502.2(a)(2). We believe this will focus the Department’s resources on Product-Chemical combinations where there is a greater opportunity for improvement to public and environmental health.

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

#### Section 69503.6 – Alternatives Analysis: Second Stage

- (a)(1)(C)(1)(a) – the section should be modified to read “Public health and environmental costs in California”
- (a)(1)(C)(1)(b) – First, the section should be modified to read “Costs to governmental agencies in California.” Second, the regulations require the costs to “non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality and wildlife” be determined as part of the Economic Impacts analysis. The scope of this provision is overly broad and unclear. Who must “charge” such non-profit organizations with protecting natural resources? Many would say they have charged themselves with such duties and such costs could be unnecessarily included in the analysis. The provision should be clarified to only such instances where the non-profit organization is working as an agent of a government

entity based in California. In cases where the non-profit organization is a contractor to such a government agency, those costs should be captured as a governmental cost.

#### **Article 6. Regulatory Response**

- We note that previous Section 69506.10 (Regulatory Response Selection and Re-Evaluation) was deleted. Subparagraph (a) stated “The Department may impose one or more regulatory responses specified in section 69506.2 and sections 69506.4 through 69506.9 to situations other than those specified in those sections.” We concur with this deletion and the elimination of the unfettered authority the Department elected to confer on itself.

#### **Article 9. Trade Secret Protection**

##### Section 69509 – Assertion of a Claim of Trade Secret Protection

- (c)(1) – We concur with the inclusion of text recognizing that a nondisclosure agreement is a legitimate element for claiming trade secret protection and may preclude the submission of materials to the Department.
- (g)(1) – The added text intended to permit masking of chemical identity during the patent application process is misguided and should be removed. The patent process is fundamentally a public process and once a person applies for a patent the information in the application would no longer be a trade secret. Therefore, the text is not meaningful.

#### **Unresolved Issues from the Initial Proposed Regulation (July 2012)**

The American Cleaning Institute submitted comments to the initial proposed regulations in a letter dated October 11, 2012.<sup>3</sup> We find that the comments in our October 11<sup>th</sup> letter enumerated below were left largely unaddressed by DTSC and note that our concerns to these issues remain.

##### Section 69501.1 – Definitions

- Section 69501.1 – Definitions
  - (2) Adverse air quality
  - (6) Adverse public health impacts
  - (8) Adverse waste and end-of-life impacts
  - (9) Adverse water quality impacts
  - (18) Bioaccumulation
  - (33) Environmental or toxicological endpoints
  - (36) Hazard trait
  - (46) Persistence
  - (57) Reliable information
  - (58) Reliable information demonstrating the occurrence of exposures to a chemical
  - (60) Responsible entity
  - (62) Safer alternative

---

<sup>3</sup>ACI’s October 11, 2012 letter commenting on the initial proposed Safer Consumer Product regulations (July 2012) may be found at: [http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP\\_Comments\\_A\\_J.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP_Comments_A_J.pdf)

- Section 69501.2 – Duty to Comply and Consequences of Non-Compliance
- Section 69501.3 – Information Submission and Retention Requirements
- Section 69501.4 – Chemical and Product Information
- Section 69501.5 – Availability of Information on the Department’s Website
- Section 69502.2(a): Candidate Chemicals List
- Section 69502.2(b): Additions to the Candidate Chemicals List
- Section 69505.1 – Alternatives Analysis: General Provisions
- Section 69505.6(d) – Alternative Selection Decision (previously Section 69505.4(c))
- Section 69505.7(d)(3) – Responsible Entity and Supply Chain Information (previously Section 69505.5(d)(3))
- Section 69505.7(i)(2) – Supporting Information (previously Section 69505.5(i)(2))
- Section 69505.7(j) – Selected Alternative (previously Section 69505.5(j))
- Section 69505.7(j)(2)(C) – Selected Alternative (previously Section 69505.5(j)(2)(C))
- Section 69506 – Regulatory Response Selection Principles
- Section 69506.2 – AA Report Supplementary Information Requirements
- Section 69506.3 – No Regulatory Response Required
- Section 69506.5 – Product Information for Consumers
- Section 69506.5 – Use Restrictions on Chemical(s) of Concern and Consumer Products
- Section 69506.6 – Product Sales Prohibition
- Section 69506.7 – Engineered Safety Measures or Administrative Controls
- Section 69506.9 – Advancement of Green Chemistry and Green Engineering
- Section 69506.10 – Regulatory Response Selection and Reevaluation
- Section 69506.11 – Exemption from Regulatory Response Requirements
- Section 69506.12 – Regulatory Response Report and Notifications
- Section 69507.1 – Informal Dispute Resolution Procedures
- Section 69508 – Audit of Materials Submitted to the Department and Regulatory Response (formerly Section 69509)
- Section 69510 – Assertion of a Claim of Trade Secret Protection



AmericanCoatings  
ASSOCIATION

February 28, 2013

Ms. Krysia Von Burg, Regulations Coordinator  
California Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
Via Electronic Mail Only to [gcreqs@dtsc.ca.gov](mailto:gcreqs@dtsc.ca.gov)

**Re: ACA Comments on the January 27, 2013 DRAFT California Safer Consumer Products Regulations**

Dear Ms. Von Burg:

The American Coatings Association (ACA or Association) submits these comments to the California Department of Toxic Substances Control (DTSC or Department) on the latest draft of the California Safer Consumer Product Alternatives Regulations and incorporates by reference all previous comments submitted by ACA to the Department.

ACA is a voluntary, nonprofit trade association representing approximately 350 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. The manufacture, sale, and distribution of paints and coatings are a \$20 billion dollar industry in the United States. ACA's membership represents over 90% of the total domestic production of paints and coatings in the United States.

The Association has been an active participant in the rulemaking process and continues to support the advancement of green chemistry. In addition, our industry is committed to reducing adverse impacts on human health and the environment. ACA appreciates DTSC's efforts to revise the draft regulations; however, as written, the current draft fails to adequately address the industry's concerns. Accordingly, we strongly urge DTSC to carefully consider and fully respond to ACA's suggestions and comments.

ACA remains hopeful that with continued collaboration between DTSC and all interested stakeholders, the California Safer Consumer Products Regulations will protect human health and the environment while promoting innovation and the free flow of commerce. For additional information or questions, please contact Alexandra Whittaker at (202) 719-3705 or at [awhittaker@paint.org](mailto:awhittaker@paint.org).

Respectfully Submitted,

Alexandra Whittaker, Esq.  
Counsel, Government Affairs

Stephen Wieroniey  
Specialist, Health, Safety and Environmental Affairs

## **General (Section 69501(a)(A))**

ACA is pleased that DTSC has excluded “consumer products 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 . . .”

As you know, there are other applicable laws that regulate consumer products, including but not limited to the CalRecycle PaintCare regulations, the Toxic Substances Control Act, and the California Health and Safety Code. However, even absent the referenced language, any regulation that DTSC proposes must not conflict with the aforementioned laws. As written, the current draft conflicts with federal law and California State programs for the reasons stated below.

## **End-of-Life Management Requirements (Section 69506.8)**

The current draft regulations authorize DTSC to require a regulatory response requirement for a product that is an alternative, and for priority products for which an alternative is not selected, or that will remain in commerce in California pending development and distribution of a selected alternative, to protect public health and the environment and maximize the use of alternatives of least concern. ACA is very concerned about the detailed and onerous end-of-life management program that is one of many regulatory response requirements that DTSC can impose. ACA previously requested and now reiterates that PaintCare and any other end-of-life management programs be exempt from a regulatory response if the responsible entity is participating in an end-of-life management or extended producer responsibility (EPR) program that is currently required pursuant to a different California statute or regulation.

While the draft regulations offer an opportunity to apply for a regulatory response exemption, its approval is left up to DTSC’s discretion and allows DTSC to go beyond what is already in the CalRecycle PaintCare regulations pursuant to AB 1343. It places the burden on the manufacturer to apply to the Department for an exemption from a regulatory response that conflicts with one or more statutory requirements, or substantially duplicates one or more statutory requirements -- “without conferring additional public health or environmental protection benefits.” Such vague wording would grant DTSC the authority to require specific EPR components that were intentionally left out of AB 1343 by ACA, allowing a back door way for CalRecycle and DTSC to pursue regulations over and above the clear language and intent of the statute itself. In fact, the requirements that DTSC would presumably impose would change the very nature of an EPR program to one that is government run, command and control – something that the Agencies could not get passed the legislature despite several attempts. Take for example the requirement that that compensation must be provided to retailers who agree to administer or participate in the collection program. EPR is a shared responsibility with all in the life-cycle of a product taking responsibility. As the ultimate seller of products, a retailer has as much responsibility – particularly to the consumer – for product stewardship. To assert that the Agency would have control over individual contract negotiations between two private parties, let alone require certain compensation, not only goes against all principles of EPR, it runs afoul of the common law tort of contract interference.

While subsection (c) of the end-of-life management requirements authorizes the manufacturer to substitute an alternative end-of-life management program, such substitution must achieve “to the

maximum extent feasible, the same results as the program required by this section." Such substitution also can't be instituted by the manufacturer unless the manufacturer receives advanced written approval from the Department. Thus, ***even though implementation of an end-of-life management program is already occurring in California – that PaintCare program would now be in jeopardy subject to competing regulations – a very real Catch 22***. Ultimately, the "maximum extent feasible" and "written approval" requirements could saddle PaintCare with both an end-of-life management program administered by DTSC as well as by CalRecycle. Such uncertainty is unwarranted and unworkable.

Further, the Green Chemistry statute in S. 25257.1 (b) and (c) provides that DTSC is not authorized "to supersede the regulatory authority of any other department or agency" or "duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." ACA will continue to request that the regulations be amended to be consistent with the specific language of the Green Chemistry statute. Manufacturers should be clearly exempt from the end-of-life management regulatory response if the manufacturer is participating in an end-of-life management or product responsibility program mandated by statute in this state, and should not have the burden to request an exemption in such cases. In addition, the regulations should delete the ability of DTSC to impose an end-of-life management program even if it provides additional public health or environmental protections. Without such changes, the regulations clearly exceed the Department's authority and fail to recognize S. 25257.1's clear mandate that DTSC cannot supersede another agency's regulatory program.

DTSC seems to recognize this in S. 69501 (A)(1), where the Department has the authority to exempt products that are already regulated by federal or California law when they address the "same potential adverse impacts, potential exposure pathways, and potential adverse waste and end-of-life effects." ACA believes that an already established program should fall within this exemption and should be automatic – not left to the discretion of the Department. The following language would work for PaintCare specifically or could be used to grandfather in any program already operating under California law.

***Suggested Exemption language for PaintCare® and similar programs required by statute***

The draft regulations require manufacturers of selected consumer products to "fund, establish, and maintain an end-of-life management program for the product." In 2010, legislation was passed in California establishing such a program for the paint industry. The program is called PaintCare®. Since PaintCare® is already established by statute; there is no reason for DTSC to subject the coatings industry to additional regulatory requirements in this area. ACA respectfully requests that DTSC include the following language in the regulations that specifically exempts PaintCare® and any other end-of-life management programs that are established by statute.

**Amend S. 69506.8. (a):**

(a) Except as provided in sections 69506.4 and 69506.8 (e), a responsible entity for a selected alternative, or 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 ensure that both of the following requirements are met:

**Add a new S. 69506.8 (e):**

(e) A responsible entity otherwise subject to the requirements of this section shall be exempt from an end-of-life management regulatory response if the responsible entity is participating in an end-of-life management or extended producer responsibility program that is currently required pursuant to a different California statute or regulation.

**Reliable Information (Section 69501.1 (a) (58))**

ACA is encouraged by the criteria for reliable information; the criterion places the emphasis on real data, rather than models. Basing the definition on actual measurable data, particularly data that demonstrates repeated findings shows a focus on sound science, particularly with respect to considering the inclusion or exclusion of such data in decision-making under the regulation.

**Chemical and Product Information (Section 69501.4 (a)(2))**

The addition of this section allows DTSC to gather information on ANY product in commerce in California, specifically any "...manufacture, importer, assembler and retailer of any product or chemical, not just those products or chemicals subject to the requirements of this chapter." ACA is concerned this usurpation of authority by DTSC will result in a "fishing exercise" for information rather than a commitment to focus on true Chemicals of Concern in Priority Products. This one line in the draft, which greatly expands the scope of the regulation, by collecting information on all products, is an extreme overreach by the agency and will interrupt business.

**Acknowledging Reformulation Efforts in Advance (Section 69501.4 (d))**

In previous sets of comments, ACA suggested that DTSC create a mechanism to acknowledge, without reporting, advanced reformulation. ACA originally was pleased to see in subsequent drafts, the creation of the "Safer Consumer Products Recognition List," but previously commented that it did not go far enough. While the current draft has a number of opportunities for product manufacturers to notify DTSC of product changes to achieve compliance without the need of a formal "Alternatives Assessment," ACA encourages DTSC to promote *voluntary action* instead of the more formal approach as in the "Removal or Replacement Notification" under section 69501.2.

**Candidate Chemicals Identification (Section 69502.2)**

With the inclusion of chemicals listed under Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Section 69502.2 (A)); endocrine disruptors from REACH's Substances of Very High Concern list (Section 69502.2 (C)); persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative from REACH's Substances of Very High Concern list (Section 69502.2 (G)) and chemicals classified as respiratory sensitizers Category 1 in Annex VI to EU Regulation 1272/2008 (Section 69502.2 (I)), the applicable "Candidate Chemicals" list has continued to inappropriately expand.

It has been ACA's longstanding position that this list should be no greater than 300 candidate chemicals established according to a science-based prioritization scheme (i.e. EPA prioritization principles). We

still advocate that, given DTSC's own stated intent to focus its regulatory efforts to a finite number of "Chemicals of Concern" and "Products of Concern" having a large "Candidate Chemicals" list (i.e. more than 300 chemicals) the expanded list is unwarranted and fails to align with any science-based prioritization scheme.

### **Adverse Impact and Exposure Factors (Section 69503.3)**

The use of the new terms "[t]he occurrence, or potential occurrence" of exposure is confusing and inconsistent with common practice for exposure assessments. "Occurrence" would seem to imply that any detectable exposure, using the most aggressive sampling and analytical methods (see comments on PQL, below), might be sufficient to bring a product under scrutiny for regulation. This stands in contrast to the language in the draft that acknowledges "contaminants" and "not intentionally added" chemicals are not covered by the rule, and that "de minimis" levels will be established on a case-by-case basis. As a result, the terms "occurrence, and potential occurrence" should be changed to reference "the exposure to, or potential exposure to."

### **Initial Priority Products List (69503.6)**

ACA is pleased that the current draft reflects DTSC's intent to include only five products on the initial Priority Products list.

### **Priority Product Notifications (Section 69503.7)**

DTSC failed to address and respond to ACA's previous comments on Priority Product notification. It remains ACA's position that DTSC should extend the notification deadline for formulated products, such as paint, to 180 days. Given the complex supply chain within the formulated products industry, an extended notification deadline is needed in order to ensure that the sources of "chemicals of concerns" are investigated.

### **Alternatives Analysis: General Provisions (Section 69505.1)**

In our previous comments, ACA requested that for formulated products, like paint, the deadline for the preliminary Alternatives Analysis Report be extended to 12 months and the deadline for the final Alternatives Analysis Report be extended to 18 months. ACA still believes these extensions are necessary to address the overly broad requirements detailed in the draft.

### **Alternative Analysis Threshold Notification in Lieu of Alternatives Analysis (Section 69505.3)**

As stated in previous submissions, ACA prefers to see a defined threshold for reporting, based on a clear "de minimis" value rather than the proposed "Practical Quantitation Level" or an "alternative analysis threshold." Again, defining this threshold as "de minimis" more clearly acknowledges that the risk is not actionable.

The addition of Practical Quantitation Limit (PQL) is extremely problematic for industry. PQL will allow DTSC to require an alternatives analysis due to the ability to measure a minimal amount of a

contaminant in a PQL analysis. Based on the definition of contaminant in section 69501, DTSC is acknowledging that these chemicals are present due to manufacturing processes and cannot be removed due to their natural occurrence. Forcing the responsible entity to perform an alternatives analysis on a contaminant is a gross exaggeration of the original purpose of the California Green Chemistry Statute.

### **Product Information for Consumers (Section 69506.3)**

The large “Candidate Chemicals” list means that most products regulated under this section will require extensive labeling. It is unclear whether DTSC has considered how that requirement will interfere with existing labeling regulations that already strain limited label space, especially for smaller-sized products. DTSC’s suggested alternatives (an accessible manual or point-of-sale posting) are inflexible given the sheer variety of products that may be subject to alternatives assessments over the years.

If an alternative is not selected, DTSC should require identification only of the Chemical of Concern (COC) that caused the Priority Product listing in the first place. If an alternative is selected, but not yet formulated into the product, and that product contains other listed Candidate Chemicals or COCs, then only the COC that serves the same function as the pending alternative COC should be required to be identified. If not, the manufacturer will be placed at an unfair disadvantage relative to competitive products that did not contain the COC that caused the Priority Product listing, but may contain other Candidate Chemicals or COCs.

### **Alternatives Analysis (Sections 69505.5, 69505.6, 69505.7 and 69505.8)**

The new language in the draft describing the “Alternatives Assessment” process and resultant reports is extremely cumbersome and unclear. By mixing and repeating terms that have many of the same modifiers, stakeholders will have difficulty in discerning which, if any aspects may apply to their products. Embedded in this consuming language is a simple concept, product reformulation to curtail use of a “Chemical of Concern.” The detailed requirements appear to be offered only to remind the manufacturer to select a replacement chemical that is (also) not a Chemical of Concern.

### **Regulation on Alternatives (Sections 69506.3, 69506.4, 69506.5 69506.6 and 69506.7)**

DTSC states in section 69506.3 that labeling requirements can be placed on selected alternatives that retain either Candidate Chemicals or Chemicals of Concern. In section 69506.4 and 69506.5, DTSC states that restrictions or prohibition requirements can be placed on selected alternatives that retain either Candidate Chemicals or Chemicals of Concern. Further, DTSC states in section 69506.6 that engineering controls can be placed on selected alternatives that retain either Candidate Chemicals or Chemicals of Concern. Finally in section 69506.7, DTSC states that end-of-life management requirements can be placed on a selected alternative, regardless if it retains a Candidate Chemical or chemical of concern.

Once a “safer alternative” has been selected, the product should be able to remain in the consumer market without restriction. Requiring products using safer alternatives to label, endure use restrictions, enact engineering requirements, and/or participate in end-of-life management is effectively regulating alternatives. DTSC’s priority should be focused on Chemicals of Concern in Priority Products and not

safer alternatives. Once a safer alternative is selected, the product should then be allowed to exit the regulatory process quickly and efficiently.

As the Candidate Chemical List is a dynamic list, it will be increasingly harder for the responsible entity to pick an unlisted safer alternative. If, while finalizing an Alternatives Assessment, DTSC decides to list your selected safer alternative as a Candidate Chemical, you could be subject to regulation based on your selection. This places a nearly impossible burden on the responsible entity, as the functionally acceptable, technically feasible, and economically reasonable alternative could change based on an update to the Candidate Chemical List. Moreover, this makes any chemical, ever listed as a Candidate Chemical a possible target for regulation.

DTSC states that to trigger an alternatives analysis the Candidate Chemical must be a Chemical of Concern linked with a Priority Product, rather than merely being listed as Candidate Chemical. Again, DTSC's priority should be focused on Chemicals of Concern in Priority Products, not safer alternatives. The Department should allow and encourage reformulation, as ACA has suggested several times before.

#### **Removal of Certified Alternatives Assessor Requirements**

ACA is pleased that DTSC removed the requirement to use a "Certified Alternatives Assessor" for the Alternatives Analysis. Removal of this requirement, while not eliminating the need for completing the assessment, allows for companies to use their own science and health professionals.

#### **Department Review of Claims of Trade Secret Protection (Section 69510.1)**

ACA previously noted that the current draft of the regulations fails to fulfill the policy set forth in the California Civil Code with respect to Confidential Business Information (CBI), and does not provide CBI for manufacturers. ACA suggested that the regulations focus on the interrelationship with preexisting California law on trade secrets. While there is the ability to assert a claim of trade secret protection with respect to documents or information submitted to the department, there are many documents and questions that will be requested by DTSC. The approval of CBI claims would be conditional based on DTSC's review. This overriding theme of manufacturers being subject to the whims of DTSC continues to be problematic. More than any other section, the CBI section must be clarified in order to adhere to the spirit and letter of the California Civil Code on trade secret protection.

This trade secret section of the regulations should focus on the interrelationship between the new Safer Consumer Products Regulations and the preexisting California laws on trade secrets. According to the California Civil Code Section 3426.1(d) "a trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process that: (1) derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

These two inquiries must be answered first in order to determine whether information claimed to be trade secret should be released by DTSC under the California Health and Safety Code Section 25257(d). Another related inquiry is whether the information is readily ascertained by reverse engineering or other

methods. If information can be readily determined through legitimate analysis or examination of a product, such information is probably not a trade secret.

As a result, ACA strongly encourages DTSC to avoid a conflict with California law and approach trade secrets by answering the above-mentioned questions. Much of the current draft regulation in Section 69510.1 is not needed to demonstrate that submitted information meets the definition of a trade secret under California law, and those items should not be required of the person or organization claiming the trade secret rights.

Finally, DTSC's requirement that one can only claim as trade secret a replacement chemical that is the subject of a patent application improperly conflates two distinct forms of intellectual property protection. There is no requirement under any current statutory or common law that requires the holder of a trade secret to seek patent protection in order to be able to maintain its property interest in the trade secret. In fact, it is a foundational principle of intellectual property law that an entity making a discovery or invention may freely choose whether to seek the potentially unlimited temporal protection of a trade secret, or alternatively, to file a patent application and thereby waive trade secret protection for the possibility of obtaining a 20 year limited exclusive right upon issuance of a patent. DTSC's proposal errs in assuming that it has a proper legal basis to require entities to either waive their property rights with respect to their existing trade secrets, or to force those entities to take on the considerable expense of preparing, filing, prosecuting and maintaining patent protection over all of their inventions and discoveries. The waiver requirement would likely be successfully challenged in court as an unconstitutional "taking" of property. Further, the "patent-filing" requirement would likely be successfully challenged in court as an unconstitutional "forced expenditure" inconsistent with the Constitutional intent underlying Patent Act, 35 U.S.C. Section 101 et seq. Ultimately, DTSC's proposed disclosure requirements would likely have the unintended consequence of placing American, and more particularly California companies, in the untenable position of having to disclose their most economically valuable trade secret product formulations in a manner which ultimately would place those trade secrets in the hands of foreign competitors.



February 28, 2013

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

Re: Recycled Products in the Safer Consumer Products Regulation

Dear Ms. Von Burg:

On behalf of the American Forest & Paper Association (AF&PA), I am writing to convey our concerns with the January 2013 draft of the Safer Consumer Products (SCP) regulation and the potential threat this regulation presents to our investment in recycling infrastructure. Below we have provided suggestions as to how the Department of Toxic Substances Control (DTSC) can provide assurance to the paper-based recycled products industry so the SCP will not lead to unnecessary costs and burdens.

AF&PA serves to advance a sustainable U.S. pulp, paper and packaging manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative - *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately 4.5 percent of the total U.S. manufacturing GDP, manufactures approximately \$190 billion in products annually, and employs nearly 900,000 men and women. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 47 states. In California, the industry employs over 22,000 individuals at over 480 manufacturing facilities, with an annual payroll of over \$1.6 billion. The industry pays an estimated \$480 million in state and local taxes that support vital public services.

Paper recycling is one of the nation's great environmental success stories and AF&PA is a leader in promoting paper recovery and recycling. More than 60 percent of paper consumed in the U.S. has been recovered for recycling in each year since 2009. The rate of paper recovery for recycling in the U.S. has nearly doubled since 1990. Paper recycling reuses a renewable resource that sequesters carbon and helps reduce greenhouse gas emissions. In addition, in 2011 the amount of paper that was recovered for recycling saved 174 million cubic yards of landfill space.

In keeping with the pulp, paper, packaging and wood products industry's legacy as a leader in sustainability, in 2011 AF&PA started the initiative *Better Practices, Better Planet 2020: Continuing AF&PA's Commitment to Sustainability*. As part of this



DTSC

February 28, 2013

Page 2

initiative, industry has set a goal to further increase paper recovery for recycling to exceed 70 percent by 2020 and will be working with communities, businesses, and schools to reach this goal. AF&PA wants to help California achieve its ambitious new 75 percent recovery goal by 2020. We also want to make sure nothing in the SCP impacts the ability of states and localities across the U.S. and internationally to meet their goals.

According to the regulation, a manufacturer is subject to the regulation if their product is listed as a priority product and the product has one of the Chemicals of Concern (COC) linked with the priority product. The product is subject to the regulation if it has an intentionally added COC or if there is a COC that is a contaminant above the designated threshold.

We do not anticipate any paper-based recycled product being listed as a priority product. Even if there is a priority product listed that includes paper-based recycled products, we do not anticipate having any of the specified COC present in the product. However, to provide needed certainty to the paper-based recycled products industry, AF&PA requests DTSC add language to the *Statement of Reasons (SOR)* Section 69501.1(a)(50) specifying that recycled paper, recycled paperboard and recycled paper-based products are not intended to be identified as priority products under the SOR Section 69501(a)(48) and are otherwise not intended to be subject to the requirements of the regulation. This language should appear again in the last line of Section 69503.5(c)(1)(C) in the SOR.

AF&PA is concerned that without the added clarification that paper-based recycled materials are not intended to be the subject to this regulation, the regulation could impose a disproportionate burden on those who use recycled feedstock. Because of all of these unintended consequences that could impact the industry, the above language could provide much needed business certainty to the paper-based recycled products industry. California should provide the industry with long-term business certainty to support businesses that use recycled content, the same businesses that can support California achieve its 75 percent recovery goal.

We plan to also submit comprehensive comments on the January 2013 SCP regulation by the February 28 deadline, but wanted to communicate with you the recommendation that could provide comfort to our recycling community.

If you have any questions please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202. We look forward to discussing how you can make the SCP more viable by helping California foster its recycling goals.

Sincerely,



Paul Noe

Vice President of Public Policy



## American Forest & Paper Association

February 28, 2013

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

### **Re: Comments on the Safer Consumer Products Proposed Regulation**

Dear Ms. Von Burg:

On behalf of the American Forest & Paper Association (AF&PA), we respectfully submit the following comments to the Department of Toxic Substances Control (DTSC) regarding the proposed Safer Consumer Products (SCP) draft regulations issued January 2013.

AF&PA serves to advance a sustainable U.S. pulp, paper and packaging manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative - *Better Practices, Better Planet 2020*. The forest products industry accounts for approximately 4.5 percent of the total U.S. manufacturing GDP, manufactures approximately \$190 billion in products annually, and employs nearly 900,000 men and women. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 47 states. In California, the industry employs over 22,000 individuals at over 480 manufacturing facilities, with an annual payroll of over \$1.6 billion. The industry pays an estimated \$480 million in state and local taxes that support vital public services.

AF&PA has worked with the Green Chemistry Alliance (GCA) in the last few years to provide the DTSC with data and expertise to assist in developing regulations that will lead to safer consumer products and avoid unnecessary obstacles and burdens to businesses. We believe DTSC has made some positive revisions to the proposed regulation. However, we believe more changes are needed for this to be a viable program for our industry.

### **Appropriate Analysis on Environmental and Economic Impacts**

AF&PA requests that DTSC complete a proper California Environmental Quality Act (CEQA) review before this regulation moves forward. CEQA requires the state to follow a protocol of analysis and public disclosure of environmental impacts of proposed projects and adopt all feasible measures to mitigate those impacts.<sup>1</sup> In March 2008, DTSC issued a CEQA Notice of Exemption from CEQA review for the SCP (DTSC 1332 (03/04/08)) stating

---

<sup>1</sup> Public Resources Code Section 21080, 14 Cal. Code Regs Section 15357.

DTSC  
February 28, 2013

that there is “no possibility of a significant effect on the environment” but that additional CEQA evaluation will be considered during implementation of the regulatory program. As we explain in more detail below, we believe the SCP could have a significant environmental impact, as it would create a disincentive for manufacturers to use recycled feedstock and could deter efforts to increase paper recovery in California and nationwide. DTSC’s suggested future environmental review does not excuse DTSC’s requirement to adequately analyze the reasonably foreseeable significant environmental effects of the proposed regulation.

In addition, the DTSC’s Economic and Fiscal Impact Statement and Economic Analysis on the SCP is inadequate and lacking any substantive information about the real costs of the proposed regulations to California, consumers, or the regulated community. DTSC states that the economic and fiscal impact of the regulation is unknown and will be quantifiable only after the regulation is implemented and operating. The open-ended and undefined requirements that DTSC has included in the proposed regulations are unacceptable. It also is unacceptable for DTSC to finalize these regulations without knowing and understanding the actual cost of the regulations and the effect on businesses and jobs in California. We strongly recommend that the regulation be tailored to ensure that responsible party compliance with this program does not lead to excessively burdensome economic effects that could unintentionally result in perverse incentives for jobs to leave the state and for citizens to be deprived of safe and beneficial products that are legally marketed throughout the rest of the US. Furthermore, as discussed below, we believe California does not have authority to set the “rules of the game” governing the interstate and international market. Please see AF&PA’s previous comments on the SCP submitted to DTSC on October 11, 2012, which we incorporate here by reference.

### **Scope of the Program**

It ultimately is DTSC’s responsibility to strike the proper balance between the scope of the program and the resources available to achieve success. A program that takes on more than it can achieve is unsustainable and will do little to advance public health and environmental protection.

We are pleased that the Department is still focusing the program initially by limiting the regulation to five Priority Products. We believe this is a more practical approach and will better enable the Department to steer the program, learn what works best, and make adjustments accordingly. We also appreciate that “Candidate Chemicals” will only become Chemicals of Concern (COC) when they are listed with a corresponding product-chemical combination as a Priority Product. We feel this is a more practical approach for the Department and industry to manage.

AF&PA supports that the January 2013 proposal differentiates between a contaminant and an intentionally-added chemical. We believe it is fully appropriate to treat chemicals unintentionally added to a product differently than intentionally- added chemicals.

### **Recycled Paper Products**

Paper recycling is one of the nation's great environmental success stories, and AF&PA is a leader in promoting paper recovery and recycling. More than 60 percent of paper consumed in the U.S. has been recovered for recycling in each year since 2009. The rate of paper recovery for recycling in the U.S. has nearly doubled since 1990. Paper recycling reuses a renewable resource that sequesters carbon and helps reduce greenhouse gas emissions. Moreover, recycling saves landfill space; and 174 million cubic yards of landfill space was saved by paper recovery in 2011.

In keeping with the forest products industry's legacy as a leader in sustainability, in 2011 AF&PA started the initiative *Better Practices, Better Planet 2020: Continuing AF&PA's Commitment to Sustainability*. As part of this initiative, industry has set a goal to further increase paper recovery for recycling to exceed 70 percent by 2020 and will be working with communities, businesses, and schools to reach this goal. AF&PA wants to help California achieve its own ambitious new 75 percent recovery goal by 2020. The Newark Group and Graphic Packaging International are two AF&PA member companies with recycled mills in California that would help California achieve this recovery goal. We want to make sure nothing in the SCP impacts the ability of states and localities across the U.S. and internationally to meet their goals.

According to the regulation, a manufacturer is subject to the regulation if their product is listed as a priority product and the product has one of the COC linked with the priority product. The product is subject to the regulation if it has an intentionally added COC or if there is a COC that is a contaminant above the designated threshold.

We do not anticipate any paper-based recycled product being listed as a priority product. Even if there is a priority product listed that includes paper-based recycled products, we do not anticipate having any of the specified COC present in the product. However, to provide needed certainty to the paper-based recycled products industry, AF&PA requests DTSC add language to the *Statement of Reasons (SOR)* Section 69501.1(a)(50) specifying that recycled paper, recycled paperboard and recycled paper-based products are not intended to be identified as priority products under the SOR Section 69501(a)(48) and are otherwise not intended to be subject to the requirements of the regulation. This language should appear again in the last line of Section 69503.5(c)(1)(C) in the SOR.

AF&PA is concerned that without the added clarification that paper-based recycled materials are not intended to be the subject to this regulation, the regulation could impose a disproportionate burden on those who use recycled feedstock. Because of all of these unintended consequences that could impact the industry, the above language could provide much needed business certainty to the paper-based recycled products industry. California should provide the industry with long-term business certainty to support businesses that use recycled content, the same businesses that can support California achieve its 75 percent recovery goal.

**Regulatory Duplication – Exemption for Food Contact Materials**

The SOR Section 69506.11,<sup>2</sup> “Exemption from Regulatory Response Requirements,” specifies the conditions and process under which a responsible entity may obtain an exemption from the requirements of a given regulatory response on the basis of regulatory duplication. The section states:

“This section provides a process for a responsible entity to request an exemption from otherwise applicable regulatory responses. The basis for the request must be that the regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement if the responsible entity could not reasonably be expected to comply with both requirements. The required regulatory response must substantially duplicate a requirement and not substantially provide additional human health or environmental protection in order to justify an exemption. DTSC may require implementation of a modified regulatory response to resolve the conflict. This provision is necessary to effectuate the non- conflict/non-duplication prohibition in the authorizing statute and to have a workable program.”

AF&PA requests a clear exemption from SCP for food contact materials (FCMs) per the SOR’s section 69506.11. The statute which the SCP implements is firm on the issue of regulatory duplication, stating that the Department should not supersede the authority of other agencies and that the Department shall not duplicate or adopt conflicting regulations for products already regulated.<sup>3</sup> It appears that this proposal goes beyond the statute to assert the Department can regulate a product if it believes it would provide a higher level of public health and environmental protection by regulating the product under the SCP. If the potential health or environmental impact from the chemical in the product is regulated by another agency, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

FCMs already are fully regulated by a comprehensive federal regulatory schedule that ensures the safety of these materials for the public health and the environment throughout the full life cycle of the materials. According to DTSC’s Initial Statement of Reasons, the GCI intends to address what it believes is a “structural weakness” in the federal Toxic Substances Control Act (TSCA). However, the safe use of FCMs is not regulated by TSCA, but rather the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA). The FDCA provides for a robust regulatory structure to protect the safety of the public health and environment. The FDA employs more than 30 chemists, toxicologists, and other scientific staff, for the sole purpose of evaluating the safety and environmental impact of chemicals in FCMs. With all of the decades of experience that the FDA has, it would be

---

<sup>2</sup> Page 190 of the ISOR

<sup>3</sup> California’s 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.”

wasteful, from both a policy and resource perspective, for DTSC to attempt to duplicate this system.

An additional layer of state regulation will inhibit technological innovation and the development of safer and more environmentally friendly food packaging materials, and, ultimately could even force safe packaging materials out of the California market. California should focus the SCP regulation on products not already subject to regulation. Since FDA regulatory system is already in place, the regulation would do nothing to further protect the public.

One of the reports that helped shape the underlying policies to GCI was *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*.<sup>4</sup> The report identified three information gaps in federal chemical policy: (1) a data gap, based on a lack of information on which chemicals are safe and what products contain them; (2) a safety gap, based on the rationale that government agencies do not have the legal tools or information to prioritize chemical hazards; and (3) a technology gap, which supposedly results in a lack of emphasis in industry on green chemistry principles. These gaps were connected to gaps in health and environmental damage occurring in California. The simple fact is that these weaknesses and information gaps do not apply to FCMs. Regulations by FDA require food contact materials manufacturers to ensure the safety of their products for the public health and environment *before* placing the product on the market. This premarket evaluation ensures that the gaps—data, safety, and technology—identified in the *Green Chemistry* report are not applicable to FCMs.

Rigorous premarket evaluation ensures that substantial amounts of data are available on FCMs and their potential exposure to the public and the environment. Modern food packaging is carefully designed to preserve the quality and safety of the food and extend the shelf life of products, preventing food waste. Other consumer products covered by the GCI are inherently designed to contact the consumer or the environment, resulting in direct exposures that are substantially higher exposures than to any food contact substance. The FDA is fully aware of the potential uses of FCMs and, if the Agency became aware that a particular use of a chemical was unsafe, could take regulatory action to remove the substance from the market.

A technology gap does not exist for FCMs because the industry is highly active in producing green, sustainable materials. The recycling of FCMs has long been of interest for materials such as paper. FDA reviews recycling processes and products are constantly being developed that are biodegradable, compostable, or are manufactured using renewable and sustainable raw materials. Of course an existing regulatory framework ensures these new materials are safe for their use. The SCP would subject innovative and beneficial FCMs to multiple regulatory schemes, delaying the arrival of such materials to the market and possibly precluding their manufacture altogether because of the increase in regulatory costs.

---

<sup>4</sup> Wilson M.P., Chia D.A., Ehlers B.C., "Green chemistry in California: a framework for leadership in chemicals policy and innovation," 2006, available at <http://coeh.berkeley.edu/FINALgreenchemistryrpt.pdf>.

We believe if DTSC attempts to duplicate FDA's regulatory framework it could result in product deselection rather than extensive analysis of chemical alternatives and is unlikely to help consumers understand the complex scientific analysis that goes into a safety evaluation for a food contact material. FCMs are designed specifically to ensure the safety of food for the entire shelf-life of a product, and reformulation could impact the efficacy of a product, potentially resulting in an increase of foodborne illness. Yet the level of a COC in an individual food packaging product may be extremely small, without any possibility for the substance to have consumer/environmental exposure. Thus, many FCMs, the safety of which has already been established under the existing FDA framework, could be forced out of the California market due solely to the presence of one Chemical of Concern.

In summary, FDA has in place a comprehensive regulatory system for FCMs that establishes a large margin of safety. The SCP would duplicate this system, yet FDA's regulatory scheme is consistent with the purposes of SCP. Thus, the inclusion of these products in the SCP would contravene the limitations proscribed by Section 25257.1(c) of the Health and Safety Code and would not promote the safety or environmental goals of the GCI.

### **Interstate Commerce**

AF&PA objects to the proposed regulation because it would impose significant burdens on businesses that import their products into California. We believe these burdens vastly outweigh any alleged benefit of the regulation. The regulation imposes burdens on the import of goods into California by requiring a detailed analysis of the contents of the products as well as the manner in which these products were produced and transported to California. DTSC acknowledges that “[r]esponsible entities will bear real costs as a result of these regulations,” but that “[s]ince most product manufacturing takes place outside California,” the expected “California employment impacts [would] be minimal.”<sup>5</sup> DTSC has adopted the view that “California firms have an edge in gaining . . . market share” for developing “greener alternatives” under the regulation.<sup>6</sup> According to DTSC, the regulations establish “new ‘rules of the game’” governing the import of products in California. Under these “new rules,” “California’s firms are likely to [be] among the most nimble in responding and thriving in the new regulatory environment.”<sup>7</sup> California does not have authority to set the “rules of the game” governing the interstate and international market for consumer goods sold in California in a manner designed to benefit California economic interests.

The regulations should not be adopted because they impose substantial barriers to the California market. These regulations allow DTSC to take over the decisions of California consumers and authorize DTSC to decide whether or not products – including safe products – can be marketed in California including, for example, the way in which they are manufactured outside California. See *Economic Analysis*, page 9 (acknowledging that some products “are likely to be banned”). The regulations authorize DTSC to deny California

---

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

<sup>6</sup> *Id.*, p 5.

<sup>7</sup> *Id.*, p 9.

DTSC  
February 28, 2013

residents the opportunity to decide whether to purchase a product based on DTSC's assessment of the manner in which the product was produced or whether another means of production would render a competing product economically feasible. These regulations impose significant costs on manufacturers that must bear the burden of testing their products, conducting alternative analyses, and then complying with the regulatory response dictated by DTSC. These barriers are especially harmful to small businesses that lack the resources to comply with these burdensome regulations.

In contrast, there are limited, if any, benefits from the regulations. Chemical ingredients in consumer products already are subject to regulation at the national level by TSCA administered by US EPA and the Federal Hazardous Substances Act as well as other statutes administered by the Consumer Product Safety Commission. In addition to these uniform federal regulations, manufacturers already have strong incentives to ensure that their products are safe and effective both by market mechanisms through which consumers, presented with a choice, will purchase products with safer ingredients as well as remedies to consumers injured by products that are actually unsafe. The proposed regulation seeks to replace these existing protections and informed consumer choice with local government mandates. Indeed, DTSC has not demonstrated that the burdens imposed by the regulations justify the substantial costs and burdens that DTSC acknowledges that would be imposed on importers of products into the California market.

We respectfully ask you to re-examine this process before these regulations move further toward completion to ensure that California's green chemistry regulations will enhance safety, rather than add needless costs and obstacles to manufacturers doing business in California.

We appreciate the opportunity to comment on the proposed SCP regulation. If you have any questions regarding AF&PA's position on the proposal, please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202. Thank you for your consideration.

Sincerely,



Paul Noe  
Vice President, Public Policy  
American Forest & Paper Association

*Attachment*

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



**American  
Forest & Paper  
Association**

February 19, 2013

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

Re: Potential Impacts on Recycling in the Safer Consumer Products Regulation

Dear Ms. Von Burg:

On behalf of the American Forest & Paper Association (AF&PA), I am writing to convey our concerns with the January 2013 draft of the Safer Consumer Products (SCP) regulation and the threat this regulation presents to our investment in recycling infrastructure.

AF&PA serves to advance a sustainable U.S. pulp, paper and packaging manufacturing industry through fact-based public policy and marketplace advocacy. AF&PA member companies make products essential for everyday life from renewable and recyclable resources and are committed to continuous improvement through the industry's sustainability initiative - Better Practices, Better Planet 2020. The forest products industry accounts for approximately 4.5 percent of the total U.S. manufacturing GDP, manufactures approximately \$190 billion in products annually, and employs nearly 900,000 men and women. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 47 states. In California, the industry employs over 22,000 individuals at over 480 manufacturing facilities, with an annual payroll of over \$1.6 billion. The industry pays an estimated \$480 million in state and local taxes that support vital public services.

Paper recycling is one of the nation's great environmental success stories and AF&PA is a leader in promoting paper recovery and recycling. More than 60 percent of paper consumed in the U.S. has been recovered for recycling in each year since 2009. The rate of paper recovery for recycling in the U.S. has nearly doubled since 1990. Paper recycling reuses a renewable resource that sequesters carbon and helps reduce greenhouse gas emissions. In addition, in 2011 the amount of paper that was recovered for recycling saved 174 million cubic yards of landfill space.

In keeping with the forest products industry's legacy as a leader in sustainability, in 2011 AF&PA started the initiative *Better Practices, Better Planet 2020: Continuing AF&PA's Commitment to Sustainability*. As part of this initiative, industry has set a goal

1111 Nineteenth Street, NW, Suite 800 • Washington, DC 20036 • 202 463-2700 Fax: 202 463-2785 • [www.afandpa.org](http://www.afandpa.org)



**BETTER PRACTICES  
BETTER PLANET**  
Continuing AF&PA's Commitment to Sustainability

DTSC

February 19, 2013

Page 2

to further increase paper recovery for recycling to exceed 70 percent by 2020 and will be working with communities, businesses, and schools to reach this goal. AF&PA wants to help California achieve its ambitious new 75 percent recovery goal by 2020, but believe provisions in the SCP could hurt California's ability to achieve this goal. Since California's SCP will impact companies across the U.S. and internationally, we believe the SCP could impact the ability of states and localities across the U.S. to meet their recovery goals.

We appreciate that you and your staff have tried to make these regulations workable for businesses. Despite this work, the January 29, 2013 version of the SCP still disadvantage those who design, manufacture and sell recycled content products in California. The January 29 proposal provides for an alternatives analysis threshold exemption for a manufacturer of a Priority Product if the Chemicals of Concern (COCs) are present in the product solely as contaminants, and the concentration of the COCs does not exceed the established threshold. This provision would require manufacturers using recycled feedstock to test their Priority Products for designated COCs to determine if the COCs are present as a contaminant (above the threshold), even if the manufacturer did not add any of the COCs. If the COCs are present above the threshold, the manufacturer would be subject to all requirements of the regulation, including submitting an alternative analysis report.

[1.]

AF&PA requests an exemption for paper products made with recycled feedstock. AF&PA is concerned this regulation will impose a disproportionate burden on those who use recycled feedstock, as it will lead to high costs for testing to detect even the smallest trace of a chemical. An exemption would prevent a host of unintended consequences including unnecessary costs and burdens that will discourage manufacturing of products that use recycled feedstock. Added costs to manufacturing of recycled content products created by this regulation could hinder California's ability to achieve its ambitious new 75 percent recovery goal by 2020.

[2.]

We plan to submit comprehensive comments on the January 2013 SCP regulation by the February 28 deadline, but wanted to bring the problems this proposal would create for manufacturers using recycled feedstock to your attention immediately.

If you have any questions please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202. We look forward to discussing how you can make the SCP more viable by helping California foster its recycling goals.

Sincerely,



Paul Noe  
Vice President of Public Policy



February 28, 2013

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

**Re: Comments on the Safer Consumer Products Proposed Regulation**

Dear Ms. Von Burg:

On behalf of the American Wood Council (AWC), we respectfully submit the following comments on the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Products (SCP) regulations issued January 2013.

AWC is the voice of North American traditional and engineered wood products, representing over 60 percent of the industry. From a renewable resource that absorbs and sequesters carbon, the wood products industry makes products that are essential to everyday life and employs about one-third of a million men and women in well-paying jobs. AWC's engineers, technologists, scientists, and building code experts develop state-of-the-art engineering data, technology, and standards on structural wood products for use by design professionals, building officials, and wood products manufacturers to assure the safe and efficient design and use of wood structural components. AWC also provides technical, legal, and economic information on wood design, green building, and manufacturing environmental regulations advocating for balanced government policies that sustain the wood products industry. In California, the wood products industry employs over 26,000 individuals at 66 manufacturing facilities, meeting an annual payroll of nearly \$1.2 billion.

**Economic Impact Analysis**

DTSC's Economic and Fiscal Impact Statement and Economic Analysis on the SCP is inadequate and lacking any substantive information about the real costs of the proposed regulations to California, consumers, or the regulated community. DTSC states that the economic and fiscal impact of the regulation is unknown and will be quantifiable only after the regulation is implemented and operating. The open-ended and undefined requirements that DTSC has included in the proposed regulations are unacceptable. It also is unacceptable for DTSC to finalize these regulations without knowing and understanding the actual cost of the regulations and the effect on businesses and jobs in California. We strongly recommend that the regulation be tailored to ensure that responsible party compliance with this program does not lead to excessively burdensome economic effects that could unintentionally result in perverse incentives for jobs to leave the state and for citizens to be deprived of safe and beneficial products that are legally marketed throughout the rest of the US. Please see AWC's previous comments on the SCP submitted to DTSC on October 11, 2012.

### **Scope of the Program**

We are pleased that the Department has chosen to focus the program initially by limiting the regulation to five Priority Products. We believe this is a practical approach that will enable the Department to steer this program and to learn what works best and make adjustments accordingly. However, the regulatory scheme DTSC has proposed is still in excess of what the initial phase should be, and far in excess of that which its own resources can support. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft. It is ultimately DTSC's responsibility to strike the proper balance between the scope of the program and the resources available in order to achieve success. A program that takes on more than it can achieve is unsustainable and will produce little to advance public health and environmental protection.

We appreciate that "Candidate Chemicals" will only become chemicals of concern when they are listed with a corresponding product-chemical combination listed as a Priority Product. We feel this is a more practical approach for the Department and industry to manage.

One of the more concerning aspects of the proposed regulation is the discretion the Department gives itself to implement the program without providing sufficient clarity for the regulated community to understand what they must do to comply.

### **Definition of Chemical and Contaminant**

AWC supports that the January 2013 proposal differentiates between a contaminant and an intentionally added chemical. We fully agree that intentionally added chemicals should be regulated differently than unintentionally added chemicals that are naturally occurring and therefore manufacturers have little to no control over whether those chemicals are present. We feel this new provision at least in part addresses our request in our October 2012 comments that the definition of chemical should exclude natural products that are not chemically altered such as lumber products.

### **Regulatory Duplication**

The statute is firm on the issue of regulatory duplication, stating that the Department should not supersede the authority of other agencies and that the Department shall not duplicate or adopt conflicting regulations for products already regulated.<sup>1</sup> However, it seems that the proposal goes beyond the statute to assert the Department can regulate a product if it believes it would provide a higher level of public health and environmental protection by regulating the product under the SCP. The Department should take a straightforward unambiguous approach to that question. If the potential health or environmental impact from the chemical in the product is regulated by another agency, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

AWC remains concerned by the references the DTSC staff has made to formaldehyde-containing products as examples of priority products. Given the prohibition on regulatory duplication, it would be inappropriate to list composite wood made with resins containing

---

<sup>1</sup> GCI Section 25257.1(c) states, "The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

formaldehyde as a priority product as it is already regulated under the California Air Resources Board's (CARB) Composite Wood Products Airborne Toxic Control Measure. This Measure was enacted specifically to reduce formaldehyde emissions from composite wood products including hardwood plywood, particleboard, medium density fiberboard, thin medium density fiberboard, furniture, and other finished products made with composite wood products. Further, in 2010 Congress passed the Formaldehyde Standards for Composite Wood Products Act which establishes national formaldehyde emission standards for composite panel products based on California's technology-based standards. In fact, the U.S. industry is already meeting those standards, which are the most stringent in the world.

We respectfully ask you to re-examine the regulations before they move further toward completion to ensure that California's green chemistry regulations will enhance safety, rather than add needless costs and obstacles to manufacturers doing business in California.

We appreciate the opportunity to comment on the proposed Safer Consumer Products regulation. If you have any questions regarding AWC's position on the proposal, please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202.

Sincerely,

A handwritten signature in black ink that reads "Robert W. Glowinski". The signature is written in a cursive style and is positioned above the printed name and title.

Robert W. Glowinski  
President & CEO

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

February 20, 2013

**PEER REVIEW REPORT FOR  
CALIFORNIA SAFER CONSUMER PRODUCT ALTERNATIVE REGULATION  
*as revised* JANUARY 2013**

**John S. Applegate**

Walter W. Foskett Professor of Law  
Indiana University Maurer School of Law  
Bloomington, Indiana

Thank you for the opportunity to conduct a peer review of the California Safer Consumer Product Alternative Regulations (CCSPAR), as revised following hearings. My comments respond to the revised regulations dated January 29, 2013. The review follows the four specific Peer Review Topics identified in the attachment to the January 30, 2013, memorandum to peer reviewers from Dr. Jeff Wong.

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

**(a)** The revised regulations include no substantial changes in the criteria for selection of lists and chemicals, and they are appropriate.

**(b)** The two newly added lists are also appropriate for the purpose of identifying Candidate Chemicals.

**(c)** As I indicated in my previous comments, the approach of using existing lists makes a great deal of sense, because using lists rapidly generates a comprehensive list of chemicals and avoids duplication of effort. The lists are compiled by reliable and authoritative governmental organizations. The ability to add or subtract from the list is also important, as new information will develop and the CCSPAR process will undoubtedly develop over time.

The change in terminology from “Chemicals of Concern” to “Candidate Chemicals” provides a clarification and an adjustment of the CCSPAR structure, even though it does not appear to change the basic operation of the regulations. “Candidate Chemicals” is probably a more accurate name for chemicals derived from existing lists, because the lists are a preliminary step in the overall analysis. The Candidate Chemicals approach also emphasizes the risk-based nature of the overall CCSPAR process to the extent that it requires consideration of both hazard (toxicity) and exposure. AB 1879, which is the basis for the CCSPAR, clearly indicates that both hazard and exposure are to be considered in evaluating products. *See* §§ 25252(a), 25253(a). Within a risk-based structure, the list of

chemicals, without more, indicates a “candidate,” and using the new nomenclature, it is clearer that chemicals only become Chemicals of Concern when they are associated with a product, and thus with *exposure* from a product. See § 69503.5(b)(2)(B) and article 3 generally.

**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.**

(a) The memorandum to peer reviewers indicates that this topic is intended to raise the question whether the revised CCSPAR, having focused the regulations more sharply on the chemical-product combination, retains the breadth to cover the range of products and dangers envisioned by the AB 1879 legislation. The issue is not, it seems to me, definitions and exclusions from the meaning of “product” or “consumer product,” though there has been some clarification of repair, replacement, and the like, which seem appropriate.

Rather, the topic focuses on the use of the term “potential” to modify both exposures and impacts/effects. As a preliminary matter, the idea of regulating potential harm, as opposed to actually realized harm, should not be controversial in this setting. It is the essence of preventive regulation, and prevention (as opposed to reparation or compensation) is the *raison d’etre* of most environmental, health, and safety regulation, including CCSPAR. The challenge confronting the rulemakers, therefore, is how to assure that the term “potential” means something more substantial than mere speculation, without depriving “potential” of the expansiveness necessary to fulfill the preventive legislative mandate.

The CCSPAR seems to address this in two ways. First, the revised CCSPAR adds a new definition of “potential” as “reasonably foreseeable based on reliable information.” § 69501.1(a)(51)(A).<sup>1</sup> This is a relatively narrow definition, as it requires some degree of both [1] foreseeability and [2] quality of information. Both of these limitations carry legal baggage:

[1] “Reasonably foreseeable” is not defined in the regulation, but it is the subject of an enormous amount of litigation and commentary in tort law, particularly in the famously knotty problem of proximate cause. The function of proximate cause in tort law is to narrow the hugely broad concept of cause in fact (“but-for” cause), so the use of the standard formula for proximate cause (reasonably foreseeable) is sensible enough here. It also makes structural sense, inasmuch as the regulations start with a broad term (“potential”) and then narrow it through the definition.

---

<sup>1</sup> The definition of “potential” does not apply in two very specific cases, but this does not change the analysis here.

However, there is a danger that foreseeability will itself become a point of contention and legal wrangling. This could be quite disruptive to an already heavily burdened regulatory system.

[2] "Reliable information" is extensively defined in the regulations. § 69501.1(a)(58)-(59). The meaning of "reliable information" is perfectly sensible in its own terms. However, as with "reasonably foreseeable," there is a possibility that DTSC action will be delayed by challenges to "potential" based on this term. That is, a great deal of time could be spent resolving the scope issue, long before the heart of the CCSPAR – the alternatives analysis – comes into play.

Second, "potential" also seems to be limited by the way that it is used in article 3.

The key section reads as follows:

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

- (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse effects.

§§ 69503.2(a); *see also* §§ 69503.2(b), 69503.3(a)(1). In this language, potential exposure seems to be qualified by the capacity of the exposure to [1] "contribute to or cause" [2] "significant or widespread" impacts or effects.

[1] The term "contribute to or cause" (or vice versa) is common in federal environmental law statutes, and it is intended to be expansive. In particular, the phrase permits (or requires) regulatory action to go forward despite the existence of scientific uncertainty. *See, e.g., Massachusetts v. EPA*, 549 U.S. 497, 506 n.7, 534-35 (2007) (interpreting the Clean Air Act, 42 U.S.C. §§ 7521(a)(1)). *See also* 42 U.S.C. § 7408(a)(1)(A) (listing of air pollutants). In other words, "contribute to or cause" should not be interpreted to require a particular level of certainty in connecting the exposure and the effect or impact. Nevertheless, since "potential" is also used in this section, it might suggest that a particular impact or effect must also be "reasonably foreseeable" from the level of exposure caused by a product. I do not think that this interpretation was intended, but the section could be read to imply a level of certainty that would be difficult to demonstrate.

[2] Likewise, while the nature and scope of impacts and effects are very comprehensively defined (as in the initial proposed regulations), the term "significant or widespread" is undefined. Presumably it is meant to mean something like "more than de minimis," but *how much* more is left open to debate. This could add unproductive complexity to the department's analysis to justify the list of Priority Products.

The foregoing is admittedly a fairly laborious analysis of the language in the regulations – perhaps too laborious. I do not suggest that the regulations are misguided in

introducing “potential” to assure that the regulations are sufficiently preventive, and then trying to place some boundaries around the naturally expansive term “potential.” There is also sense in using familiar terms like “reasonably foreseeable” and “reliable information.” Nevertheless, the definitions and the way that “potential” is used in the regulations could be more limiting to the coverage of the CCSPAR than intended. Furthermore, both the terms themselves and the way that “potential” is used invite an affected party to bring in a large body of law and to parse the statutory language minutely at a very early stage in the proceedings, before the real work of the CCSPAR alternatives analysis has begun. Given the resource challenges that DTSC faces in implementing the CCSPAR, this must be considered carefully.

**(b)** Given the breadth of the CCSPAR, it is useful that the regulations repeatedly emphasize that other adequate regulatory regimes are an appropriate reason for DTSC *not* to act under CCSPAR. *See* §§ 69503.2(b)(2), 69501.1(b)(3). These anti-duplication provisions are good additions in the revised regulations.

**(c)** Section § 69503.2(b)(3) adds a new provision that permits DTSC to “consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.” Presumably the purpose of this new section is to allow the inclusion of a chemical-product combination as a Priority Product if there is such an alternative, or to allow exclusion if no such alternative exists. This makes sense, but within the structure of the CCSPAR it is not clear how this provision in article 3 is related to the formal Alternatives Analysis in article 5. Does it preempt or substitute for the Alternatives Analysis in some cases? Is it a preliminary alternatives analysis that will be repeated more fully later in the process?

It is possible that the answer is the unusually narrow meaning of “economically feasible.” “Economically feasible” is defined as an alternative that “does not significantly reduce the manufacturer’s operating margin.” § 69501.1(a)(29). The more common understanding of “feasible” is much broader. For example, as described in the well known *Cotton Dust* case, “feasible” includes anything which is “capable of being done.” *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 508-509 (1981). That is, a feasibility-based standard requires the manufacturer to stretch to the limits of what it can do, and so in the case of economically feasible, to the limits of what it can afford. The new CCSPAR definition would seem to treat as infeasible nearly anything that costs money (unless the whole cost can be passed along to the consumer, I suppose). So, given this narrow meaning, is § 69503.2(b)(3) to be understood to allow exclusion or inclusion only where the alternative or lack of alternative is extremely obvious and does not require the analysis in article 5? In any event, the relationship between the chapter 3 and chapter 5 provisions should be clarified.

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

(a) The revised regulations limit the use of the Alternatives Analysis Threshold (AAT) – which is in effect the exception process for Priority Products – to the Practical Quantitation Limit (PQL) of a *contaminant* in a product. § 69501.1(a)(12). PQLs, in turn, refer to the lowest measurable quantity of the contaminant. § 69501.1(a)(52). The effect of this change is greatly to limit the scope of the prior AAT exceptions process. Assuming that limitation is intended, the rationale is presumably that, especially in such comprehensive regulatory regime, DTSC should be focusing its limited resources only on those contaminants which it can readily measure. This is sensible, just as it is sensible to treat intentionally added chemicals differently. § 69501.1(a)(26). As a practical matter, intentionally added chemicals are likely to be easier than contaminants to control, delete, or substitute in products.

(b) The fuller description of this question in the Scope of Work also notes the new requirement that the list of Priority Products is subject to the California APA. § 69503.4(a). It is not immediately obvious why the question to reviewers links the AAT-PQL process to the APA change, except that the narrowing of AAT-PQL means that little will be excluded from the Priority Product list, and so more Priority Products will be subject to APA procedures. (At least, that is how I read it.) It is hard to object to using a regular administrative process to promulgate and seek comment on administrative action, but – as above – the CCSPAR process will be an enormous undertaking at best, and this will require greater departmental resources.

**4. The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” are 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.**

(a) I observed in my report on the initial draft of the regulations that the term “adverse” is very broad, and it comprehensively covers the impacts and effects that AB 1879 and the CCSPAR seeks to prevent. For emissions and discharges, the adverse aspect is the emission itself, which has the potential to cause adverse effects or impacts (*e.g.*, § 69501.1(a)(9)(E) (water)). For adverse effects and impacts, the definitions focus on the harm that can be caused by exposure to the chemical in question (*e.g.*, § 69501.1(a)(7) (soil)). Between them, they cover the causes and effects comprehensively, and the recent changes in the definitions do not appear to change the broad scope at all.

(b) The question also states that a qualitative or quantitative determination of adverseness can be made, and that either is adequately protective if reliable information is available. I agree with this statement. Qualitative information must frequently be relied upon when quantitative information is absent, limited, or of questionable reliability – and this situation is common, if not typical, among toxics.

The acceptance of both quantitative and qualitative information is implied rather than expressly stated in the CCSPAR. (The actual words “quantitative” and “qualitative” are

only used in the regulations incidentally and in relation to Alternatives Analysis.) While the definition of “reliable information” as it relates to exposure mainly points to quantified information (such as monitoring data, § 69501.1(a)(58)), the general definition of “reliable information” is quite clearly *not* limited to quantitative information. § 69501.1(a)(57). Since the general definition is the one that would be used on the more uncertain toxicity side of the risk equation, this provides some assurance that quantification will not be a severe obstacle to protective regulation. Another indication of the validity of qualitative information is the acceptance of structural and mechanistic similarities as evidence of toxicity. § 69503.3(a)(3). Such similarities are indeed useful evidence, but one can rarely make a quantitative leap from one structure to another without data concerning both chemicals. Thus, to accept similarities *themselves* as evidence implies the acceptability of qualitative information.

- - -

Thank you again for the opportunity to review the revised California Safer Consumer Product Alternative Regulations. I will be happy to clarify any of the foregoing comments or address other issues, should that be of assistance.

**COMMENTARY ON THE REVISED CALIFORNIA SAFER CONSUMER PRODUCT REGULATIONS (and Summary of Significant Changes) (dated January 2013)**

**Nicholas A. Ashford, PhD, JD  
President Ashford Associates, and  
Professor, Massachusetts Institute of Technology**

**Evaluation of the Key Criteria:**

- 1. The initial Candidate Chemicals that are chemicals listed by one or more of the sources named in the regulations and that have hazard traits that have public health and environmental concerns are appropriate.**
- 2. The evaluation criteria for prioritizing the product-chemical combinations in Article 3 for identifying all types of consumer products containing Candidate Chemicals as potential Priority Products are sufficient and appropriate. Revised regulations appropriately 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 meet the key prioritization criteria.**
- 3. The principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold for COCs that are contaminants in Priority Products are scientifically understood and practical**
- 4. The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” used throughout the proposed regulations are appropriate. 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.**

**In general, the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. However, while the rule is basically sound, some clarifying changes need to be made.**

**General remarks:** Being able to classify as a chemical of concern on the basis of the availability of a safer *chemical* substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, the rule (and the summary of significant changes) is inappropriately structured and written in language that discusses only *chemical* substitution. More prominence needs to be given to substitutions or alternatives that include ‘use of a safer technological or administrative approach that delivers a comparable functional purpose’.

In the four-page document entitled **Summary of Significant Changes**, bullet four on page 2 reads:

“The regulations clarify that the required AA evaluation of chemical hazards and adverse impacts is limited in scope to the COCs, alternative replacement chemicals, and any other chemicals in the alternatives that differ from the chemicals in the Priority Product”

However, the rule itself obliquely, but specifically, requires that *non-chemical* alternatives are to be included in the alternatives analysis and the regulatory responses required of the manufacturer of the COCs. This is missing from the statement above.

The Definitions section 69501.1 (a)(10) clearly considers “alternative” to include changes in the “manufacturing process.”

### **Article 5 Alternatives Analysis - Section 69505**

Unfortunately, reference to this expansive and inclusive definition of alternatives is only obliquely referenced in the section dealing with ‘identification of Alternatives’ - Section 69505.5 (b)(1A) on page 62 reads:

In addition to any alternative identified under section (a)(3)(B), the responsible entity shall identify and consider alternatives that meet the definition of ‘alternative’ under section 69501.1...

Fortunately, Section 60505.6 (a)(2)((B) on page 64 does consider non-chemical alternatives, but in general the rule is poorly written in bringing attention to these. **The rule should be re-written.**

In addition, under the discussion of Alternatives Analysis, bullet four on page 2 of the **Summary Document** should be amended to read:

“The regulations clarify that the required AA evaluation of chemical hazards and adverse impacts is limited in scope to the COCs, alternative replacement chemicals, **and any other chemicals in the alternatives that differ from the chemicals in the Priority Product, and safer technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs.**”

### **Article 6 Regulatory Responses - Section 69506**

Section 69506.6(a): line 1 (page 83) [sentence continued from page 82, last line] delete the word “product” and substitute the words **“technology or approach”** so that it reads “a selected alternative technology or approach”

In addition, in the discussion Regulatory Responses in the four-page document entitled **Summary of Significant Changes**, add the following to the end of bullet two:

**“or safer technological or administrative approaches that deliver a comparable, but safer functional purpose as the COCs.”**

I question the limitation of bullet 7 on ‘DTSC not being able to require a new Alternatives Assessment based on the receipt of new information’ and in the text of the regulation itself to that effect. I recommend its elimination.

## **ADDITIONAL REMARKS REGARDING THE ECONOMIC IMPACT OF THE PROPOSED RULE**

While not asked to comment upon the likely economic impact of the rule, I offer the following remarks.

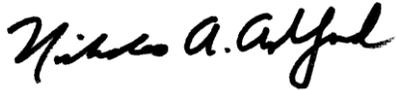
1. The costs of additional tasks imposed upon the proposed rule should be balanced against (1) the public health and environmental consequences of not implementing the rule, and (2) the benefits of stimulating replacement of problematic chemicals (derived from the list of chemicals of concern) by more benign chemicals, changes in reformulated or substitute products, process technology, and other technological and administrative practices.
2. In general, much chemical production and usage has remain static for decades, while new products, synthetic pathways, ad approaches have been the focus of innovation that have insufficiently penetrated the market and general practice. Thus, the proposed rule can properly be interpreted as a ‘modernization of the chemical industry’ [1].
3. There will be winners and losers among industrial actors, but innovation and economic growth crucially depends on industry and product turnover and evolution. Otherwise the industrial sectors and nations in which they are embedded remain static and uncompetitive.
4. Europe and Asia are advancing in chemical innovation, and the chemical industry in the United States cannot afford to lag behind in the development and deployment of environmentally safer chemicals and processes.
5. Finally, the proposed rule advances the regulation of chemicals from an exclusively risk-driven process towards a technology-based process which is less expensive by not requiring detailed and full-fledged risk analysis, and instead fostering *comparative* risk analysis and functional analysis -- and the identification of better technologies and approaches [2].

[1] "Using Regulation to Change the Market for Innovation," N.A. Ashford, C. Ayers, R.F. Stone, *Harvard Environmental Law Review*, Volume 9, Number 2, Summer 1985, pp. 419-466. Available at <http://hdl.handle.net/1721.1/1555>

[2] “Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH”, Lars Koch and Nicholas A. Ashford, *Journal of Cleaner Production* 14(1): 31-46 2006. Available at <http://hdl.handle.net/1721.1/38476> Revised version published in

*Environmental Law Network International* 2(2005):22-37. Available at  
<http://hdl.handle.net/1721.1/55292>

Respectfully submitted,

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

Nicholas A. Ashford, Ph.D., J.D.  
President, Ashford Associates, and  
Professor of Technology and Policy  
Submitted 3 March 2013 in response to Service Authorization Number OSA 12-055

February 28, 2013

Deborah Raphael, Director  
California Department of Toxic Substances Control  
1001 "I" Street  
Sacramento, CA 95812

**Re: Safer Consumer Products; Text of Proposed Regulations – Post-Hearing Changes, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (R-2011-02, January 29, 2013)  
(Submitted via Email)**

Dear Ms. Raphael:

The Technical Affairs Committee of the Association of Global Automakers, Inc.<sup>1</sup> (Global Automakers) appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) on the Post-Hearing Changes to the Proposed Safer Consumer Products Regulations, released on January 29, 2013.

Global Automakers and its members have consistently supported the development and use of safe chemicals and products available for use in the automotive industry. Through the application of green chemistry principles and sound scientific methods, Global Automakers believes that the design and development of new chemistries and technologies will continue to provide innovative solutions to current and emerging environmental challenges. Our goal is to ensure that our members have the opportunity to provide high quality, environmentally sound, safe products and services. With these goals in mind, we look for ways to provide tools to our members to facilitate continuous improvement and to ensure that wherever possible we assist them to not only meet but exceed safety and environmental standards.

Global Automakers has been actively engaged in the development of the Safer Consumer Products (SCP) regulations from the outset of this effort. Beginning in 2010, we have invested in review and comment for each of the iterations of these regulations; we have participated in public meetings and listened intently to

---

<sup>1</sup> The Association of Global Automakers represents international motor vehicle manufacturers, original equipment suppliers, and other automotive-related trade associations. Our Technical Affairs Committee members include: American Honda Motor Co., American Suzuki Motor Corp., Aston Martin Lagonda of North America, Inc., Ferrari North America, Inc., Hyundai Motor America, Isuzu Motors America, Inc., Kia Motors America, Inc., Maserati North America, Inc., McLaren Automotive Ltd., Nissan North America, Inc. Peugeot Motors of America Subaru of America, Inc., ADVICS North America, Inc., Delphi Corporation, Denso International America, Inc., and Robert Bosch Corporation. We work with industry leaders, legislators, and regulators in the United States to create public policies that improve motor vehicle safety, encourage technological innovation, and protect our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. For more information, visit [www.globalautomakers.org](http://www.globalautomakers.org).

the debates and discussions of the Green Ribbon Science Panels. We have appreciated the opportunity to meet with DTSC to provide constructive recommendations for areas of interest to us.

Global Automakers recognizes that DTSC has been working diligently to balance the requirements of AB 1879 and SB 509, as well as the input from a wide variety of interested and important stakeholders. We would like to recognize the considerable progress that has been made in a number of areas but also believe that as currently drafted, the regulations may create an unworkable system, resulting in unintended chemical and/or product substitutions and misdirected resource investments in low rather than high priority areas.

Wherever possible we have commented on specific provisions of the regulations and tried to offer alternative strategies that Global Automakers believes will make these regulations more workable not only for the regulated community but for DTSC and the public as well. We recognize the enormity of the task at hand and would like to make clear that we support the overarching goals of the law and regulations. It is with that same goal in mind that we offer the following comments and recommendations.

Global Automakers thanks you for your consideration of these comments and would welcome the opportunity to provide any additional information you may need. If you have any questions, please contact me at [jrege@globalautomakers.org](mailto:jrege@globalautomakers.org) or (202) 650-5559.

Sincerely,



Julia M. Rege  
Senior Manager, Environment & Energy

CC: Odette Madriago, DTSC Deputy Director  
Kryisia Von Burg, Safer Consumer Product Alternatives Regulation Coordinator

**Comments submitted by  
The Association of Global Automakers**

**Regarding the Post-Hearing Changes to the Proposed Regulations for  
Division 4.5, Title 22, California Code of Regulations  
Chapter 55. Safer Consumer Products Regulations (R-2011-02, January 29, 2013)**

On July 29, 2013, the California Department of Toxic Substances Control (“DTSC” or “Department”) released the post-hearing changes for the proposed regulatory text of the Safer Consumer Products (SCP) Regulations, which would require the manufacturers of certain chemical and product combinations to assess the relative hazards, exposures and functionality of available alternatives and through a comparative assessment process, select alternatives, when appropriate, that demonstrate a safer environmental profile. This proposal is the ninth iteration in the development of these regulations. Throughout this lengthy development stage, the Association of Global Automakers, Inc. (Global Automakers) has actively participated by providing DTSC with industry specific concerns about the workability of the proposed regulations, as well as reasonable options and alternatives that would address those concerns.

Global Automakers has filed comments and provided substantive and constructive feedback on each version. While we continue to believe that the breadth of consumer products contemplated under the guiding statutes (AB 1879 and SB 509) did not appropriately consider the differences between product types, we also recognize that, if DTSC moves forward with its current intent to include the components of motor vehicles and other complex durable goods<sup>2</sup> in these regulations, there is a compelling need to provide the maximum degree of clarity, as well as concise definitions, exemptions and regulatory requirements.<sup>3</sup> We remain concerned that the proposed regulations create an unworkable regulatory scheme for complex durable goods. At the November 2011 Green Ribbon Science Panel (GRSP) meeting, DTSC reiterated that these regulations need to be meaningful, practical and legally defensible, as they will set the precedent for the rest of the country. We cannot agree more and, in that spirit, offer these comments and recommendations.

---

<sup>2</sup>From the proposed regulations, § 69503.5 Priority Products List, a “highly durable product,” or complex durable goods as we refer to it, means:

*For purposes of subparagraph 3., “Complex Durable Product” means a product that meets all of the following criteria:*

- a. The product is assembled from 100 or more manufactured components;*
- b. Manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five (5) or more years; and*
- c. The product is typically not consumed, destroyed, or discarded after a single use.*

<sup>3</sup> Global Automakers believes that light-duty automobiles should be excluded from the definition of manufacturers subject to the SCP regulations, as reflected in the letter of October 8, 2012 sent to Governor Brown, California EPA and DTSC. However, if the Department decides not to do so, Global Automakers hopes DTSC will give these comments and the concerns expressed therein its serious attention.

Global Automakers represents 13 international motor vehicle manufacturers, as well as certain original equipment suppliers and automotive-related trade associations. Our members have invested \$40.2 billion in U.S. operations, including 300 facilities and 82,000 jobs for Americans with an annual payroll of \$6 billion. Most of our motor vehicle manufacturer members not only sell their products in the United States but also design and manufacture them here, including the ground up work for designing or redesigning motor vehicles; the manufacture of vehicles' components, body, frames, engines, and other aspects needed to assemble a vehicle; and the import and export of both components and whole vehicles in the United States. Due to the global nature of our business and the complexities of our products, we believe there will be many challenges that complex durable goods will face when meeting California's SCP regulations.

As we have stated throughout this process, we recognize that DTSC is working to develop a balanced regulatory scheme. We also recognize that the regulated community is not the only stakeholder that has raised issues and concerns regarding the various proposals. However, the regulated community does have the technical knowledge and experience to know when a proposed regulatory scheme is unworkable, and we urge you to listen to the concerns we are raising. As currently drafted, this proposal builds so much uncertainty into the regulatory process that it will be impossible to predict the outcome of any DTSC regulatory response. Predictability is a key aspect of regulation for manufacturers, importers and/or assemblers of complex durable goods. The lead time necessary to develop new components for those that DTSC will regulate requires years, not months. As Priority Product are listed, we need some certainty in terms of how DTSC will address replacement parts, products already regulated under other Federal or state laws, clear definitions of assemblers and importers, and other key aspects of this regulatory proposal. We will address each area of uncertainty in detail later in these comments.

Although our comments are focused on the fundamental technical problems with the regulations that still remain, Global Automakers would like to recognize the efforts that DSTC has put into attempting to balance the various views and perspectives of all stakeholders, including the following positive developments:

- We appreciate that DTSC has listened to the concerns about the certified assessor requirements and has deleted that section. We do have concerns about the addition of the public comment requirement for the manufacturer (or whoever assumes the duty to comply) and will address that issue in our detailed comments.
- We also appreciate the recognition that not all chemicals on the "list of lists" (or list based on other existing lists) are chemicals of concern and appreciate the renaming of that list to the Candidate Chemical List.

- We believe that retaining the limitation of five Priority Products for the initial Priority Product List is a positive and necessary approach but must raise our concern about the unlimited number of chemicals that could be identified for any one of those products.

Global Automakers also would like to thank DTSC for the opportunity to present our views during an October 4, 2012 teleconference with Global Automakers. During that meeting, DTSC reiterated that the SCP regulations will only be “forward-looking,” not to regulate products (or components) manufactured and placed in the stream of commerce in California prior to the implementation date for any selected regulatory control option. Specifically we understood that DTSC had no intention of trying to regulate replacement parts that met the above definition. As a general overarching theme, this concept is important to recognize; as a regulatory principle, it is critical to clearly articulate that understanding and specifically define the scope of the regulations and those products which fall under regulatory jurisdiction and those that will not.

While in the past, we have addressed the overarching principles of the regulation, such as the chemical of concern list (now including the Candidate Chemical List), the prioritization process, etc., these comments are focused on the technical details that we believe are critical to the ability of automakers and the manufacturers of components contained within such products, to comply with the SCP regulations and to plan for predictable regulatory outcomes. Our concerns continue to include that the regulations lack certainty and clarity, especially for complex durable goods. As DTSC’s intent behind many of these changes is not clearly articulated (see Section 2 below), it is difficult to ascertain the rationale for some of the revisions. We believe some of the revisions are intended to provide regulatory certainty, however, based on our interpretation of the revised requirements; they fall well short of doing so. We continue to support the comments that we have previously submitted<sup>4</sup> but are providing comments today that focus on changes made since the proposal.<sup>5</sup> Our comments fall into two major categories, and we provide suggested regulatory text where appropriate:

1. Regulatory Uncertainty and Lack of Clarity
  - a. §69501(b) Duplicative Regulatory Requirements
  - b. §69501(b) Up-Front Applicability Exemption for Certain Products
  - c. §69501.1(a)(12) Alternatives Analysis Threshold Exemption
  - d. §69501.1 Definitions and §69501.2 Duty to Comply and Consequences of Non-Compliance: Duty to Comply; Addition of the term “assembler”; Modification of the definition of “manufacture” and “manufacturer”; and related changes
  - e. §69501.1(a)(62) Safer Alternative
  - f. §69503.6(b) Initial Priority Products List

---

<sup>4</sup>Comments submitted by the Association of Global Automakers, October 10, 2012, [http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP\\_Comments\\_A\\_J.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP_Comments_A_J.pdf), page 213.

<sup>5</sup> In addition to our written comments, we adopt the comments submitted by the Durable Goods Coalition.

- g. §69505.1(d) Consideration of Information and Public Comments
- h. §69506.1(f)(4) Replacement Parts
- 2. Compliance with Administrative Procedures Act (APA) requirements
- 3. Conclusion

Based on our understanding of the current draft, we have a number of recommendations that we believe will strengthen the workability of these regulations, conform to DTSC's intent as regards complex durable goods and replacement parts, and provide a degree of regulatory certainty for both the regulated community and DTSC:

- We request that DTSC provide for a clear and explicit exemption for consumer products that are regulated by one or more federal and/or California State regulatory program(s). Specifically, Global Automakers asks that DTSC retain the language and exemption for these particular products as reflected in the July 2012 Proposed Regulations (see Section 1.a Duplicative Regulatory Requirements below).
- DTSC has deleted the applicability exemption for products placed in the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of consumer product. Global Automakers asks that DTSC retain the language and exemption for these particular products as reflected in the July 2012 Proposed Regulations (see Section 1.b Up Front Applicability Exemption for Certain Products below).
- We request that DTSC reinstate the Alternative Analysis Threshold (ATT) exemption, not only for Chemicals of Concern present as contaminants but for all Chemicals of Concern in Priority Products. We also continue to recommend that DTSC adopt a default 0.1% AAT for Chemicals of Concern in Priority Products (see Section 1.c Alternative Analysis Threshold Exemption below).
- Global Automakers recommends that DTSC exempt the automotive sector from the provisions of this regulation. As is obvious from the issues that have arisen from this proposal, the automotive sector is a complex and already highly regulated sector. While we appreciate the effort that DTSC has undertaken to carve out exclusions for the manufacturers and/or assemblers of durable goods, unfortunately, the new definitions and the modifications to §69501.1 and §69501.2 have created a confusing and extremely limited area of relief for "assemblers". Rather than continue to wordsmith definitions to exclude the automotive sector, we request that DTSC provide for an upfront exemption. Alternatively, we offer some revisions to the definitions and also support the recommendations made in the February 28, 2013, Complex Durable Goods Coalition comments to DTSC (see Section 1.d Duty to Comply; Addition of the term "assembler"; Modification of the definition of "manufacture" and "manufacturer"; and related changes below).
- Global Automakers requests that DTSC revisit the definition of safer alternative and delete the language that implies that Candidate Chemicals are also of concern as potential

replacements. We recommend that DTSC use the definition found in the July 2012 Proposed Regulations, thereby deleting the Candidate Chemicals from the definition of Safer Alternative (see Section 1.e Safer Alternative below).

- We ask that DTSC extend the reasoning behind keeping the initial Priority Product list to a manageable size and modify §69503.6(b) to state that no more than one chemical per priority product will be identified for the Initial Priority Products list (see Section 1.f Initial Priority Products List below).
- If DTSC determines that soliciting public comment on each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan is essential, then DTSC should solicit those comments and address them in their final regulatory determination. Resolution of comments can be achieved through discussion between DTSC and the responsible party submitting the AA (see Section 1.g Consideration of Information and Public Comments below).
- The issue of replacement parts has been in our first tier of priorities since we began working with DTSC to make this regulatory scheme practical and workable. We appreciate that DTSC has added language in the regulatory response section that would permit DTSC to exempt replacement parts from regulation on a case by case basis. However, the uncertainty inherent in this unpredictable approach will leave the automotive sector in limbo until DTSC makes a final determination at the end of the Alternative Assessment process. We strongly urge that DTSC reconsider this issue and, in keeping with implementing a forward-looking regulation, provide for a clear and complete exclusion for replacement parts. We believe, based on our conversations with DTSC staff that this is DTSC's intent (see Section 1.h Replacement Parts below).
- Finally, we ask that DTSC re-release these revised regulations with an accompanying Statement of Reasons to clarify why such changes were made under the full 45-day notice and comment process pursuant to Government Code Section 11346.4 (see Section 2. Compliance with the Administrative Procedures Act below).

Our detailed comments follow.

## **1. Regulatory Uncertainty and Lack of Clarity**

### **a. §69501(b) Duplicative Regulatory Requirements**

We appreciate that DTSC has added a potential exemption for chemicals/products regulated by other statutes:

*§69501(b)(3)(A) 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, that, in combination:*

- 1. Address the same potential adverse impacts, potential exposure pathways, and potential adverse waste and end-of-life effects that could otherwise be the basis for the product being listed as a Priority Product; and*
- 2. Provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were listed as a Priority Product.*

However, by including all of the limiting factors in (1) and (2) above, DTSC has essentially removed any certainty from that exemption and leaves the regulated community still uncertain as to whether they will be subject to multiple state and federal regulatory requirements at any stage of a products lifecycle. Numerous commenters have asked that DTSC provide a clear exemption for consumer products already regulated at the state or federal level as provided by the guiding statutes, and we reiterate that request here. As DTSC moves forward to identify the highest priority chemicals/products for assessment, those that have already been regulated should be placed aside from further review at this time. We request that DTSC replace the current proposed language with a straightforward and clear exemption for consumer products that are regulated by one or more federal and/or California State regulatory program(s).

**b. §69501(b) Up-Front Applicability Exemption for Certain Products**

DTSC has deleted the applicability exemption for products placed in the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of consumer product. The factors below are no longer upfront exemptions and are instead included as product prioritization factors in §69503.3(b)(3).

*(B) Whether the product is manufactured or stored in, or transported through, California solely for use outside of California;*

*(C) Whether the product is used in California solely for the manufacture of one or more of the products exempted from the definition of “consumer product”.*

It is unclear as to why DTSC decided to remove this upfront exemption. In the absence of a current Statement of Reasons, Global Automakers cannot discern why this change was made or what purpose its removal serves in meeting the goals of the guiding statutes. By removing this exemption and replacing it with the somewhat subjective approach DTSC has adopted for prioritization, manufacturers of such products have no certainty as to their status.

Global Automakers asks that DTSC retain the language and exemption for these particular products as reflected in the July, 2012 Proposed Regulations. Specifically re-add:

§69501(b)(3) “This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California.”

**c. §69501.1(a)(12) Alternatives Analysis Threshold Exemption**

Over the course of the development of these regulations, DTSC has put forward a number of different approaches to establishing an exemption for chemical concentrations that fall below a certain limit or threshold and proposed an Alternative Analysis Threshold (AAT) in the July, 2012 Proposed Regulations. Chemicals of Concern above the stipulated threshold would trigger the requirement for an Alternative Analysis (AA) to be completed for the Chemical of Concern in a Priority Product, while Chemicals of Concern present in concentrations below a determined threshold would not be subject to an AA in recognition that the exposure is limited at such a low concentration. The current proposal no longer identifies a consistent default concentration-based trigger that determines whether a manufacturer can qualify for an exemption from the AA requirement. Instead, DTSC has chosen to adopt the concept of “practical quantitation limit” (PQL) and has limited the ability to request an exemption only for chemicals present as contaminants. As presented in the current revised regulations, PQL refers to “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures”. DTSC has not identified what reliable source they will use for PQL determination, and we request that DTSC identify that source and invite public comment on its utility and accuracy.

With the phenomenal advances in analytical technologies, the quantitation limit of any given chemical is: (1) an ever decreasing number and (2) representative of miniscule presence, not exposure potential. Using the PQL as the default threshold value provides no distinction between insignificant risk potential and potential risk and consequently provides no value in terms of priority setting. In its previous proposal, DTSC indicated that the PQL would be the “floor” or the lowest level below which DTSC would not go for the AAT, because the concentration below a PQL could not be reasonably or consistently tested. It now appears that DTSC is proposing that the PQL be the threshold or maximum. DTSC has not provided any explanation for this significant change in threshold levels and without the ability to review and understand the rationale for this major science policy shift, DTSC has limited our ability to provide informed comments on this specific approach.

The reason that this issue is of such concern to Global Automakers and its member companies is two-fold. First, in those instances where a Chemical of Concern may be identified in a product, we will work in cooperation with DTSC to fully assess the nature of the concern and the potential for exposure and risk. Committing to such an assessment is costly, time consuming and will drain resources from our future-oriented research and development work. When DTSC identifies its

priority list of chemical and product combinations, we want to be sure that we are all focused on significant and relevant issues – not “minimal” risk and not “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.” We should all be focused on those chemical and product combinations where the hazard is well characterized, the exposure potential is clearly present, and the risk is genuine.

The second and equally important basis for our concern is the direct relationship between whatever threshold level is established by DTSC and the automotive industry’s ability to continue to use its two main sources of product information and data – the Global Automotive Declarable Substance List (GADSL) and the International Material Data System (IMDS). GADSL provides a definitive list of substances that are regulated by governments – both domestic and international. Its intent is to ensure cost-effective management of regulatory requirements along a complex supply chain. GADSL includes information on regulated substances relevant to parts and materials supplied throughout the automotive value chain. GADSL includes substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale. In most cases, the listings in GADSL are based on the threshold levels routinely assigned at 0.1%.

In response to GADSL, the automotive industry developed IMDS to serve as the automotive industry’s material data system. It has been adopted as the global standard for reporting material content in the automotive industry and recognizing what chemicals, when contained or released from finished materials and components for the automotive industry, are of concern to human health, environmental safety and/or recycling. IMDS is used primarily by automotive original equipment manufacturers (OEMs) to understand and manage environmentally relevant aspects of the design and development of different parts used in vehicles. In most cases, the threshold for reporting for this system is 0.1% by weight.

If a threshold level for setting priorities for alternative assessments is set below the 0.1%, a threshold that has been almost universally adopted by international regulatory bodies, in most cases the automotive sector will lose the ability to use the very set of tools which will allow it to identify what parts or components of their products contain the Priority Chemical. While DTSC has deemed the chemical lists generated at these levels to be appropriate for wholesale adoption, DTSC appears to have determined that these same organizations are using inadequate threshold levels. The automotive sector has made significant investments in these data systems over the past 10-12 years so that the sector could be forward thinking, could make informed environmental choices and be in compliance with regulations impacting our products. If DTSC adopts a threshold level lower than the 0.1% used by these systems, our industry will likely have no readily available source of supplier information. In the short term, the impact on our industry will be significant as we struggle to access information from a wide and diverse supply chain, many of which are very small businesses that cannot afford the equipment necessary to measure down to the levels that would

be required by the regulation, to ascertain which of our products may contain listed chemicals. The costs in time and dollars will be massive with minimal benefit to the SCP program. DTSC should reinstate the AAT exemption, not only for Chemicals of Concern present as contaminants but for all Chemicals of Concern in Priority Products. We continue to request that DTSC adopt a default 0.1% AAT for Chemicals of Concern in Priority Products.

**d. §69501.1 Definitions and §69501.2 Duty to Comply and Consequences of Non-Compliance: Duty to Comply; Addition of the term “assembler”; Modification of the definition of “manufacture” and “manufacturer”; and related changes**

Global Automakers has grouped these three issues together because taken as a whole we believe that this reflects DTSC’s efforts to respond to the unique characteristics associated with complex durable goods and those that assemble them. Unfortunately, the new definitions and the modifications to §69501.1 and §69501.2 have created a confusing and extremely limited area of relief for automobile assemblers.

*§69501.1(a)(15) “Assemble” means to fit, join, put, or otherwise bring together components to create a consumer product.*

*§69501.1(a)(16) “Assembler” means any person who assembles a product containing a component that is a product subject to the requirements of this chapter.*

*§69501.1(a)(43) “Manufacture” means to make or produce. “Manufacture” does not include acts that meet the definition of “assemble.”*

*§69501.1(a)(44) “Manufacturer” means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, or has the capacity to specify the use of chemicals in, such a product.*

We believe that it was DTSC’s intent to provide some regulatory relief to complex durable goods assemblers by adding the new definition of assembler, specifically decoupling assembler from manufacturer and then clarifying in §69501.2(a)(1)(A) that:

*A manufacturer has the principal duty to comply with requirements applicable to a responsible entity. In the event a manufacturer does not comply, it shall be the duty of the importer, if any, to comply if the Department provides notice to the importer under subsection (c)(1). A retailer or assembler is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer have failed to comply and the Department provides notice to the retailer or*

*assembler of such non-compliance by posting the information on the Failure to Comply List.*

Unfortunately, taken together these changes provide little if any relief for the complex durable goods assembler and in fact, create multiple paths of regulatory uncertainty. Our understanding of the impact of these regulations on complex durable goods assemblers based on the revisions to the regulations is as follows:

- If a complex durable goods manufacturer obtains all of their components domestically from sources other than themselves, then they may be able to take advantage of the newly added “ assembler” definition
- If a complex durable goods manufacturer purchases and obtains any of their components from outside the U.S. and imports the component for assembly into the assembled product, then they would fall under the category of importer for any imported component
- If a complex durable goods manufacturer “imports” the assembled (or nearly completely assembled) complex durable goods into the U.S. for sale, then they would be an importer
- If a complex durable goods manufacturer provides design specifications (which is usual practice for manufacturers) and/or other policies related to component design to their suppliers, even if they do not control the final product composition, then the complex durable goods manufacturer may be considered a “manufacturer” based on the newly added criteria added to the manufacturer definition (“or has the capacity to specify the use of chemicals in such a product”, §69501.1(a)(44)).

The only limited scenario in which this combination of changes would allow an automobile assembler to fall under the new definition of assembler would be if the automobile assembler:

- Assembled components into an automobile in the U.S.
- Acquired all components from a U.S. manufacturer
- Did not import the assembled vehicle or components of the vehicle from overseas (otherwise they would be an importer)
- Did not stipulate any component specifications, e.g., safety requirements, performance, functionality, durability, etc. (otherwise they would be a manufacturer)

This limited scenario does not reflect the reality that the global supply chain for these goods is multi-tiered and multi-faceted, from foundational raw materials to finished systems’ components for final assembly and installation.

Global Automakers recommends that DTSC reconsider Global Automakers earlier requests to exempt the automotive sector from the provisions of this regulation. As is obvious from the issues that have arisen from this proposal, the automotive sector is a complex and already highly regulated community. The majority of the components that we use to assemble our products will either (1) fall under the SCP regulations because they are manufactured domestically or (2) fall under international regulatory requirements such as REACH, The Toxics Substances Control Act (TSCA), other EPA statutes such as the Clean Air Act (CAA), the Clean Water Act (CWA), Consumer Product Safety Act (CPSA) regulations or other international regulatory schemes such as the Canadian Environmental Protection Act (CEPA). We appreciate that DTSC has added the terms “assembler” and “assemble” to carve out an exclusion for the automotive sector and other manufacturers of complex goods, however the complexity of the sector and the supply chain requires a more explicit fix than the addition of those two terms and the corresponding definitional changes in the revised proposal.

Alternatively, we support the recommendations made in the February 28, 2013, Complex Durable Goods Coalition comments to DTSC. Specifically, we recommend the following proposed revisions to the regulatory language (additions in underline; deletions in strikethrough:

1. Move the definition of “complex durable product” now contained in Section 69503.5(c)(2) to new Section 69501.1(a)(23) and renumber subsequent sections accordingly.
  
2. Revise Section 6950101(a)(23)(A):  
  
“Component” means a uniquely identifiable homogeneous material, part, or piece, ~~assembly, or subassembly~~ that is a necessary or intended element of an assembled consumer product
  
3. Revise Section 69501.1(a)(39):  
  
“Importer” means a person who imports a product that is subject to the requirements of this chapter. “Importer” does not include:
  - A. a person that imports a product solely for use in that person’s workplace if that product is not sold or distributed by that person to others; or
  - B. complex durable good assemblers.
  
4. Revise section 69501.1(a)(44):

“Manufacturer” means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, ~~or has the capacity to specify the use of chemicals in,~~ such a product.

***e. §69501.1(a)(62) Safer Alternative***

By redefining “safer alternative” in this revised regulatory text, DTSC has done two things. First, it has significantly expanded the universe of determinations that need to be made by the manufacturer, including comparison to other products for which the manufacturer has no reliable information, and second, it has greatly reduced the universe of alternatives to be considered. When compared to the definition of safer alternative in the previous proposal, a manufacturer must now assess not only the relative hazards and exposure of the chemical in the product, but also with the manufacturing process itself. This extension into the manufacturing process seems unduly cumbersome when the intent of the legislation is to focus on products. Requiring a comparison to other products beyond the Priority Product requires information that may well be trade secret or proprietary and unavailable. DTSC’s latest definition is:

***§69501.1(a)(62) “Safer alternative” means an alternative that, in comparison with another product or product manufacturing process, has reduced potential adverse impacts and/or potential exposures associated with one or more Candidate Chemical(s), Chemical(s) of Concern, and/or replacement chemicals, whichever is/are applicable”.***

In the July 2012 Proposed Regulation, DTSC proposed the following:

“Safer alternative” means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts. (§69501.1(a)(56), July 2012 Proposed Regulatory Text)

By redefining the term, DTSC has also narrowed the universe of chemicals that a manufacturer can consider when looking for viable alternatives. In the earlier version, the focus was on Chemicals of Concern, the only applicable list of chemicals covered by the regulation. DTSC has now recognized that the starting list of approximately 1200 chemicals is now more appropriately named the Candidate Chemical List, while Chemicals of Concern are only identified in combination with Priority Products. This new, more appropriate terminology reflects the fact that DTSC has not determined that all of these chemicals present a risk when combined with the product under consideration. It is therefore not appropriate to include the Candidate Chemical list in this definition and resulting assessment scope.

Global Automakers requests that DTSC revisit this issue and use the definition found in the July 2012 Proposed Regulations, thereby deleting the Candidate Chemicals from the definition of Safer Alternative.

***f. §69503.6(b) Initial Priority Products List***

Global Automakers supports DTSC's commitment to keeping the initial Priority Products list small in size, as provided in §69503.6(b):

*(b) Size of the List. The initial final list of Priority Products shall include no more than five (5) Priority Products. The list may identify more than one Chemical of Concern for each listed product.*

By limiting the initial number of products to no more than five, DTSC will allow themselves, the regulated community and the public to gain the experience necessary to successfully implement this far-reaching program.

We are very concerned, however, by DTSC's willingness to enlarge the initial scope by contemplating more than one chemical per product. This expansion undercuts the very rationale for keeping the initial list small. By starting with five products and five (or fewer) chemicals, DTSC will allow both themselves and the manufacturer to work through the process in a thoughtful and instructive manner. As with any new regulatory program, issues can be expected to arise, and thus the first efforts to implement the program become both learning and modification experiences. By identifying more than one chemical per product, the same manufacturer will be responsible for performing multiple AAs at the same time.

We ask that DTSC consider the reasoning behind keeping the initial list to a manageable size and that DTSC:

1. *Modify §69503.6(b) to state:*

*(b) Size of the List. The initial final list of Priority Products shall include no more than five (5) Priority Products. ~~The list may identify more than one Chemical of Concern for each listed product and no more than one (1)~~ Chemical of Concern per product.*

**g. §69505.1(d) Consideration of Information and Public Comments**

Global Automakers appreciates that DTSC has removed the requirement that a certified assessor either perform or direct the development of the AA. We believe this is a positive outcome of the last round of comments. We are concerned, however, that DTSC has replaced what we believed to be a costly and unnecessary step with one that is, as or more, cumbersome. The requirement for the responsible entity, rather than DTSC, to receive and respond to public comments on a Preliminary AA, a draft Abridged AA or an Alternate Process AA Work Plan proposes a completely new and unprecedented approach to inform and engage the public in regulatory decision-making. DTSC has shifted the burden of soliciting public comments from DTSC to the manufacturer (importer, assembler or retailer) in §69505.1(d):

*(d) Consideration of Information and Public Comments.*

*(1) A responsible entity conducting an AA shall consider all relevant information made available on the Department's website, including any relevant public comments, and any additional information or technical assistance the Department may provide regarding alternatives analysis. The responsible entity shall summarize these efforts in the Final AA Report or final Abridged AA Report, whichever is applicable.*

*(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 to exceed forty-five (45) 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.*

If DTSC determines that soliciting public comment on of each stage of the AA is essential, then DTSC should solicit those comments and address them in their final regulatory determination. Resolution of comments can be achieved through discussion between DTSC and the responsible party submitting the AA.

**h. §69506.1(f)(4) Replacement Parts**

Global Automakers met with staff from DTSC on October 4, 2012 to discuss a number of concerns with the July 27, 2012 proposal. During that meeting, DTSC reiterated that the SCP regulations would be "forward-looking," and not focused on regulating products (or components) manufactured and placed in the stream of commerce in California prior to the implementation date for any selected regulatory control option. Specifically we understood that DTSC had no intention of trying to regulate replacement parts that met the above definition.

In this current version of the revised regulatory text, DTSC has attempted to address the need to provide regulatory certainty regarding the availability of replacement parts for the repair and refurbishment of complex durable goods, such as automobiles, by including language in the Regulatory Response section that would allow DTSC to exempt replacement parts from any particular regulatory response requirement in §69506.1(f)(4):

*(4) The Department’s determination as to whether or not the regulatory response(s) apply(ies) to either or both of the following:*

*(A) Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale by the retailer as of the date of the final regulatory response determination notice; and/or*

*(B) Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice.*

At the same time, the new definition of “manufacture” in §69501.1(a)(2)(43) now contains no exclusion for repair, refurbishment or maintenance activities in any form. DTSC may have intended the “assemble” exclusion, contained in that definition, to encompass such activities. However, the definition of “assemble” does not achieve that goal for two primary reasons. First, by referencing the creation of a consumer product, that definition could be interpreted as not reaching repair, refurbishment or maintenance activities for existing products. Second, “responsible entity” under the Revised SCP Regulations is a term that includes assemblers – a definition that would thwart the goal of excluding from the AA process those persons and entities merely conducting repair and maintenance services.

The end result of the newly added language in the regulatory response section and the deletion of the reference to “repair, refurbishment or maintenance activities” from the definition of manufacture is to leave manufacturers, assemblers and those who perform repair and maintenance activities in limbo as to whether replacement parts will be exempted. The case-by-case approach that DTSC has proposed does not provide the certainty that the regulated community has requested; it does not meet the spirit of a forward-looking regulatory scheme, and in those cases where DTSC determines not to exempt replacement parts, it will create the untenable situation of leaving consumers without the option of repairing products that have a significant life span. We refer DTSC to our previous comments (submitted to DTSC October 11, 2012) that explain in more detail the serious implications that will ensue if replacement parts to repair products as produced are not available.

We strongly urge that DTSC reconsider this issue and, in keeping with implementing a forward-looking regulation, provide for a clear and complete exclusion for replacement parts. Specifically we recommend that DTSC:

1. *Revise §69501.1(a) to add a new definition (additions are shown in underlined text):*

“Replacement Parts” means any part, component, subcomponent or product needed to repair a product as produced.

(A) Replacement parts must meet the regulatory requirements in place at the time of original production of the product.

(B) Replacement parts are exempt from coverage under these regulations if they are produced to repair a product manufactured prior to any determined regulatory response.

2. *Add the following language to §69506.1:*

In keeping with the forward-looking nature of these regulations and recognizing the economic and social benefits that replacement parts provide, replacement parts as defined in §69501.1(a) are exempt from regulatory response requirement.

Global Automakers also supports the alternate language provided by the Durable Goods Coalition in its comments on this proposal. Specifically:

3. *Revise Section 69501.1(a)(43):*

“Manufacture” means to make or produce. “Manufacture” does not include:

(A) acts that meet the definition of “assemble;” or

(B) repair or refurbishment of an existing consumer product; or

(C) installation of components to an existing consumer product; or

(D) making non-material alterations to an existing consumer product.

4. *Revise Section 69501.1(a)(24) to add:*

(D) “Consumer product” does not mean replacement parts used to repair, refurbish or maintain existing consumer products.

## **2. Administrative Procedures Act Requirements**

Global Automakers has reviewed this revised proposal and is concerned that DTSC has provided a very narrow window of opportunity to fully assess the impacts of the major revisions made to this proposal. The ability to assess these changes has been made even more difficult by the absence of a current and corresponding Statement of Reasons. The changes made between the July 27, 2012 proposal and this January 29, 2013 revised regulatory proposal are significant and far-reaching.

While we believe that many of the changes DTSC has made since the proposal are intended to respond to our comments and provide clarity and certainty, the revisions are in fact not clear. We do not believe that they provide the certainty that we need, and DTSC has not provided explanatory text to aid us in assessing the impact of these changes.

California Government Code Section 11346.8(c) allows for an abbreviated review cycle only if the changes to a proposal are either “non-substantial or solely grammatical in nature”. While it could be argued that the changes that have been made are an outgrowth of the public comment process, many of the changes could not have been anticipated based on the previously proposed text and therefore the argument cannot be made that the DTSC had placed the public on notice that these new requirements, approaches and definitions could reasonably be foreseen. For example,

- The requirement for the responsible entity, rather than DTSC, to receive and respond to public comments on a Preliminary AA, a draft Abridged AA or an Alternate Process AA Work Plan proposes a completely new and unprecedented approach to inform and engage the public in regulatory decision-making.
- The adoption of the Practical Quantification Limit (PQL) as the maximum level of a chemical that can be present in order to qualify for an AAT exemption could not have been anticipated from the last proposal.
- The qualifying term “potential” being added to the terms “exposure” and “hazard” significantly lowers DTSC’s burden of proof in listing a Chemical of Concern and Priority Product combination. This addition is a major change in the selection process.
- DTSC has deleted the statement that products placed in the stream of commerce in California solely for the manufacture of one or more of the products are exempted from the definition of consumer product. The factors below are no longer upfront applicability exemptions, and are instead included as product prioritization factors. This change significantly broadens DTSC’s scope of regulatory coverage.

Accordingly, we request the Revised SCP Regulatory Text should be the subject of a 45-day notice period and public hearing pursuant to Government Code section 11346.4. We ask that DTSC re-release these revised regulations with an accompanying Statement of Reasons to clarify why such changes were made under the full 45-day notice and comment process.

### **3. Conclusion**

In conclusion, Global Automakers believes that as currently proposed these regulations build so much uncertainty into the regulatory process that it will be impossible to predict the outcome of any DTSC regulatory response. Predictability is a key aspect of regulation for manufacturers, importers and/or assemblers of complex durable goods. The lead time necessary to develop new

components for those that DTSC will regulate requires years, not months. As Priority Product are listed, we need some certainty in terms of how DTSC will address replacement parts, products already regulated under other Federal or state laws, clear definitions of assemblers and importers, and other key aspects of this regulatory proposal. We do recognize and appreciate that DTSC has worked to address a number of our top priority concerns by modifying definitions and adding flexibility that would allow DTSC to exempt certain regulated products if they were manufactured before a certain date. We stress that we are not looking for flexibility on DTSC's part but rather regulatory certainty for our sector.



1111 19th Street NW > Suite 402 > Washington, DC 20036  
t 202.872.5955 f 202.872.9354 www.aham.org

February 28, 2013

Krycia Von Burg  
Regulations Coordinator  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
Re: Proposed Regulations, R-2011-02, Safer Consumer Products

Submitted via E-Mail

Dear Ms. Von Burg:

On behalf of the Association of Home Appliance Manufacturers (AHAM), I would like to provide our comments on the California Department of Toxic Substances Control's (DTSC) Proposed Regulation R-2011-02 Safer Consumer Products.

AHAM represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's membership includes over 150 companies throughout the world. In the U.S., AHAM members employ tens of thousands of people and produce more than 95% of the household appliances shipped for sale. The factory shipment value of these products is more than \$30 billion annually. The home appliance industry, through its products and innovation, is essential to U.S. consumer lifestyle, health, safety and convenience. Through its technology, employees and productivity, the industry contributes significantly to U.S. jobs and economic security. Home appliances are also a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs.

AHAM supports DTSC's intent to limit potential exposures or the level of potential adverse impacts posed by toxic chemicals in consumer products. However, the scope of the regulation is unnecessarily broad and AHAM believes that because home appliances are well-regulated in this area already, they should not be the focus of this regulation, if not entirely excluded from the prioritization process. DTSC's treatment of home appliances in such a manner would be consistent with the Department's objectives for the following reasons.

I. Home appliances are well-regulated by other entities

Sections 69503.2 and 69503.3 of the proposed regulation both state that "Other Regulatory Programs" are among the factors DTSC must consider in its prioritization process. With respect to home appliances, this factor should be dispositive in granting AHAM products a very low

priority, or excluding them entirely. Home appliances are already well-regulated at the federal level through a number of agencies.

Under the Consumer Product Safety Commission alone, AHAM's members must conform to regulations under several laws, including the Consumer Product Safety Act, The Consumer Product Safety Improvement Act, and the Refrigerator Safety Act. The Toxic Substances Control Act, as administered by the U.S. Environmental Protection Agency (EPA), also requires mandatory reporting and safety requirements relating to chemicals that pose potential risks. This is in addition to mandatory greenhouse gas reporting rules. In addition, the U.S. Department of Energy (DOE) regulates energy conservation of appliances under the Energy Policy and Conservation Act of 1975 (EPCA), as amended by the Energy Policy Act of 2005 and the Energy Independence and Security Act of 2007. The Federal Trade Commission also mandates energy labeling for many of these same products under EPCA. In addition, though not a mandatory regulatory program, the success of the ENERGY STAR program, administered by DOE and EPA, has made it mandatory in the market place.

Furthermore, the appliance industry is already taking significant voluntary steps to achieve the goals of DTSC's proposed regulations. AHAM is publishing a series of sustainability standards for major, portable and floor care appliances that address materials of concern. The Safer Consumer Products regulations would therefore not have any significant impact in protecting human or environmental health, but would instead simply serve as an unnecessary burden on an already stressed industry.

## II. Prioritization Factors

### A. Intended Product Uses

Section 69503.2(b)(1)(A) of the proposed regulation states that “[t]he listing of a product-chemical combination as a Priority Product shall be based on one or more of the factors listed in section 69503.3(a) and one or more of the factors listed in section 69503.3(b), in addition to the other factors specified in this section.” Among the factors given in 69503.3(b), which deals with exposures, are the “[i]ntended product use(s), and types and age groups of targeted customer base(s).”

While AHAM acknowledges that its members' products are used by a broad cross-section of consumers, the products do not contribute to or cause widespread adverse public health and/or environmental impacts. If AHAM products are not going to be excluded from the prioritization process, then this provision of the regulation seems to indicate that they warrant special consideration and lower prioritization than products that are directly aimed at these individuals.

### B. Containment of Chemicals of Concern

Section 69503.2(b) of the proposed regulation states that another factor for DTSC to consider is the “potential accessibility to the Candidate Chemical(s) during the useful life of the product and the potential for releases of the Candidate Chemical(s) during the useful life and at the end-of-life.”

As stated before, any direct exposure to chemicals from appliances is already regulated by other entities. Therefore, this provision goes toward any other Candidate Chemical(s) that may be present. If a Candidate Chemical were to be present in home appliance products, it is likely to be part of a component contained within the appliance. Such components present much less of a risk to the consumer than those that involve direct contact with the user. The fact that such a chemical would largely be contained within the appliance furthers the reasons that home appliances are low enough priority under the proposed regulations that they should be excluded from its scope.

### C. Disposal of home appliances at end-of-life

Section 69503.2(b) of the proposed regulation states that DTSC must consider potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures during the life cycle of the product.” Subsequent provisions state that DTSC should also consider product end-of-life scenarios that minimize adverse consumer impacts.

Especially with regard to major appliances, the home appliance industry and its products with end of life value already benefit from a decades-old established market-based system in which these units are collected and recycled at over 90 percent. The fact that the home appliance industry is far ahead of most others in developing a system to deal with end-of-life issues further illustrates that the industry should not be included during DTSC’s prioritization process. To the extent that these regulations apply, they should only apply in instances where end-of-life issues are not being dealt with by existing market-based programs.

## III. Other Concerns

### A. Definitions and Terms

With respect to Candidate Chemicals, the phrase “ability to cause harm” has been replaced with “potential to cause harm.” This term is used in the regulations primarily with respect to adverse impacts and exposures associated with a chemical or a product. The regulations define “potential” to mean that the phenomenon described is reasonably foreseeable based on reliable information. This change unnecessarily broadens the level of risk associated with a chemical. Any substance has the potential to cause harm if used in an improper way, so the definition should be narrowed to reflect a reasonable level of hazard a chemical poses when used as designed.

Additionally, the term “assembler” is new to the most recent version of the regulations. “Assemble” is defined to mean “fit, join, put, or otherwise bring together components to create a consumer product.” “Assembler” is defined as someone who “assembles a product containing a component that is a product subject to the requirements” of the regulations (i.e., a component that is listed as a Priority Product). The distinction between a manufacturer and an assembler is confusing, making it difficult for a potentially regulated entity to determine whether it falls within the scope of the regulations.

The Alternatives Analysis Threshold (AAT) 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. The PQL is the limit at which a chemical of concern is present in a product solely as a contaminant. This terminology raises concern because it essentially eliminates any *de minimis* threshold because any detectable amount of a COC is now subject to regulation, even if it is a contaminant. The PQL should be replaced with a quantified *de minimis* threshold.

#### B. Trade Secrets

The trade secret protection provisions pertaining to hazard trait submissions have been revised to allow masking of precise chemical identity only for an alternate chemical being considered or proposed for which a patent application is pending. If there is no patent application, the identity will not be masked. Masking will only be allowed until the patent application is granted or denied.

This is of great concern to those companies who choose to protect proprietary information by maintaining it as Confidential Business Information rather than going through the patent process. The proposed regulations do not offer sufficient protection for such information. Confidential Business Information should be given the same level of protection that is given to information contained within a patent application.

#### IV. Conclusion

AHAM emphasizes that DTSC's proposed regulations have too broad a scope, and that the scope should be altered to exclude home appliances. These products are well-regulated and DTSC's action will not decrease any risk these products might pose, but would instead impose unnecessary burdens on their manufacturers during an already challenging economic time. If DTSC chooses not to exclude these products, the provisions specified above show that home appliances should not be considered a priority product under reasonable circumstances.

Submitted respectfully,



Kevin Messner  
Vice President, Policy & Government Relations

February 28, 2013

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

RE: Comments of the Automotive Aftermarket Industry Association and California Automotive Wholesalers Association on Post-Hearing Revised Safer Consumer Products Proposed Regulations (R-2011-02)

Dear Ms. Von Burg:

The Automotive Aftermarket Industry Association (AAIA), on behalf of our member organization, the California Automotive Wholesalers Association (CAWA), and our full membership base thank you for this opportunity to provide comments regarding the revised proposed Safer Consumer Products regulations (22 CCR, div 4.5, ch. 55).

AAIA is recognized as the pre-eminent trade association and voice for the \$297.5 billion motor vehicle aftermarket, which employs four million people and contributes more than two percent of the U.S. gross domestic product. AAIA's more than 23,000 member and affiliates manufacture, distribute and sell motor vehicle parts, accessories, service, tools, equipment, materials and supplies across the country. Through its membership, AAIA represents more than 100,000 repair shops, parts stores and distribution outlets nationally.

CAWA is a non-profit trade association representing 450 automotive aftermarket parts manufacturers, jobbers, warehouse distributors and retailers in California, Nevada, and Arizona. The Association was formed in 1955 and serves as the voice of the aftermarket parts industry in the West. CAWA prides itself on quality customer service to its members and the industry.

**Statement of Concern:**

As previously stated in the AAIA comments dated October 10, 2012 relating to the previous proposed regulations text, the associations and our member companies appreciate the goals of green chemistry. Additionally, we wish to work with the California Department of Toxic Substance Control (DTSC) in order to create meaningful action to better safeguard the public health and environment while not impeding the existence of automotive aftermarket-related businesses that contribute significantly to the state economy.

AAIA thanks the DTSC for making revisions to the 2012 proposed regulations text in an effort to address the concerns of stakeholders. However, the AAIA has identified problematic regulatory language that has carried forward from the previous version, as well as new concepts that we believe have only served to further convolute the regulation.

As a member of the Complex Durable Goods Coalition, AAIA agrees with that organization's recently submitted comments in full and has included them as an extension of these comments with the intention of associating ourselves with that comprehensive and detailed document (enclosure). These public

comments are to further emphasize specific concepts that are of particular concern to the member companies of the AAIA and CAWA.

In summary, AAIA and CAWA have the following concerns:

- In previous comments, the AAIA raised issues with several areas of the 69501.1, "Definitions." In its recent proposal, we recognize that the DTSC has made an attempt to address concerns of the industry with the inclusion of a new definition for "assembler." However, in the case of the automotive aftermarket industry, the revisions appear to increase the difficulty a company will experience in determining which the category of responsibility under the rules that they would be placed.
- The alterations made to "manufacture" reversed the previous position of the proposed regulations by attempting to address the concept of repair and refurbishment activities in an alternative manner. However, the method provided can create a much more confusing regulatory response structure than the previous clear exemption.
- Lastly, the new section 69505.1(d) requiring the consideration and response to all public comments by the responsible entities conducting the Alternatives Analysis process is unachievable. Responsible entities will be, for the most part, private companies, the vast majority of which do not have the infrastructure to respond to all public comments received in a manner expected of a public process such as the one created by this regulation.

Further details and recommendations for these items are listed below.

### **Recommendations:**

- 1) Separation of "assembler" as a new definition and additional definition clarity.

The AAIA recognizes the inclusion of the term "assembler" as an effort to further delineate responsibilities with regard to fulfillment of the various sections of the proposed regulation. However, the definition needs additional clarification to create these clear separations.

The automotive aftermarket has a thoroughly complex supply chain that could create confusion over who the SCP regulation determines is the responsible entity. As the different stages of the supply chain become involved, it may become more difficult to readily identify what regulator responsibilities, if any, an individual aftermarket organization may have.

Additionally, if it is the intent of the SCP regulation to focus on the entity with the most control over the introduction of candidate chemicals or chemicals of concern into a consumer product and to then efficiently and effectively respond to the presence of those chemicals, the DTSC must be explicit as to who in the process will be considered by the Commission as the responsible entity. The definitions for "assembler," "importer," "manufacturer," as well as the definition of a "component" need revision to achieve this goal.

### **Suggested Revisions:** (Language to include. ~~Language to strike~~)

- 1) §69501.1 (16) "Assembler" means any person who assembles a product containing a component that is a product subject to the requirements of this chapter. An "assembler" is neither an "importer" nor a "manufacturer."
- 2) §69501.1 (~~3639~~) "Importer" means a person who imports a ~~consumer product into the United States~~ product that is subject to the requirements of this chapter. "Importer" does not include a person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others. An "importer" is neither an "assembler" nor a "manufacturer."

- 3) §69501.1 (4043) "Manufacture" means to make or produce, ~~or assemble~~. "Manufacture" does not include any acts that meet the definition of "assemble" or "import."
- 4) §69501.1 (44) "Manufacturer" means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the specifications and design of, or manufacturing process for, or has the capacity to specify the use of materials chemicals in, such a product. A "manufacturer" is neither an "assembler" nor an "importer."
- 5) §69501.1 (2423)(A) "Component" means a uniquely identifiable homogeneous material, part, or piece, ~~assembly, or subassembly~~,

## 2) Revised definition of "manufacture"

The revised SCP regulation made a dramatic and problematic edit to the definition of "manufacture" that AAIA believes must be addressed. As discussed in comments relating to the previous version of the proposed regulations, activities relating to the repair and refurbishment of consumer products have special levels of considerations within the marketplace that should justify an exemption for such activities from the regulation.

We appreciate the DTSCs attempt to address the concerns over repair and refurbishment activities by creating the new "assembler" definition. However, the new definitions provided have reversed the previous position of the proposed regulation to eliminate the repair and refurbishment exclusion.

As AAIA noted in comments dated October 10, 2012, "The manufacturing of items required to undertake automotive repair have occurred long before and by several other entities prior to reaching the repair-focused business." In an attempt to address this problem, the "assembler" definition was included. However, as noted above, there is still a lack of clarity as to what category a repair business could fall under within the scope of the definitions. The AAIA requests that the explicit exemption language be re-included.

### **Suggested Revisions:** (Language to include. ~~Language to strike~~)

- 1) §69501.1 (4043) "Manufacture" means to make or produce, ~~or assemble~~. "Manufacture" does not include any acts that meet the definition of "assemble," "import," or the following:
  - (A) Repair or refurbishment of an existing consumer product;
  - (B) Installation of standardized components to an existing consumer product; or
  - (C) Making non-material alterations to an existing consumer product.

## **3) Public comment process for responsible entities regarding elements of the Alternatives Analysis (AA) regulatory requirements**

It is important that the final SCP process be transparent and responsive to the public. However, the process for responses to public comments outline in §69505.1, "Consideration of Information and Public Comments," creates a burden on responsible entities that is unreasonable private companies to fulfill.

The section attempts to establish a requirement that responsible entities must consider all public comments received after DTSC has posted the Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan to their website. Consideration of these comments must then be included in the final AA. Of concern is the lack of infrastructure at many organizations outside of public agencies to fulfill the role of responding to the wealth of public comments that may be received on these critical steps leading up to the final AA Report. Setting up a structure to take in, analyze, thoughtfully consider, respond to and then summarize responses would take an extensive amount of time and money. This would be an additional burdensome layer for responsible entities to face and may result in the opposite of the intended goal of an open and responsive process.

Therefore, the AAIA believes the section placing the burden on responsible entities should be struck.

Suggested Revisions: (Language to include. ~~Language to strike~~)

1) §69505.1(d) Consideration of information and public comments.

(4) A responsible entity conducting an AA shall consider all relevant information made available on the Department's website, ~~including any relevant public comments~~, and any additional information or technical assistance the Department may provide regarding alternatives analysis. The responsible entity shall summarize these efforts in the Final AA Report or final Abridged AA Report, whichever is applicable.

~~(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 Workplan submitted to the Department. The notice shall include the time period, not to exceed forty five (45) days, during which the public may submit comments, and the methods 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.~~

The AAIA and CAWA remain concerned about the practical application of the proposed SCP regulation. We recognize and appreciate the many revisions made to the previous draft to and believe it is important for both DTSC and stakeholders to continue to work together to further improve the regulatory text.

Thank you for the opportunity to provide our comments on the revised proposed SCP regulation. We look forward to collaborating with the DTSC in a productive manner that produces mutually agreeable outcomes for both public health and businesses.

Sincerely,



Aaron Lowe  
Vice President, Government Affairs  
AAIA

Enclosure



December 30, 2011

**VIA ELECTRONIC FILING**

Department of Toxic Substances Control  
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A  
P.O. Box 806  
Sacramento, CA 95812-0806  
[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Re: California DTSC Safer Consumer Products Regulations Draft

Dear Ms. Jones:

The Battery Council International (BCI) is pleased to submit these comments on the California Department of Toxic Substances Control's (DTSC) informal draft regulations for Safer Consumer Products. Health and Safety Code sections 25252 and 25253 require DTSC to adopt these regulations to: 1) establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized; and 2) develop criteria by which chemicals and their alternatives may be evaluated and reduce exposure to these chemicals and the hazards posed by them.

BCI is a non-profit trade association whose members are engaged in the manufacture, distribution and reclamation of lead batteries. BCI members account for over 98% of the U.S. lead battery production and over 80% of its recycling capacity (*i.e.*, secondary lead smelting). Our industry promotes lead-acid battery recycling by collecting and recycling lead batteries, encouraging the enactment of mandatory lead battery recycling laws, and supporting ongoing consumer and industry environment, health and safety education efforts. The vast majority of used lead-acid batteries are collected initially for recycling from consumers, either at retail outlets that sell new batteries, or at retail facilities where new batteries are both sold and installed. These batteries are picked up from retailers by battery distributors, battery manufacturers or secondary lead smelters and delivered to recycling facilities. The U.S. recycling rate for lead from lead-acid batteries is very close to 100%.<sup>1</sup>

For the reasons presented below, BCI recommends that the DTSC exempt lead-acid batteries from the requirements of the Safer Products regulations. Lead-acid batteries and

---

<sup>1</sup> Smith, Bucklin and Associates, Inc., *BCI National Recycling Rate Study* (August 2009). The recycling rate for lead from lead-acid batteries across the years 2004 – 2008 was 96.0%. The plastic battery casings also are recovered and processed into raw material for new products.

their production and recycling are time-tested and already highly successful and regulated. There also are no viable substitutes that meet the critical performance and cost efficiency (technical and cost feasibility) requirements demanded by the marketplace and the rule's Alternatives Assessment provisions.

### Comments

#### **1. Lead-Acid Batteries Should Be Exempted From the Rule as They Are Already Highly Regulated**

DTSC recognizes in the draft proposal that an exemption should be provided for products that are already regulated by one or more federal, California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that

“address[es] the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and provide[s] 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.”

Lead-acid batteries are such a product. As more fully explained in the following subsections, they are already subject to a state disposal prohibition and mandatory recycling (end-of-life product management), they must display consumer warnings pursuant to both Proposition 65 and U.S. Consumer Product Safety Commission (CPSC) requirements, and lead-acid battery manufacturing and recycling are both strictly regulated under the Clean Air Act, the Clean Water Act and California's hazardous waste regulations. Cal/OSHA's general industry lead standard also serves to control worker exposure to lead during battery manufacturing and recycling. Indeed, Cal/OSHA has this year initiated a rulemaking process that may make its lead standard more stringent.

These characteristics are precisely those which, under the proposed regulation, would support DTSC excluding lead-acid batteries. But this could only be done after an independent Alternatives Assessment was completed. There is no reason for resources to be wasted in that effort. Lead-acid batteries should be excluded from the start.

##### **a. End of Life Product Management for Lead-Acid Batteries**

With BCI's strong support, thirty-nine states, including California, have enacted laws that assure “cradle to grave” stewardship of lead batteries. These laws prohibit municipal solid waste landfill or incinerator disposal of used batteries and require battery retailers to accept used batteries from customers and advertise their collection

obligations. Battery manufacturers and distributors, in turn, must accept the used batteries from retailers and transport them to recycling facilities at their own expense.<sup>2</sup>

The existing reverse distribution system – whereby the same network that distributes new batteries also safely collects and returns used batteries for recycling – satisfies these legal requirements and assures that batteries are recycled at very high levels, regardless of the price of lead. Lead battery manufacturers also developed an industry battery label to further assure lead-acid battery recycling. It consists of the words “LEAD-RETURN-RECYCLE” surrounding the three-chasing-arrows recycling symbol.

Furthermore, California’s end-of-life product management law specifically prohibits municipal solid waste landfill or incinerator disposal of used lead batteries, and requires battery retailers to accept used lead batteries offered by customers. Battery manufacturers and distributors, in turn, must accept the used batteries from retailers and ensure for recycling. Battery manufacturers must notify retailers and distributors of these requirements. Cal. Health & Safety Code § 25215.

As noted above, the U.S. recycling rate for lead from lead-acid batteries is very close to 100% – a rate that is unsurpassed by any other battery chemistry or consumer product. All of the plastic from lead-acid batteries is also recycled. The sulfuric acid electrolyte from used batteries is either recycled or neutralized. Indeed, lead-acid battery stewardship practices set the standard for other products.

b. Consumer Warnings on Lead-Acid Batteries

BCI has provided battery use and safety labeling recommendations to its members since 1989, and these are used virtually universally. They are included in BCI’s *Recommended Practices for Warning Messages, General Labeling & Marking and Shipping & Packaging* (last updated August 2009) and is the industry standard. These labels initially were designed to comply with very detailed and stringent CPSC regulations, and since have been expanded to reflect California “Proposition 65” requirements. The recommended labels are easily visible to consumers and store clerks and convey necessary information about potential hazards and safety precautions applicable to lead-acid batteries.

For example, consistent with CPSC requirements, lead-acid batteries for consumer use (*e.g.*, batteries for cars, boats, lawnmowers and power sport vehicles such as motorcycles, jet skis and snowmobiles) must be labeled with safety warnings indicating the presence of sulfuric acid, that they pose a DANGER and that acid is a POISON. Special handling and first aid instructions also are included, as well as the phrase “KEEP OUT OF THE REACH OF CHILDREN.”<sup>3</sup> These warning statements are

---

<sup>2</sup> An additional five states have more narrow laws that strictly prohibit municipal solid waste disposal.

<sup>3</sup> 16 C.F.R §§ 1500.121 and 1500.3.

located prominently on labels and appear in conspicuous and legible type in contrast by typography, layout or color with other printed material on the label. A sample label with CPSC required language is shown as Attachment 1. A nearly identical label is used on industrial lead-acid batteries to comply with U.S. Occupational Safety and Health (OSHA) requirements.

Similarly, lead-acid batteries for the U.S. market are labeled with the California Proposition 65 warning statement that indicates the presence and hazards of lead and “other chemicals known to the State of California to cause cancer” (referring to sulfuric acid mist). That statement reads as follows:

**WARNING:** Battery posts, terminals, and related accessories contain lead and lead compounds, chemicals known to the State of California to cause cancer and reproductive harm. Batteries also contain other chemicals known to the State of California to cause cancer. Wash hands after handling.

c. Other Regulatory Controls on Lead-Acid Batteries

The lead-acid battery manufacturing and recycling industries are strictly regulated by federal and state air, water and hazardous waste rules and regulations. Worker safety is further protected by the federal and State general industry lead standard and applicable hazard communication standards.

California implements and enforces Clean Air Act requirements that carefully limit stack emissions and the ambient air levels of lead for both battery manufacturers and battery recyclers. These requirements include the National Emissions Standards for Hazardous Air Pollutants and the National Ambient Air Quality Standard (NAAQS) for lead. The NESHAP regulations for both industries were recently updated (2007 for manufacturers and 2011 for recyclers) and the lead NAAQS was revised downward from  $1.5 \mu\text{g}/\text{m}^3$  to  $0.15 \mu\text{g}/\text{m}^3$  in 2008. A review of the 2008 NAAQS standard is also underway.

Water effluent limits applicable to battery manufacturers tightly control waterway and sewer water releases of lead, copper, iron, oil and grease, total suspended solids (TSS) and pH levels. Battery recyclers must meet stringent effluent limits for antimony, arsenic, lead, zinc, ammonia, TSS and pH (sulfuric acid from used batteries is separated for recycling or neutralized). Storm water releases at these facilities are also tightly controlled.

Lead-acid battery manufacturers and recyclers are also stringently regulated by the full panoply of California’s hazardous waste rules for all hazardous wastes that they generate through processes at their plants. This includes containment, storage time, recordkeeping, annual reporting, manifesting, hazardous waste hauler requirements and land disposal restrictions, among other obligations.

Generators, transporters and storage facilities handling used lead-acid batteries before recycling are covered by streamlined hazardous waste requirements that include manifesting, recordkeeping and, except generators, annual reporting obligations. 22 Cal. Code Regs. §§ 66266.80-81. In addition, any damaged batteries must be stored and transported in a non-reactive, structurally secure, closed container capable of preventing the release of acid and lead, and packed in the transport vehicle in a manner that prevents the container from tipping, spilling or breaking. Section 66266.81(b)(1).<sup>4</sup> The handling of large quantities of lead-acid batteries, long-term storage of such batteries and electrolyte removal (any quantity) also trigger the full panoply of hazardous waste regulations in California described above. This covers storage of more than one ton of batteries for more than 180 days, or, one ton or less of batteries for more than one year. This latter requirement serves to minimize or even eliminate long-term storage of used batteries by generators, transporters and storage facilities.

As noted above, Cal/OSHA's general industry lead standard serves to control worker exposure to lead during battery manufacturing and recycling. Cal. Code Regs. tit. 8 § 5198. It sets personal hygiene and facility housekeeping standards that are critical to keeping blood lead levels down, as well as similarly critical limits on the allowable level of lead in the air and in workers' blood. Also, as noted above, Cal/OSHA has this year initiated a rulemaking process to make its lead standard more stringent.

## **2. There are No Viable Substitutes for Lead-Acid Batteries that Meet Performance and Cost Efficiency Requirements**

The Safer Consumer Products proposal includes in its Alternatives Assessment provisions a requirement that viable substitutes meet specific technological and economic feasibility standards.

### **a. Lead-Acid Battery Performance**

There are no viable substitutes to the lead-acid battery that meet the critical performance and cost efficiency requirements demanded by the marketplace or the proposed Safer Consumer Products rule's Alternatives Assessment. Because of its unsurpassed recycling rate and regulatory controls, lead-acid batteries also are a superior product if California is looking to protect the environment and ensure human health and safety.

While batteries store electricity using a variety of different chemistries, there are no "environmentally safer" alternatives to lead-acid batteries in the uses to which they currently are put that California could identify through an Alternatives Assessment. Only one other battery chemistry, nickel-cadmium, has the capability to function as a reliable starter battery (automotive, aviation, marine and lawn and garden), especially in the colder temperatures

---

<sup>4</sup> [http://www.dtsc.ca.gov/LawsRegsPolicies/Title22/upload/OEARA\\_REG\\_Title22\\_Ch16\\_Art7.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Title22/upload/OEARA_REG_Title22_Ch16_Art7.pdf)

that are typical to the U.S., including parts of California. However, nickel-cadmium has toxicity concerns equivalent to lead-acid batteries, is cost prohibitive for consumer applications, and has no established recycling system. Lithium-ion chemistry batteries face significant technical limitations preventing widespread use as starter batteries. For example, the only lithium-ion vehicle starter battery currently on the market is offered as an optional spare part for certain luxury sports cars, but can only be used in weather conditions above freezing (32° F). Moreover, hybrid electric vehicles that utilize non-lead technologies for the motive power battery use a separate lead-acid battery as the starter battery.

Lead-acid batteries also safely serve other diverse non-consumer applications such as medical, nuclear, motive power (*e.g.*, forklifts), standby, uninterruptible power supplies (UPS), energy storage (*e.g.*, wind, solar), load leveling (power company applications), security, emergency lighting and certain electric and hybrid electric vehicles. They operate safely and reliably at widely ranging ambient temperatures and in every geographical location, from hot desert to cold arctic environments.

New sealed (valve regulated) lead-acid battery designs have made the use of the lead-acid technology even safer in many applications. With these non-spillable batteries, the chances of acid leaking from the battery are minimal. Also, in the event of a car accident, no acid will spill out even if the battery is cracked or punctured.

The lead-acid battery is abuse tolerant, versatile and a safe and reliable battery technology.

b. Lead-Acid Battery Cost Efficiency

Lead-acid batteries are also the most affordable option when it comes to rechargeable battery technologies. Regardless of the type of application, lead-based technology delivers the lowest cost of energy and power output per kilowatt hour. No other starter battery technology is as affordable, for example. While more heavily focused in the non-consumer market, newly developed carbon-based advanced lead-acid batteries also are the most affordable battery in their class. These batteries can be used for energy storage, extended float/cycle service, UPS and hybrid electric vehicles. Advanced lead-acid batteries are 1/3<sup>rd</sup> to 1/4<sup>th</sup> the cost of competing advanced battery technologies.

An established infrastructure of manufacturing and recycling ensures that lead is one of the most stable and cost effective energy storage technologies. The recycling that is hallmark to lead-acid batteries is more energy-efficient than mining and smelting new lead or other metals for other battery chemistries. The lead from a dead battery can be refined into new alloy over and over again indefinitely. Its sustainability is unmatched and serves as a buffer to raw material price fluctuations that could compromise the practicality of commercial use. Also, the supply of lead is not dependent on one dominating international source, unlike material used in some other forms of energy power storage. The vast domestic collection and recycling infrastructure, plus the contributions from many

developed countries with safe lead-acid battery recycling facilities, also make lead one of the most reliable and environmentally sound raw materials for battery production.

\* \* \* \*

As stated at the beginning of these comments, BCI is recommending that the DTSC exempt lead-acid batteries from the requirements of the Safer Products regulations for all of the reasons described above. Lead-acid batteries and their production and recycling are time-tested and already highly successful and regulated. There also are no viable starter battery substitutes that meet the critical performance and cost efficiency requirements demanded by the marketplace, and the more expensive substitute that does exist has toxicity concerns equivalent to lead-acid batteries.

BCI appreciates the opportunity to provide these comments. If you have questions about this submittal, please contact David Weinberg, BCI's general counsel, at 202-719-7102 or [dweinberg@wileyrein.com](mailto:dweinberg@wileyrein.com).

Respectfully submitted,

*Tim J. Lafond*

Timothy J. Lafond, P.E.  
BCI Environmental Committee Chairman



Date February 28, 2013

Debbie Raphael, Director  
Department of Toxic Substances Control (DTSC)  
P.O. Box 806  
Sacramento, CA 95812-0806

*Submitted electronically to [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)*

## **BACWA Comments on Revised Proposed Safer Consumer Products Regulations**

Dear Director Raphael:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for another opportunity to comment on the Revised Proposed Safer Consumer Products Regulations (revised proposed regulations). We appreciate the revisions DTSC included to address BACWA's concerns, as outlined in our previous comment letters. We also wish to commend you and the DTSC staff for your efforts to conduct an open, transparent process for developing these regulations.

BACWA's members include fifty-five publicly-owned wastewater treatment facilities and collection system agencies serving 6.5 million San Francisco Bay Area residents. Wastewater agencies are faced with increasingly strict regulatory standards to protect our water resources. Because we take our responsibility for safeguarding our receiving waters seriously, we are very concerned about discharges of certain chemicals into wastewater systems. The growing tide of unregulated chemicals in consumer products poses a threat to wastewater effluent quality, biosolids management options and our compliance with National Pollution Discharge Elimination System (NPDES) permit requirements.

### **Support for Revised Proposed Regulations**

In general, BACWA is pleased to support the revised proposed regulations and encourages DTSC to move forward with finalization of the regulations so that implementation of the Safer Consumer Products program can begin. Specifically, we appreciate the following revisions:

- Incorporation of the highest priority water pollutants – the 303(d) list – in the list of Candidate Chemicals
- Specific addition of wastewater impacts in the definition of “Adverse waste and end-of-life effects”
- Inclusion of “Adverse waste and end-of-life effects” in Product-Chemical Identification and Prioritization Factors (§69503.2)
- Improved clarity for petitions process

- Changes allowing DTSC to consider “management and clean-up costs imposed on public agencies by the ongoing sale of the Priority Product or a selected alternative” (§69506 (c) (3) (a)) in its regulatory response
- Improved requirements for manufacturers to provide consumer communication regarding product end-of-life management (§ 69506.3)
- Requirement that Preliminary AA Work Plans must identify exposure pathways

While BACWA supports the proposed regulations, we also have some concerns and suggestions regarding specific sections, detailed below.

### **Non-Duplication of Regulation**

DTSC has incorporated new language to avoid duplication of regulation. BACWA requests that DTSC clarify in the record that the new language in § 69501 (b) (2) (A) will not interfere with DTSC’s ability to address water pollution from Chemicals of Concern and/or problem consumer products.

### **Public Comment Period in AA Process**

We thank DTSC for specifying a formal public comment period for the AA process. However, DTSC has not specified a minimum comment period. We believe that even the maximum comment period of 45 days specified in the regulations is too short for many public entities to provide substantive comments. Many public agencies and their associations are resource-constrained and have lengthy approval processes for providing public comments. At a minimum, a sixty-day comment period would allow for more thorough review, and where possible, we encourage DTSC to allow ninety-day comment periods.

### **Ensure Preliminary AA Reports are Transparent and Accessible**

BACWA believes that Preliminary AA Reports should summarize chemical information so that the public is able to understand it and therefore able to provide substantive comments. A matrix format will assist in this endeavor if it provides a summary of chemical information, but a matrix presentation of the entire set of chemical data would not be comprehensible for the public. We suggest that DTSC provide a sample Preliminary AA Report as a guide for manufacturers in their preparation of Preliminary AA Reports.

### **Develop Criteria for Allowing AA Extensions**

We believe that DTSC should be able to consider whether extensions requests in the AA process are acceptable based on overall time needed to complete regulatory action for a Chemical of Concern or a Priority Product. All too often, regulatory processes take many years to complete, at the cost of human and environmental health in the meantime. We suggest that DTSC incorporate criteria in §69506 so that staff may consider timely completion as a regulatory response selection criteria in the AA process.

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

BACWA also appreciates that DTSC has included provisions that allow DTSC to require engineering safety measures on consumer products (§ 69506.6); however, we believe that the regulations, as currently written, do not allow DTSC to require these controls for releases of Chemicals of Concern from Priority Products to the environment. We encourage DTSC to review this section and add specific language that allows DTSC to require the manufacturer to engineer safety measures for environmental releases of a Chemical of Concern.

### **Performance Standards for End-of-Life Management Programs**

BACWA believes strongly that 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. We suggest that DTSC incorporate language in §69506.7 which would provide for performance standards to be developed by DTSC in collaboration with manufacturers, stewardship organizations and other affected stakeholders.

### **End-of-Life Management Requirements Should Apply During Phase-Outs**

Removal of a chemical from a consumer product or complete removal of a consumer product from the marketplace may take many years to complete, at the cost of public and/or environmental health during the phase-out period. Therefore, BACWA believes that management of these products may be necessary during the phase-out period. However, it appears that language in §69506.1 (a) (3) may interfere with such management as proposed in §69507 (a). We urge DTSC to review these sections so as to ensure that DTSC may require management programs during phase-out periods when necessary.

### **Exemption Process Should Be Subject to Public Comment**

BACWA believes that exemption requests should be subject to public review and comment. We request that DTSC provide a formal public comment period of a minimum of sixty days for all exemption requests.

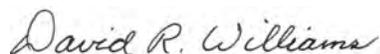
### **Include Water Pollutant in Initial Final List of Priority Products**

BACWA understands 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. We request that DTSC staff include at least one water-polluting product, so as to evaluate whether the new program sufficiently addresses consumer products that only have known effects on environmental health (as opposed to those with human health concerns).

Once again, BACWA would like to commend DTSC's efforts in developing these revised proposed regulations. We believe that timely and robust implementation of these regulations is critical so that the most pervasive and hazardous chemicals are removed from commerce and our environment.

Thank you for your consideration of our comments. We look forward to participating in the process of furthering safer consumer products in California. If you have any questions, please contact BACWA's Project Manager, Melody LaBella, at (925) 229-7370 or [mlabella@centralsan.org](mailto:mlabella@centralsan.org).

Sincerely,



David R. Williams  
Executive Director

cc: Tom Howard, Executive Director, State Water Resources Control Board  
Jonathan Bishop, Chief Deputy Director, State Water Resources Control Board  
Charles Hoppin, Chair, State Water Resources Control Board  
Frances Spivy-Weber, Vice Chair, State Water Resources Control Board  
Steven Moore, Board Member, State Water Resources Control Board  
Tam Dudoc, Board Member, State Water Resources Control Board  
Felicia Marcus, Board Member, State Water Resources Control Board  
Thomas Howard, Board Member, State Water Resources Control Board  
Bruce Wolfe, Executive Officer, San Francisco Regional Water Quality Control Board  
Tom Mumley, San Francisco Bay Regional Water Quality Control Board  
Dylan Garner, San Francisco Bay Regional Water Quality Control Board  
John Muller, Chair, San Francisco Bay Regional Water Quality Control Board  
Terry Young, Vice Chair, San Francisco Bay Regional Water Quality Control Board  
Margaret Abe-Koga, Board Member, San Francisco Bay Regional Water Quality Control Board  
Jim McGrath, Board Member, San Francisco Bay Regional Water Quality Control Board  
William Kissinger, Board Member, San Francisco Bay Regional Water Quality Control Board  
Gina Solomon, Cal-EPA Deputy Secretary for Science and Health

## Peer Review of Revised Safer Consumer Products Regulations

Deborah H Bennett

### Topic 1: Listing of Initial Candidate Chemicals

The revised regulation broadens the lists used to compile the initial candidate chemical list by adding respiratory sensitizers defined by the European Union and a more complete listing of chemicals considered under the federal Clean Water Act. I think that is very appropriate to broaden the list in this way as it will provide for a more complete listing of chemicals that cause potential harm.

### Topic 2: Criteria for prioritizing product-chemical combinations

I am somewhat concerned with the language in 69503.2,a,2, specifically “potential for one or more exposures can contribute to or cause *significant or widespread* adverse impacts.” There appears to be no definition for significant or widespread and I feel this criteria can be interpreted in a variable manner by the regulating body and the regulated entity.

I was very pleased with the additions of evaluating chemicals with structurally or mechanistically similar chemicals which there is a known toxicity profile, the addition of workplace presence of the chemical, and the inclusion of releases of the product in schools.

In section 69503.3,b,4, there is a list of factors to be considered. The items under A and D-H all appear to be factors related to quantifying the likely exposure to the public. In the prior version, items B and C, both related to chemicals that are basically never released in California, were an exemption. By placing them in this current list, it seems like one would be expected to evaluate exposures related to these compounds even though there is little chance for exposure. If the desire is do not have these as exemptions, but in some way have some sort of minimal evaluation, this intent should be made more clearly. Perhaps they could be listed together in their own subsection and it could be clearly stated that there is likely to be minimal exposure due to these scenarios.

In section 69503.4, the focus is on the process for identifying Priority Products. It is not clear from the regulation how broadly the product categories are defined. If a chemical is used in two very different product categories, which are not both being considered in the development of the priority product work plan, it is not inherently clear from the regulation that aggregate exposures from both product categories will be considered. There is some mention of aggregate exposures in the document, and the department may be planning on including aggregate exposures from multiple product categories, but it is not clearly stated. Aggregate exposure for

multiple use categories of products containing the same chemical of concern should be considered.

Topic 3: Alternative analysis threshold

I thought that the changes to the alternative analysis threshold were very clear and appropriate.

Topic 4: Use of the word “adverse”

With the exception of the statement “cause significant or widespread adverse impacts” in which significant and widespread were not defined, I thought that the uses of adverse in the document were clear and appropriate.



February 28, 2013

Debbie Raphael, Director  
Department of Toxic Substances Control  
1001 I Street  
Sacramento, CA 95812-0806

Dear Ms. Raphael,

On behalf of BizNGO, we are very encouraged by the progress that DTSC is making towards robust and effective regulations for implementing AB 1879. The basic SCP framework mirrors in large part the best practices among downstream user companies in BizNGO. Our comments are designed to support the development of an AA process that can be effectively implemented by users of chemicals of concern in priority products. Below is a summary of BizNGO's comments and recommendations.

- Streamline the AA process while ensuring it meets the intent of AB 1879. To that end, BizNGO recommends that DTSC provides more guidance on what is sufficient for the first stage AA.
- The second stage AA should also be streamlined in the following ways:
  - If a company chooses to switch out of the chemical of concern into an identified safer alternative, the economic analysis should not be required.
  - Remove the additional requirement for human and environmental health review, which is required in the first stage AA.
- BizNGO is concerned that in issuing a regulatory response for each AA submitted by each responsible entity DTSC is created an uneven playing field. Some entities will receive longer periods and possibly less stringent regulatory responses than other entities. To create a level playing field, which is what the regulations should accomplish, DTSC needs to release a single regulatory response for each COC/Priority Product combination. All responsible entities filing AA reports for COC/Priority Product combination should have the same time to prepare and submit their reports and the same regulatory response.
- Recommends that the regulations promote transparency as much as possible, including using data already in the public domain.
- Strongly supports in Article 2 the Candidate Chemicals List with the recommendation that it be regularly updated, at least every 12 months to reflect revisions to the reference lists.
- Supports the inclusion in Article 4 of the right to petition for a chemical list as well as a chemical.
- Recommends simplifying Article 5 as much as possible, including relying on the Guidance Materials to provide greater detail when needed on what is required for an AA.
- Strongly support Article 5, Section 69505.6, that the public have the right to submit comments on the publicly available AA executive summary before DTSC issues a determination notice on the AA.
- Information that is made publicly available from the AAs must be sufficient for the public to understand how the alternative recommendation and regulatory response determinations were made and submit comments for the public review.



Sincerely,

Mark S. Rossi, PhD  
Co-Chair, BizNGO  
1310 Broadway  
Somerville, MA 02144  
t) 781.391.6743  
e) [Mark@CleanProduction.org](mailto:Mark@CleanProduction.org)

**BizNGO Note on Government Policy Positions**

*Participants in BizNGO are all working towards the use of safer chemicals in commerce. Reflecting the diversity of participants in the Working Group, we have a diversity of perspectives on government, NGO and industry initiatives. While BizNGO strives for consensus on all of its policy positions and all participants agree on the government policy issues we address, we may not achieve consensus on the specifics of every BizNGO policy statement.*

#### § 69501.1(a) Definitions

(29) “Economically feasible”

BizNGO recommends the following change:

“Economically feasible” means that an alternative product or replacement chemical is **commercially available for a similar functional use in similar products** ~~does not significantly reduce the manufacturer’s operating margin.~~

Rationale: Market availability of an alternative is the best indicator of the economic feasibility of an alternative. If an alternative is in use in a similar, if not exactly the same, product type then it demonstrates the economic viability of the alternative. Also it places the analysis at the appropriate level of the market versus the responsible entity. BizNGO’s proposed definition of “economic feasibility” aligns with the same level of analysis as the definition of “technical feasibility”, which is at the level of marketplace not the level of a responsible entity’s technical knowledge, equipment, and materials. The definitions of “technical feasibility” and “economic feasibility” should both be at the same level of analysis—the marketplace. Marketplace level of determination of economic feasibility is also important for consortia performing AAs.

(51) “Potential” – BizNGO supports this definition

(56) “Safer alternative”

(65) “Technically feasible” – BizNGO supports this definition

#### § 69501.4 Chemical and Product Information

(d) Safer Consumer Products Partner Recognition List

BizNGO supports the Recognition List as a means of creating a community of practitioners in support of the program.

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

BizNGO is strongly supportive of the provisions in this section. In general, transparency will be critical to the success of the program. Providing AAs to the public will enhance the quality of AA submissions and further the development and dissemination of safer alternatives.

#### § 69502.2. Chemicals of Concern Identification.

(a) Candidate Chemicals List.

BizNGO supports the Candidate Chemicals List and the use of authoritative bodies to identify the chemicals on that list. It mirrors processes developed by the states of Maine, Minnesota, and Washington to identify chemicals of high concern as well as how GreenScreen quickly screens for chemicals of high concern to human health or the environment.

(1)(C) BizNGO supports including endocrine disruptors identified by the European Commission.

(1)(I) BizNGO supports including respiratory sensitizers identified by the European Commission.

#### § 69502.3. Candidate Chemicals List.

(a) Informational List.

BizNGO recommends updating the list annually:

“The Department shall post an informational list of the chemicals identified as Candidate Chemicals of Concern under section 69502.2(a) on the Department’s website within thirty (30) days after the effective date of these regulations. The Department shall ~~periodically~~ update the list **AT LEAST EVERY 12 MONTHS** to reflect changes to the

underlying lists and sources from which it is drawn, using the procedures specified in subsections (c) and (d).”

Rationale: Given that the authoritative bodies that generate the lists referred to in § 69502.2(a) regularly update their lists, the Department needs to develop a process for keeping these lists up-to-date. An annual automatic update of the lists based on changes by the relevant authoritative bodies is an easy task.

### **§ 69503.2.(b)(3) Safer Alternatives.**

BizNGO supports the availability of safer alternatives as part of its decision in listing a product-chemical combination as a Priority Product.

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

#### (a) Petition Process

BizNGO supports the provision “to add to or remove from the lists specified in section 69502.2(a)”. It is important that the lists from authoritative bodies be updated periodically updated as new scientific research emerges.

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

#### (d)(2) Public review and comment

BizNGO strongly supports this provision, which provides for the “public review and comment of each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan”. It is the quality assurance mechanism that is needed now that the certified assessors and accreditation bodies’ provision has been removed.

BizNGO recommends adding “Final AA Report to this provision:

“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~~ Alternative Process AA Work Plan, **and Final AA Report** submitted to the Department.”

Rationale:

Without adding “Final AA Report” there will be no quality assurance review of the final AA, which includes economic and technical feasibility.

### **§ 69505.2 Removal/Replacement Notifications in Lieu of Alternatives Analysis.**

#### (b)(9)(D) The name of the replacement chemicals

BizNGO supports the requirement to provide information on the name of the replacement chemicals, concentration, and hazard traits. This information is necessary for the Department to ensure that the removal or reformulation does not increase potential exposures or adverse impacts.

#### (e)(2)(B) “The replacement chemical(s) meet the criteria specified in subparagraph 1. or subparagraph 2. of subsection (b)(9)(F)”

BizNGO recommends the following change:

“The replacement chemical(s) meet the criteria specified in subparagraph 1. ~~or~~ **subparagraph 2.** of subsection (b)(9)(F)”.

Rationale: As written in b)(9)(F) subparagraph 2., the Department will allow the replacement of a Chemical of Concern in a Priority Product with a Candidate Chemical to happen without an Alternatives Analysis. This is an example of a regrettable substitution. The Department should not allow a Priority Product to be replaced with a Candidate Chemical without an Alternatives Analysis done to determine if a safer alternative exists to both the Priority Product and the Candidate Chemical.

#### § 69505.4. Alternatives Analysis Process and Options

##### (b) Abridged AA Reports

BizNGO recommends adding to the list of requirements an Abridged AA Report must meet:

NEW 69505.4(b)(5) The responsible entity demonstrates that no functionally acceptable or technically feasible alternatives is/are available, including why Sample Alternatives Analyses for similar products listed by the Department per section 69505.(b) are not relevant, and providing equivalent data as required in section 69505.7(j)(2)(A)”

Rationale: The Responsible Entity needs to identify the sources used to determine the availability of alternatives and why any alternative found was determined not to be equivalent and thereby qualifies for an Abridged AA Report.

#### § 69505.5. Alternatives Analysis: First Stage

(b)(1)(B) BizNGO supports allowing the responsible entity to “consider any identified alternative in the AA, or explain in the AA Report why such an alternative is not viable for consideration.”

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

BizNGO suggests the following changes in bold:

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

(A) Use available information on hazard traits and environmental and toxicological endpoints and any other relevant information to identify the following for each alternative replacement chemical under consideration:

1. Adverse environmental impacts;
2. Adverse public health impacts;
3. Environmental fate;
4. Physical chemical hazards; and
5. Physicochemical properties.

**The Department may specify in guidance materials tools that are sufficient for meeting the requirements of this subparagraph.**

(B) Compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated under subparagraph (A). **The Department may specify in guidance materials tools methods that are sufficient for meeting the requirements of this subparagraph.**

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

Rational: Given the scope of endpoints involved in compliance with this provision, BizNGO recommends that the Department identify through Guidance Materials (69505.(a)) tools that are sufficient for meeting the requirements of this section.

(c)(2) BizNGO recommends that the Department specify that alternatives equivalent to the existing chemical(s) of concern be dropped from further consideration in the first stage:

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

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

**Rationale:** The regulations currently do not require a responsible entity to eliminate a chemical that has the potential to pose adverse impacts equal to or greater than those posed by the Chemical of Concern. It would be more consistent to ensure that replacement chemicals that pose adverse impacts equal to or greater than those posed by the Chemical of Concern.

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

§ 69505.6. (a)(1) BizNGO recommends combining exposure pathway determinations in Section 69505.6(a)(1) and 69505.6(a)(3).

§ 69505.6. (a)(2)(A) BizNGO recommends the following change:

Multimedia life cycle impacts for the Priority Product and alternatives under consideration, and chemical hazards and adverse impacts for the Chemical(s) of Concern and any alternative replacement chemical(s) or other chemicals in the alternatives that differ from the chemicals in the Priority Product. This evaluation shall be based on available information and shall include the following factors to the extent relevant:

- 1. Adverse environmental impacts;**
- 2. Adverse public health impacts;**
3. Adverse waste and end-of-life effects;
- 4. Environmental fate;**
5. Materials and resource consumption impacts;
- 6. Physical chemical hazards; and**
- 7. Physicochemical properties.**

**Rationale:** The Department has not explained how the evaluation under Section 69505.6. (a)(2)(A) differs from the evaluation required under the first stage at Section 69505.5(c)(1)(A). The Department must clarify the Regulations to distinguish the analysis to be conducted between the first stage and second stage and ensure that any duplicative analysis is eliminated. BizNGO recommends modifying Stage 2 to focus on life cycle issues, including material and resource consumption impacts and waste and end-of life impacts not addressed in Stage 1. By focusing on the resource consumption and waste impacts, standard LCA-based approaches open up as a possibility for completing the Stage 2 analysis.

§ 69505.6. (a)(2)(C)(2) BizNGO recommends the following change:

(B) Economic impacts.

1. If none of the alternatives under consideration are Candidate Chemicals or Chemical(s) of Concern, no economic analysis is required.
2. If any replacement chemical under consideration is a Candidate Chemical, or if the Priority Product with the Chemical(s) of Concern is to be retained, the responsible entity shall evaluate, monetize, and compare the following impacts of the Priority Product and the alternatives:
  - a. Quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs;

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

Rationale: The Regulations have been revised regarding the economic impacts, but unfortunately the Department has retained the requirement that responsible entities monetize and evaluate externalized costs. The type of economic impact analysis required is extremely difficult to perform, particularly when there are multiple alternatives under consideration or when no alternative under consideration shows significant burden shifting. BizNGO recommends tiering the economic analysis requirements such that eliminating the Chemical of Concern and replacing it with a non-Candidate chemical requires no economic analysis, and that retaining the Chemical of Concern or replacing it with a Candidate Chemical requires a complete economic analysis, including consideration of externalized costs. (Externalized costs are extraordinarily hard to calculate, and should not be required for cases where the Chemical of Concern is being phased out.)

§ 69505.7.(a)(4)(A) BizNGO supports the provision that a responsible entity claiming information in an AA Report as trade secret provide a separate publicly available AA Report with trade secret information removed. The Department could clarify here and elsewhere in the Regulations that it is only this redacted AA Report for which it would seek public comments.

§ 69505.7. (d)(3) BizNGO encourages the Department to avoid requirements that include commercial sensitive information in a AA Report, which will serve as a disincentive for responsible entities to prepare a joint AA. The Department should be encouraging the development of a single AA for a particular chemical-product combination, for this will decrease review burdens and allow for uniform, fair regulatory responses. Particular responsible entity and supply chain information could be submitted later in the process in response to an audit request under Section 69508 or as part of the regulatory response. At a minimum, the Department should allow for separate attachments to the AA for individual responsible entities submitting commercially sensitive information.

§ 69505.7. (j) BizNGO supports the Department's revision to allow the selection of more than one alternative.

§ 69505.8.(b)(4)(A) BizNGO recommends the following change:

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 **for each chemical product combination**. The Department shall specify a due date that is twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify an extended due date for submission of the Final AA Report **for a chemical-product combination** if it determines based on information in **any of** the Preliminary AA Reports or Alternate Process AA Work Plans that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report **for a chemical-product combination** if **any** the responsible entity submits a request under section 69505.7(k)(1)(B).

Rationale: The Department must state clearly that all AA Reports and Work Plans will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all. Just as the Department extends a comment period for all persons based on the

extension request of one, so too must the Department ensure that all AA Reports and Work Plans are submitted simultaneously to ensure that entities are treated fairly in having the same amount of time to prepare AA Reports and Work Plans. Equally importantly, entities must not be disadvantaged by the Department reviewing AA Reports and Work Plans successively and making regulatory response determinations.

§ 69506(a) BizNGO recommends the following change:

(a) Need for Regulatory Response. The Department shall identify and require implementation of one or more regulatory responses **applicable to all responsible entities** for Priority Products and/or selected alternative products when the Department determines such regulatory responses are necessary to protect public health and/or the environment. In selecting regulatory responses, the Department shall seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.

Rationale: In these proposed regulations the Department is theoretically allowed to select different regulatory responses for different responsible entities. BizNGO finds this possibility unfair and believes it creates a situation ripe for claims of impropriety by the Department with regard to different treatment for different entities. Also, compliance and verification of compliance within the regulated community is greatly complicated if different entities have different requirements for similar Priority Products. If the Department is concerned with ensuring that its procedures are standardized, fair, and objective, then the Department should ensure the regulations provide a level playing field by stating that all AAs for the same chemical-product combination will be reviewed by the Department at the same time, and that the Department will issue a uniform regulatory response. For the Department to conduct simultaneous reviews, it must also ensure that the deadlines for submission as the same.

§ 69506(c) BizNGO recommends the following change:

Notice of Proposed Determination. After issuing a notice of compliance or a notice of disapproval for a Final AA Report or a final Abridged AA Report, the Department shall issue a notice of the Department's proposed determination **applicable to all responsible entities for a chemical-product combination** that one or more of the regulatory responses specified in this article is/are required, or that no regulatory response is required.

Rationale: The Regulations must be revised throughout to reflect the fact that the Department will issue uniform regulatory response(s) for a particular chemical-product combination.

§ 69506.4 BizNGO supports the revisions that state the Department may impose restrictions on replacement Candidate Chemicals as that may discourage the use of other Candidate Chemicals to replace Chemicals of Concern and specifies that the Department can control replacement alternatives when

**Ansis M. Helmanis, Esq.**

**Special Counsel**

4834 Van Ness St NW  
2<sup>nd</sup> Floor  
Washington, DC 20016  
Telephone: (202) 244-9586  
Telefax: (202) 244-9581  
ahelmanis@mac.com

February 27, 2013

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

RE: Comments on Regulations for Safer Consumer Products Department  
Reference Number: R-2011-02  
Office of Administrative Law Notice File Number: Z-2012-0717-04

Boots Retail USA appreciates the extent to which the Department of Toxic Substances Control (DTSC) has addressed comments submitted by Boots in December 2011 on the Draft Regulations for Safer Consumer Products. We do, however, wish to draw your attention to the following additional comments concerning the Post-Hearing Changes made to the Proposed Regulations:

Sec. 69501.1(a)(57): Definition of “Reliable Information”

The Post-Hearing changes to the definition of “Reliable Information” in the Proposed Regulations appear to open the door to the acceptance by the DTSC of non-scientific information in support of petitions to amend the Candidate Chemicals List and Priority Products List. We recommend amending the definition to explicitly recognize only data that has been developed according to established Good Laboratory Practices (GLPs). For example, the data that supported the regulatory decisions to include the chemicals in each of the European Union lists in the Candidate Chemicals List were developed in compliance with established GLPs.

Moreover, the federal Environmental Protection Agency (EPA) relies on Good Laboratory Practice Standards (GLPS) to ensure the quality and integrity of test data submitted to the EPA in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), section 5 of the Toxic Substances Control Act (TSCA) relating to a federal list of chemicals of concern, and pursuant to testing consent agreements and test rules issued under section 4 of TSCA with regard to hazard and exposure findings..

**Ansis M. Helmanis, Esq.**  
**Special Counsel**

Data developed according to established GLPs provide regulatory authorities in the U.S. and Europe with the assurance that the information can be relied upon when making assessments as to the hazards and risks to users, consumers and third parties, including the environment, posed by chemicals in pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. The assurance rests on the fact that the supporting data was developed within an internationally harmonized science-based framework wherein the studies were planned, performed, monitored, recorded, reported and archived.

The DTSC should base its decision-making under the Proposed Regulations on the same GLP science-based evidence that was used to support the regulatory decisions to include the chemicals that are now in the lists that form the core of the Proposed Regulations, namely the Candidate Chemicals List.

Section 69505.6: Alternatives Analysis: Second Stage

The Post-Hearing changes to this section add a new economic impact assessment obligation, namely “Public health and environmental costs”, and further expands to include non-profit organizations a revised second assessment category - “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.”

Before finalizing the Proposed Regulation, we would recommend that the DTSC assess the extent of the economic impact that these substantially expanded assessment obligations would now impose on a company whose product has the misfortune to be included in the Priority Products List. Federal regulatory agencies, such as the EPA, are obligated by Executive Order 13563 to design regulations in the most efficient, least burdensome, and most cost-effective manner - and so should the DTSC, especially now in an economy struggling to recover.

Executive Order 13563 requires federal agencies “to use the best available techniques to quantify anticipated present and future benefits and costs [of the proposed regulation] as accurately as possible.” The impact analysis is intended to “provide a reasoned determination” by the federal agency that the benefits of the proposal justify the costs. We recommend that the DTSC undertake such a cost-benefit assessment of the Proposed Regulations.

Sincerely,

Ansis M. Helmanis

cc: Steve Lloyd, CEO, Boots Retail USA



February 28, 2013

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

Via Fax (916) 323-5542 and E-Mail [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**SUBJECT: Draft Regulations for Safer Consumer Products (January 29, 2013 Release)**

Dear Ms. Von Burg:

The California Chamber of Commerce (CalChamber) submits these comments to the Department of Toxic Substances Control (DTSC or Department) regarding its proposed Safer Consumer Products Regulations (Proposal or Proposed Regulations) as released on January 29, 2013.

The CalChamber represents the interests of more than 13,000 California businesses. Nearly three-fourths of CalChamber members are small businesses with 100 or fewer employees. Nearly one-quarter of all jobs in the private sector in California are provided by our members.

Simply put, businesses need to be able to objectively determine what their regulatory compliance obligations and associated costs will be in order to plan, hire and invest appropriately. The CalChamber's primary objective throughout the development of the Proposed Regulations has been to help educate the Department about the way businesses operate to ensure that the final program will be workable, and allow for efficient regulation of truly hazardous chemicals that pose real health risks to consumers. While we appreciate all the work the Department has put in over the past four years to develop such a program, and acknowledge there have been numerous changes and additions to the various drafts to try and address specific concerns raised by the business community, the most recent version still fundamentally fails to meet these basic objectives.

The Proposed Regulations still do not provide adequate information about how large and small businesses will be impacted, how they will be regulated, or how their compliance will be judged by the Department. There is no way to accurately predict how many thousands of CalChamber members will eventually be regulated under the program by looking at the expansive list of chemicals that may be targeted by DTSC, based on their use in any number of still-undefined product categories. Furthermore, because the Department has failed to articulate the specific obligations regulated entities will be asked to comply with, we cannot advise our members about what these Proposed Regulations will cost or how to best plan for compliance.

The CalChamber continues to believe that the Proposed Regulations can be dramatically improved to adequately define the responsibilities and liabilities of regulated businesses, and provide them with adequate tools to fulfill their obligations, while ensuring protection of consumers. However, we also understand that the Department intends to wrap up this process within the next few months, and it may not be possible to address the many residual concerns raised by the CalChamber and other business groups during prior comment periods. At a bare minimum then, we would like to see the final draft of the Proposal include four key changes:

- 1) **A meaningful peer-reviewed economic analysis completed *prior* to submission of the Proposal to the Office of Administrative Law (OAL).**
- 2) **Elimination of the public review and comment component for Preliminary AA Reports, draft Abridged AA Reports, and Alternate Process AA Work Plans.**
- 3) **A penalty exemption (financial and otherwise) for the first round of regulated entities.**
- 4) **Addition of a review and revision period to follow completion of the first round of implementation.**

### **Perform a Meaningful Economic Analysis**

On October 5, 2012, in a letter responding to Senator Michael Rubio and 15 other legislators, Director Deborah Raphael stated that DTSC intends to conduct a “rigorous and comprehensive economic analysis at the time of Priority Product selection,” that will include information about the effects of the regulations on job creation/elimination, business competitiveness in California, investments in the state, incentives for innovation, and benefits of the regulations. As an explanation for the delayed timing of the analysis, Ms. Raphael stated, “the regulations that DTSC has proposed establish a process only and, “at this point, the regulations do not impose any duties on any business in California.” Therefore, “the economic impact of the regulations cannot be known,” until implementation is underway.

While the CalChamber is pleased that the Department plans, at some point, to conduct an economic impact analysis as required by California Government Code Section 11346.3, enacted by SB 617 (Calderon; D-Montebello) in 2011, and while we understand that the Department feels it will be in a better position to assess the costs of the program once implementation has begun, we do not believe the analysis the Department has in mind complies with the new law.

The language of Government Code Section 11346.3 (e) states that an economic analysis should be conducted, “prior to submitting a proposal to adopt, amend, or repeal a regulation to the office.” It goes on to say that, “analyses conducted pursuant to this section are intended to provide agencies and the public with tools to determine whether the regulatory proposal is an efficient and effective means of implementing the policy decisions enacted in statute or by other provisions of law in the least burdensome manner.” The baseline for the analysis should be the, “most cost-effective set of regulatory measures that are equally effective in achieving the purpose of the regulation...” This language, taken together, shows that the economic analysis is to be conducted *before* regulations are submitted to the OAL for review, and certainly before implementation begins, because the whole purpose of the analysis is to inform the decision making of the regulatory agency and make sure the regulatory program that is ultimately adopted in the most cost-effective way to effectuate the purpose of the underlying statute.

While it is true that work on the Proposed Regulations began before passage of SB 617, the law requires an economic analysis for regulations promulgated before November 1, 2013<sup>1</sup> prior to submission of those proposed regulations to the OAL. As such, it would be contrary to law, not to mention illogical, for the Department to wait until implementation has begun to evaluate whether the program itself should be implemented in its current form.

Nor is it sufficient for the Department to answer that the information sought by the economic analysis is “unknowable at this time” because the Proposed Regulations “do not yet impose any duties on any business in California,<sup>2</sup>” or identify which chemicals will be regulated as part of which product categories.

---

<sup>1</sup> Government Code Section 11346.3 (a)(3) “An economic analysis prepared pursuant to this subdivision for a proposed regulation that is not a major regulation or that is a major regulation proposed prior to November 1, 2013, shall be prepared in accordance with subdivision (b).”

<sup>2</sup> See page 2, letter to Members of the Legislature, October 5, 2012, by Director Deborah O. Raphael, which states, “The characterization of the economic impacts as ‘unknown’ may have been better stated as ‘unknowable at this time.’ It is important to note that the regulations that DTSC has proposed establish a process only and at this point, the regulations do not impose any duties on any business in California. The economic impact

The Department has, draft after draft, refused to narrow the list of chemicals it may choose to regulate or to define how it will select chemicals from that list and identify product categories for regulation. It cannot now use that lack of specificity as a justification for not knowing what the economic impact of the regulatory program will be. If the Department cannot determine, in any way, what possible range of economic impacts the Proposed Regulations might have on the economy, it is an indication that the Proposal is too vague to be implemented, as the business community has argued from the beginning, not a justification to proceed with implementation regardless of the potentially enormous economic impact it could have, depending on what the Department chooses to do with its unlimited discretion down the road.

Furthermore, other regulations set forth a process without imposing an automatic duty on a business. Are all future regulations of this type to be exempt from the economic analysis requirement established by SB 617? Looking to the California Environmental Quality Act (CEQA) as an example, that law and the related regulations establish a process by which an agency, having decided to undertake a project, must determine whether the project could have a significant impact on the environment, whether that project is exempt from CEQA, and whether the agency needs to do an Economic Impact Analysis or some other type of analysis. Until an agency decides to undertake a project, CEQA imposes no duty on anyone, and even once an agency identifies a project it wants to undertake, the range of costs faced by that agency can vary dramatically depending on whether the project qualifies for an exemption or requires a full EIR, and on whether that EIR is challenged in court down the road, not to mention all the economic impacts the project may have on others outside of the agency.

The Legislature, in enacting SB 617, cannot have intended to let new regulatory schemes of this magnitude go without an economic impact analysis, yet the Department seems to be asserting that if the economic impact cannot be assessed with certainty, or if the regulation merely proposes a process, a regulatory agency can skip this step altogether or at least wait until implementation is already underway before conducting its analysis. The CalChamber wholeheartedly disagrees with this view and asks that the Department conduct a meaningful, peer-reviewed economic impact analysis of the Proposed Regulations *prior* to submitting them to OAL for approval, as is required by law.

### **Delete the Onerous Public Comment Component**

In the Proposed Regulations, Article 5, Section 69505.1 (d) now clarifies that DTSC plans to post each Preliminary Alternatives Analysis (AA) Report, draft Abridged AA Report, and Alternate Process AA Work Plan on its website for public review and comment. These comments are to be submitted directly to the regulated entity who drafted the document so that that entity can summarize its consideration of these comments in its final report to the Department. To the best of our knowledge, this is the only proposal of its kind in California which, if enacted, would impose a substantial and inappropriate burden on businesses.

Public review and comment requirements within the regulatory realm are usually imposed to make sure a regulatory body complies with statutory requirements, creates a feasible program, and considers a variety of stakeholder concerns when doing so. Again looking to CEQA as an example, within the CEQA review process the goal of publishing documents and allowing for public comment is to give the public the opportunity to hold government entities (lead agencies) accountable for their decision making as it affects the environment. While those lead agencies may confer with business to inform their responses to the public, it is the agency that is ultimately accountable and responsible for responding to the public. This proposal would turn that model on its head, requiring businesses that are already required to be responsive to the Department to then respond to any and all questions and alternatives raised by members of the public, without regard to their reasonableness or germaneness.

Furthermore, asking a business to respond to public comments is not appropriate during the AA process. These documents are a regulated entities' chance to explain to the Department what it deems feasible

---

of the regulations cannot be known until DTSC, in carrying out this process, identifies a particular chemical of concern in a consumer product that is subject to the duty to perform an alternatives analysis.”

and cost-effective, based on its unique business concerns and constraints. It should be the Department's responsibility to use its scientific expertise and understanding of industry concerns to weigh this input against other feedback it receives when determining what regulatory responses are necessary and appropriate in any given circumstance.

### **Provide Penalty Relief and the Promise of Certainty**

California Health & Safety Code section 25253 (c) charges the Department with making, "every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchasing decisions." Rather than providing simplified and accessible tools at the outset, though, the Department has repeatedly stated that it will be in a better position to clarify what it needs from regulated entities, and to develop tools to help those businesses comply, once it begins implementation of the program. This viewpoint effectively treats the first group of regulated entities as guinea pigs who will be subject to whims of the Department while it figures out what it wants through trial and error. Under this approach, those first businesses will be subject to higher costs, more burdensome information requests, and greater uncertainty than those who are regulated in the future.

The CalChamber feels that the Department should fulfill its statutory obligation and provide manufacturers, distributors, and retailers with adequate tools up front. However, if the Department feels this cannot be done until it has begun implementation of the program, it should, alternatively, build a review and revision period into the regulations, and commit to taking the time to create those tools and add necessary details to the regulations once the first round of compliance concludes. This will make sure that entities subject to regulation in the future have the guidance they need and were promised by the law, and that the deadlines and requirements in the regulations are both feasible and reasonable.

In addition, if the Department chooses to finalize the Proposal without addressing this pervasive lack of specificity and guidance, we ask that the final regulations at least include a penalty relief provision so that the first group of regulated entities can collaborate with the Department without fear of possible financial penalties<sup>3</sup> or formal declarations that they are out of compliance<sup>4</sup>.

### **Conclusion**

While many of CalChamber's specific concerns with the language in the Proposal, as raised in our prior comment letters and through our participation in the Green Chemistry Alliance, remain unresolved, we are cognizant of the Department's desire to move ahead and begin implementation. As such, we have chosen to focus on those issues that are most critical to ensuring the long term success of the Safer Consumer Products Initiative. It is our sincere hope that the four recommendations discussed in this letter will be adopted prior to submission of the Draft Proposal to OAL.

We look forward to assisting the Department as it reconsiders and revises its Proposal. Should you have any questions, please feel free to contact me at 916-444-6670.

Sincerely,



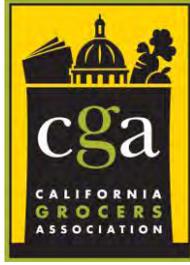
Mira Guertin  
Policy Advocate

---

<sup>3</sup> See California's Health and Safety Code, Section 25251.2.

<sup>4</sup> See section 69501.2 of the Proposed Regulations, Duty to Comply and Consequences of Non-Compliance.

cc: Debbie Raphael, Director, Department of Toxic Substances Control  
Martha Guzman-Aceves, Deputy Legislative Secretary, Office of Governor Edmund G. Brown



February 28, 2013

Krycia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
Sent via e-mail to: gcregs@dtsc.ca.gov

**Re: Division 4.5, Title 22, California Code of Regulations Chapter 55. Safer Consumer Products – Proposed Regulations, R-2011-02 (January, 2013)**

Dear Ms. Von Burg:

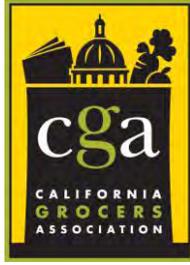
On behalf of the California Grocers Association and its member companies, I respectfully submit the following comments relative to the Safer Consumer Products (Chapter 55 of Division 4.5 of Title 22, California Code of Regulations) July 2012 Proposed Regulations (Green Chemistry).

CGA is a non-profit, statewide trade association representing the retail food industry since 1898. CGA represents approximately 400 retail members including chain and independent supermarkets, convenience stores and mass merchandisers operating over 6,000 food stores in California and Nevada, along with approximately 300 grocery supplier companies.

We appreciate the Department's efforts in redrafting portions of the proposed regulation, significant concerns remain with several sections. I have noted the most significant below.

**Definitions – Section 69501.1**

“MANUFACTURER”: The addition of new verbiage still creates confusion as to whether a retailer would be considered a product manufacturer despite the fact that they do not in fact manufacture a product or actually exercise control over what chemicals are used in the product. It is unrealistic to expect a private label retailer to have knowledge of specific ingredients of products they do not themselves manufacture, even if they specify characteristics like scent, color, etc... Use of the phrase, “...has the capacity to specify” chemicals is overly broad. Theoretical capacity is a very different matter than actual business practice. What the new verbiage in effect does is place every retailer in the position of a manufacturer because there is a theoretical possibility that they would dictate chemical usage in products. Even in cases where a private label retailer specifies that a product should be free of a given chemical (BPA free for example), they are not in a position to determine what chemical(s) a manufacturer uses instead. Yet use of the phrase “had the capacity to specify” ignores that practical fact.



Ms. Krysia Von Burg  
February 28, 2012  
Page 2 of 2

The issue of defining a manufacturer is a difficult one, indeed, but we feel there is a way to properly outline roles and responsibilities and ensure actual manufacturers are primarily responsible for the products they manufacture. We suggested language in our comment letter dated October 11, 2012 and in fact also found the definition used by the Department in the July, 2012 draft acceptable as well. The underlying statute is clear, product manufacturers are the primary entities responsible for compliance and any definition of “manufacturer” should be true to that mandate.

### **Priority Products List – Section 69503.5**

A significant issue appears to remain with regard to retailers and the requirement to provide the Department with certain information about priority products. On Page 40, line 4 the regulation requires, “... each responsible entity...” to submit detailed information to the Department about priority products and contact information for the person responsible for complying with the requirements of the regulation unless other specified notices have been submitted. We believe the Department will be inundated with thousands of pieces of paper. A much more rational approach would be to require only one responsible entity, the manufacturer, to submit such information and require other parties to do so only if manufacturers fail to comply.

### **Dispute Resolution – Section 69507**

Significant concerns remain with the proposed regulation in the area of dispute resolution. The proposal still appears exclude significant sections of the regulation (ie identification of candidate chemicals, petition process, trade secret protection) from dispute resolution entirely. While we appreciate the attempt to respond to some comments made regarding the area of dispute resolution we are unsure what authority the Department has to limit or eliminate due process rights of regulated entities.

I thank you in advance for consideration of these comments. While we do appreciate the efforts made in several areas we still feel additional work must be done to draft a proper regulation in this arena. Should you have any questions about these comments, please do not hesitate to contact me. And thank you, again, for consideration of noted concerns.

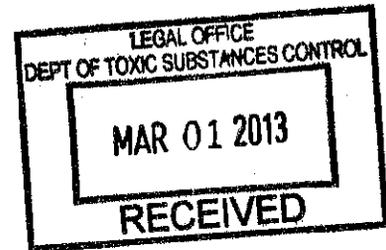
Thank You,

A handwritten signature in black ink that reads "Keri Askew Bailey". The signature is written in a cursive, flowing style.

Keri Askew Bailey  
Vice President, Government Relations  
California Grocers Association

February 28, 2013

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



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

Dear Ms. Von Burg:

On behalf of the California Healthcare Institute (CHI), I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") revised proposed Safer Consumer Products Regulation ("regulation") of January 2013. Additionally, CHI has filed comments to all prior iterations of the regulations, including the July 2012 proposal.

CHI was founded in 1993 and represents California's premier biotechnology, pharmaceutical, diagnostics and device companies, venture capital firms, public and private universities and academic research institutions. California is home to over 2,300 biomedical companies, the largest number of biomedical companies of any state in the country. California's biomedical companies generated annual revenues of nearly \$70 billion. The biomedical industry employs approximately 270,000 people in California, paying \$15.5 billion in annual wages.

CHI appreciates the goal of California's Green Chemistry Initiative to significantly reducing adverse impact to human health and the environment. We are committed to the goals of the legislation but remain concerned that the sufficient standards of scientific scrutiny and protection of intellectual property have not been met in this latest iteration.

Many of our members produce FDA-cleared medicines and devices, and are thus exempted from the subject regulations. The regulations, however, risk choking off the very R&D that enables such breakthroughs. It is within the purview of the DTSC to "gap fill" this anomaly by extending the exemption for FDA-cleared products to the preceding R&D, or through one of the exemptions proposed below, and we encourage you to do so.

CHI is focusing these comments on the need for codified exemptions to the Safer Consumer Products Regulations, to protect important research conducted in environments removed from retail consumers. 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 the 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 human and environmental exposure to chemicals. Second, 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 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 that 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 US Department of Transportation, and the US 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 due to 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, and pharmaceutical markets. 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, pharmaceutical and biomedical device manufacturing and development laboratories.

For these reasons, we recommend that DTSC incorporate an exemption into the Safer Consumer Products regulations to exempt products manufactured for (i) R&D use or

manufactured in an R&D setting, or (ii) use in standards and other tests used to determine whether such Chemicals of Concern are present in the environment or in a particular product. 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

An exemption for laboratory use is justified for many of the same reasons supporting an R&D exemption. 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 Product 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. It is commonly recognized that exposure is affected by the net quantity and how a chemical substance is dispersed into the environment. Establishing a threshold for R&D materials, consistent with the most proactive and restrictive international regulations, would be in the interest of protecting public health and the environment. Typically, these limits are 100 - 1000Kg depending on the stated toxicity of the substance.

#### DTSC Should Reinstate the Bulk Chemicals Exemption

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 less sophisticated retail consumers; rather, they are intended for intermediate uses like by manufacturers for the purpose of manufacturing end-use products that will then be made available to retail consumers.

This exemption would help DTSC maintain focus on retail consumer products typically used in the home, which, because of the sophistication of the consumers, are the class of products that pose greater overall actual risk for human health and environment based on potential for exposure and likelihood of harm data. This is the class of products where DTSC can most impact the protection of human health and the environment. We also believe these are the products that are the target of the law that forms the foundation of this regulatory program. Importantly, this exemption would not altogether exempt chemicals from review under the Safer Consumer Product regulations. Such chemicals could still be reviewed if, after sold by the manufacturer in bulk, they are later incorporated into a retail consumer product. The exemption would allow for 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 is added to 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 logical place for the obligations such as the alternative analysis to lie, because the retail product manufacturer is more familiar with the technical and commercial information required by the draft regulations to be considered. A bulk chemical manufacturer not selling to retail consumers may not have this information, particularly for bulk chemicals that may have dozens or hundreds of applications.

We appreciate your consideration of our concerns. For further information, please contact me at [stewart@chi.org](mailto:stewart@chi.org) or 916-233-3490.

Sincerely,

A handwritten signature in black ink, appearing to read "Victoria Stewart", with a long horizontal line extending to the right.

Victoria Stewart  
Associate Director – State Government Affairs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & 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



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

**CIHC Board:**

President, Ron Hutton, CIH  
Pacific Health & Safety, Inc.  
Mission Viejo, CA

Vice-President, Edward Klineberg, PhD, CIH  
Northrop Grumman Information Systems  
McClellan, CA

Treasurer, Richard Bohner, MS, CIH  
Health Science Associates  
Sacramento, CA

Secretary, Samantha Chiss, MS, CIH  
General Atomics  
San Diego, CA

**Directors:**

Gloria Chen, CIH  
County of San Diego Environmental  
Health/DMP  
San Diego, CA

Stephen Derman  
MediSHARE Environmental Health &  
Safety Services  
Cupertino, CA

Julia J. Kinnedy, PhD, CIH  
UCLA School of Public Health  
Los Angeles, CA

Chris Latsze-Davis, MS, CIH  
The Environmental Quality Organization, LLC  
Aluminum Consulting Engineers (ACE)  
Lafayette, CA

Howard Spaulman, PE, CIH, CSP, REHS  
Health Science Associates  
Folsom, CA

Jaime Steadman-Lytle, CIH  
Health Science Associates  
Los Alamitos, CA

**Alternates:**

Joel Cohen, MPH, CIH  
The Cohen Group  
San Mateo, CA

Alex Graham, CIH  
U.S. Navy  
San Diego, CA

Patricia Kivvild, CIH  
IWA Safety & HAZMAT Consultants, Inc.  
El Dorado, CA

Leo Vortum, PE, CIH, MS, MPH, REHS  
Nisepex Beach, CA

**Special Advisors:**

Patricia Beach, MS, CIH  
Francis & Lee Environmental Services, LLC  
San Francisco, CA

Larry Giblin, MPH, MPH, CIH  
Stanford University  
Palo Alto, CA

Deb Martin, MS, CIH  
Pacific Biosciences  
Menlo Park, CA

Wick Wells, MS, CIH, CSP  
Director, Occupational Safety & Health  
San Francisco Department of Health  
San Francisco, CA

**Sacramento Advocacy:**  
Catherine Baranik  
CIHC Legislative Office  
Sacramento, CA

February 26, 2013

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

**Re: Comments on Safer Consumer Products. Reference Number: R-2011-02**

Dear Ms. Von Burg:

The California Industrial Hygiene Council (CIHC) is very pleased with the Department of Toxic Substance's efforts to incorporate stakeholder inputs in this latest version of the Safer Consumer Products Regulation.

Founded in 1990, the CIHC represents the occupational and environmental health profession in California and is affiliated with the American Industrial Hygiene Association (AIHA), an 11,000 member national organization, as well as the International Occupational Hygiene Association (IOHA), which represents the global community of Occupational Hygiene organizations in over 34 countries.

We do, however, respectfully submit the following comments regarding the latest version of the Safer Consumer Products, Chapter 55 of Division 4.5, Title 22, California Code of Regulations to recognize the regulation's improvements, as well as outstanding areas of concern, which ensure that its actual implementation is achievable and adds value to California's overarching efforts to manage risk properly.

**Recognized Improvements:**

The CIHC is encouraged by the following improvements:

***Elimination of Certified Assessor-*** CIHC supports the removal of the "certified assessor" requirement and supports the quality assurance mechanism and public review process.

***Candidate Chemical-*** CIHC supports the change in terminology to "candidate chemical" unless the chemical becomes listed in a "priority product" and designated as a "chemical of concern" with respect to the specific product. The move towards a more focused set of "chemical candidates" is favorable since it incorporates both hazard trait **and** exposure when identifying human health and environmental safety concerns.

***Priority Product "Phase-In"-*** CIHC supports the focused start-up with the decision to select a maximum of five priority products to start the program. An initial beta-test phase for implementation will help resolve data management and administrative issues, while optimizing resources and ensuring that the regulation accomplishes its desired objectives.

**Outstanding Concerns:**

This newest version still does not address our most central comments (as outlined in previous submittals) and echoed in the scientific peer review process. The CIHC restates the need to focus the regulation on consumer product substances that pose "true risks" for human health and the environment (based on hazard, exposure, and probability of harm) as opposed to substances identified on the basis of "hazard traits" alone.

Key areas that pose a challenge for the successful adoption of the regulation include the following:

***Product Prioritization (PP) Process:***

While the CIHC supports the phase-in approach for PP, it is not clear how the DTSC will select the first set of products to “beta-test” the regulation. It is critical for the agency to be transparent in detailing the selection criteria and rationale to support the decision making process for the initial product prioritization.

***Availability of Data:***

The regulatory process is contingent on having quality data that is reliable, reproducible, and publically available. The data required to demonstrate functional and technical equivalence is unlikely to be readily available for comparisons, thus making the alternative assessment process problematic. It is unclear how the data gap issue will be addressed.

***Alternative Assessment (AA) Methodology:***

The Alternative Assessment (AA) process is unlikely to yield results that evidence clear benefits across the spectrum of environmental and human health end points. The AA process will likely involve weighing additional competitive functional and commercial parameters which rely on factors such as performance, availability, and cost, among others. A transparent decision making process should be outlined that combines the use of scientific data and value judgments needed for the comparative assessment processes.

***Alternatives Assessment (AA) Timeframe:***

The timeframe for the AA process is unreasonable, particularly given how resource intensive it is. The AA process encompasses the following: 1) consolidate the inventory across the supply chain, 2) conduct the impact assessment, 3) analyze and validate the results, and 4) innovate and manufacture a new alternative product. The proposed timeframes and resources for the AA process reflect an implementation naivety that will prove very challenging and costly for manufacturers to meet.

***Practical Quantitation Limit:***

The CIHC is concerned about the Agency’s change in the proposed regulation which would set the threshold for an Alternatives Assessment exemption using the Practical Quantitation Limit (PQL) of the priority product’s specified chemical of concern, as opposed to defining a specific *de minimis* concentration for the substance. This would mean that any detectable level of chemical, even at the parts per trillion level, could trigger the need for an AA. This approach ignores the “threshold” concept of toxicity concern, and completely eliminates the concept of *de minimis* concentration as a threshold concept. It replaces the appropriate science of toxicology and dose-response with the technological ability and sensitivity of analytical instrumentation. This is critical!

It is the sincere hope of the CIHC that we can continue to assist in helping craft a process that is transparent and effective in endorsing products that mitigate adverse environmental and human health exposures to both workers and the general public alike.

Should you wish to discuss our comments further, please contact us.

Respectfully Submitted,

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

Deborah Martin, MS, CIH  
Special Advisor  
P: (650)-269-1512  
[dmartin@pacificbiosciences.com](mailto:dmartin@pacificbiosciences.com)



February 28, 2013

**VIA EMAIL**

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

**RE: Revised Regulations for Safer Consumer Products (R-2011-02)**

Dear Ms. Burg:

The California Manufacturers and Technology Association (CMTA) submits the following comments to the Department of Toxic Substances Control (DTSC) regarding the revised regulations for Safer Consumer Products issued on January 29, 2013.

This ninth iteration of regulations still contains the majority of the same problems that we have voiced following the release of earlier drafts. The manner in which DTSC has dealt with trade secrets, end of life, duplication of authority, the alternatives assessment threshold, time restrictions, assembled products, the global supply chain and many other factors portray a simplistic knowledge of how complex manufacturing is and how many decisions must be weighed in producing a consumer product.

We echo the concerns raised by the Green Chemistry Alliance, the Toy Industry Association, the Food Packaging Coalition, the American Chemistry Council and the Durable Goods Coalition in their letters on this draft. The regulations as proposed will be extremely costly for those companies unfortunate enough to be selected and will likely seriously jeopardize their continued viability.

We have no doubt that there may be consumer products on the market that could be manufactured using less toxic chemicals and could be just as effective, but we maintain that they are few and far between.

Due to the fact that you have retained unfettered discretion on virtually every aspect of the regulations, companies have no idea what it will take to satisfy you. We aren't sure if it is going to cost a couple hundred thousand dollars to comply or a couple million. The uncertainty leaves DTSC vulnerable to tremendous political pressures that they would not be subjected to if there was a known scientific process that described how your decisions will be made.

CMTA understands that you have very likely made all of the major changes that you plan. In that light, we agree wholeheartedly with the course of action recommended by the California Chamber of Commerce. The first companies that find themselves faced with the daunting task of trying to figure out what will satisfy your department will definitely require additional guidance. We would like to see DTSC specify a group of individuals within the department who will collaborate with these companies so that they will know exactly what it will take to be in compliance.

That said, we honestly believe that you need to take another look at the way you have constructed these regulations. This could have been done in a manner which would satisfy the law and at the same time been far less destructive to California's economy. The uncertainty that these regulations cause due to their breadth and vagueness will have a detrimental effect on investment capital being spent on expansion at California facilities and the potential attraction of new manufacturing.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Rogge". The signature is fluid and cursive, with the first name "Michael" being the most prominent part.

Michael J. Rogge  
Policy Director, Environmental Quality



## ***California New Car Dealers Association***

---

February 28, 2013

Ms. Deborah Raphael  
Director  
Department of Toxic Substances Control (DTSC)  
P.O. Box 806  
Sacramento, CA 95812-0806

***RE: PROPOSED SAFER CONSUMER PRODUCTS REGULATION***

Dear Director Raphael:

The California New Car Dealers Association (CNCDA) is a statewide trade association which represents the interests of over 1,300 franchised new car and truck dealer members. CNCDA members are primarily engaged in the retail sale of new and used motor vehicles, but also engage in automotive service, repair, and parts sales. We are writing to provide comments and suggested solutions to issues raised by the proposed amendments to the “Safer Consumer Product Alternatives” (Green Chemistry) Regulations.

CNCDA has actively participated in commenting on the Green Chemistry Regulations since before the initial draft Regulations were circulated in 2010. We have supported the development of a science-based process to improve the safety and reduce the environmental impact of consumer products in California, but have had significant concerns with previous drafts due to the burdens those proposals placed on California dealers and other retailers. While the currently proposed regulation marks an improvement from previous drafts, CNCDA still has procedural and policy concerns with several provisions.

Each comment described herein also contains suggested amendments to address our concerns. We appreciate this opportunity to provide comments and suggestions to the Department and look forward to continuing to work with the Department on amendments.

**REPLACEMENT PARTS FOR FORMER PRODUCTS**

The fact that the proposed regulation applies to replacement parts for products no longer manufactured (and therefore not subject to the regulation) creates uncertainty for manufacturers, retailers, and consumers. Manufacturers currently design original and replacement parts concurrently, but will continue to manufacture replacement parts to fulfill warranty obligations to consumers. Retailers depend upon the availability of replacement parts to repair products they sell. Consumers depend upon the availability to replacement parts to repair products to extend

their useful life. With replacement parts subject to the regulatory proposal, manufacturers of existing products will be forced to either produce a large number of replacement parts at once, and bear the storage expense over the remaining warranty period, or risk the expenses of having the replacement parts subject to Green Chemistry requirements (which may involve reengineering, use restrictions, or sale prohibitions). This is CNCDA's largest remaining concern with the regulatory proposal, and we reiterate our request that the existing regulatory exemption for products that ceased to be manufactured prior to being listed as a Priority Product be expanded to include replacement parts for such products.

*Suggested Fix –*

(24)(A) “Consumer product” or “Product” means any of the following:

1. A “consumer product” as defined in Health and Safety Code section 25251; or
2. When applicable, a component of an assembled “consumer product.”

(B) “Consumer product” or “Product” does not mean a product that ceased to be manufactured prior to the date the product is listed as a Priority Product, or a replacement part for such a product.

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

**CERTAIN RESPONSIBLE ENTITY MANDATES LACK CLARITY**

Section 69501.2 provides that retailers and assemblers must comply with requirements applicable to a responsible entity only after the manufacturer and importer have failed to comply and a notice of non-compliance is posted on the Failure to Comply list. This properly reflects the manner in which the burdens of compliance should be allocated. Sections 69503.5(e) and 69503.7(a), however, require “each responsible entity” for a product-chemical combination listed on the Priority Products List to provide a Priority Product Notification to the Department within 60 days. This language is ambiguous, as retailers and assemblers of such products are unsure whether they must provide this notification, or whether the mandate applies only to the responsible entity subject to the Duty to Comply provisions (i.e., the manufacturer, then the importer if notified, then the retailer/assemblers if notified). Without further clarification from the Department, these provisions fail to adhere to the Clarity standard of the Administrative Procedures Act, as they are reasonably susceptible to multiple interpretations.

*Suggested Fixes –*

- 1) On page 40, line 4, delete “Each” and insert “The”.
- 2) On page 43, line 30, delete “each” and insert “the”.

**THE DEPARTMENT LACKS AUTHORITY FOR EXPANDED CHEMICAL AND PRODUCT  
INFORMATION REQUESTS**

The amended draft dramatically expands the ability of the Department to require entities to submit or generate information. While the previous draft gave the Department the authority to request the applicable responsible entity of a product or chemical to provide existing information or generate new information, the amendments provide the Department with unfettered authority to request such information from any product or chemical manufacturer, importer, retailer, or assembler. This authority is further expanded in applicability by changing the definitions of such entities, for purposes of the section, to include entities in the supply chain of products *expressly exempted by the legislature* from the Green Chemistry regulations. The Department could, effectively, require any entity on the planet to provide any information it deems (in its sole judgment) necessary to implement the regulation. The legislature clearly did not intend to grant the Department with such unlimited discretion and authority. Accordingly, the recent amendments should be withdrawn.

**“MANUFACTURER” DEFINITION IS OVERBROAD AND LACKS CLARITY**

While the recent amendments to the definition of “manufacture” provide a significant improvement, the amendments to the definition of “manufacturer” in §69501.1(a)(44) create additional concerns. The amended definition reads as follows:

“Manufacturer” means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, *or has the capacity to specify* the use of chemicals in, such a product. (emphasis added).

By including in the definition of manufacturer all parties who have the “capacity to specify” the use of chemicals in a product, the Department takes what should be and was previously a patent definition and turns it into a latent definition. In other words, the definition of “manufacturer” should be based upon *activities* taken by the entity—if an entity does X, it is considered a manufacturer under the regulations. Instead, that latest amendment defines manufacturers—the entities saddled with primary responsibility for regulatory compliance—as entities *capable* of acting. If an *actual* manufacturer (an entity that produces a product) provides an option of using various chemicals in the composition of the product (e.g., plastic bottles containing BPA or BPA-free bottles), all entities who purchase either version of the product would qualify as the manufacturer of the product. While we believe the language of this definition is intended to apply to situations where a retailer directs a manufacturer as to the substances to be used in creating a custom-made consumer product, this language is susceptible to a much broader interpretation. The Department must establish a clear line of demarcation to

Director Deborah Raphael

February 28, 2013

Page 4 of 4

clarify when activity crosses the line from merely causing a product to be manufactured, as opposed to manufacturing activity itself.

*Suggested Fix* – Provide language in the draft definition to clarify that configuring a product does not render a person as a manufacturer.

“Manufacturer” means any person who manufactures a product that is subject to the requirements of this chapter, or any person that controls the manufacturing process for, or ~~has the capacity to specify~~ *specifies* the use of chemicals in, such a product. (emphasis added).

### CONCLUSION

Thank you for this opportunity to comment on the proposed regulation. We look forward to working with DTSC to address our concerns in the near future. If you have any questions or comments concerning this letter or Green Chemistry issues in general, please feel free to contact me at (916) 441-2599, or at [jmorrison@cncda.org](mailto:jmorrison@cncda.org).

Sincerely,



Jonathan Morrison  
Director of Legal & Regulatory Affairs

February 25, 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](mailto:gcregs@dtsc.ca.gov)

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

Dear Director Raphael:

The California Product Stewardship Council (CPSC) is an organization of local governments and businesses from all parts of California who have come together to support a transition to producer responsibility for managing discarded products. California local governments have now passed 133 resolutions supporting producer responsibility, representing sixty-three percent of the state's population. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. We support the development of regulations that would promote the re-design of these problem products.

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

Thank you for being receptive to our comments dated October 5, 2012, on the previous version of the regulations, to ensure we have stakeholder input annually on the manufacturer's end-of-life management plan.

While **we strongly support the proposed regulations**, we suggest that you make the following modifications.

Section 69501. Purpose and Applicability:

- (1) **Definitions** – Section 69501.1 should be expanded to provide clear definitions of the terms “recycling,” “recyclability” and “capture rate.”
- (2) **Applicability and Non-Duplication** – The language regarding overlapping regulatory programs appears to interfere with the Department's ability to regulate discarded products that may contain water pollutants or other constituents that would make them regulated household hazardous wastes. Specifically, it appears to allow exclusion based on regulation of the pollutant in emissions or discharges (e.g., Clean Air Act, Clean Water Act) rather than regulation of the product itself. Products containing water pollutants or other constituents which would cause them to be deemed household hazardous waste should not be allowed to be excluded from this Chapter. *It is exceptionally important that household hazardous waste products not be excluded from these regulations. To clarify, we suggest deleting Section 69501(b)(3)(A) (page 5, starting on line 20).*

Section 69506.7. End-of-Life Management Requirements:

- (3) **Program performance goals** – In order to ensure the proper role of government in any producer responsibility system, the State should establish the performance standards in consultation with the manufacturers, as well as other affected stakeholders, such as local government agencies that bear a cost burden associated with the current end of life management of the product. The manufacturers or stewardship organizations should identify how to attain those standards in their stewardship plans, and report on their progress annually. Additionally, it should be noted that not all hazardous products are recyclable and can only be used “beneficially” to produce energy. As such, the end-of-life management requirements should not exclude or prohibit the beneficial use of hazardous materials, and should encourage source reduction. Therefore, we suggest the following language (page 63, starting on line 37): *(H) Program performance goals established by the Department in consultation with the manufacturers or stewardship organizations and affected stakeholders, which shall be quantitative to the extent feasible, for: 1. Increasing the capture rate of covered products at the end-of-life; ~~and~~ 2. Increasing recyclability, ~~and~~ recycling rate, and beneficial use; and 3. reducing waste generation. (I) A description of how each program performance goal will be achieved by the manufacturer or stewardship organization.*
- (4) **Annual reports** – In order to ensure transparency, any producer responsibility system should require audited financial statements in the annual reports. This is especially critical to make certain that funds raised to implement the end of life management plan are not used to fund litigation against DTSC or other State departments. Therefore, we suggest the following language (page 63, starting on line 18): *(5)...The report must include, ~~by total tonnage:~~ (A) The quantity, by total tonnage, of products placed into the stream of commerce in California over the previous one-year period; ~~and~~ (B) The quantity, by total tonnage, of products recovered over the same one-year period; and (C) an independent financial audit of the end-of-life management program. The audit shall be conducted in accordance with auditing standards generally accepted in the United States of America, and standards set forth in Government Auditing Standards issued by the Comptroller General of the United States.*
- (5) **Alternative End-of-Life Programs** – In order to allow effective, flexible and diverse programs, producer responsibility systems should not be limited to retail take-back as the sole collection mechanism. Therefore, we suggest the following language (page 64, starting on line 25): *(d)...A manufacturer subject to this section may request the Department’s approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A manufacturer may not propose an in-store take-back program as part of an alternative program unless the manufacturer provides in the plan evidence that a sufficient number of retailers have agreed in writing to participate. ~~If a manufacturer’s alternative end of life program relies on other persons to achieve its capture or recycling rates, be it retailer, contractors, or others, manufacturers must provide written substantiation of their participation~~ to insure successful implementation of the plan as proposed.*
- (6) **Sales prohibition** – The end-of-life management section implies but does not explicitly state that non-compliant manufacturers are prohibited from selling subject products in the State. To clarify the intent, we suggest adding the following statement to the end of section 69506.7.(a) (page 62, starting on line 34): *A manufacturer of a product subject to this section that is not in compliance with this section must cease placing the subject product into the stream of commerce in California, directly or indirectly.*
- (7) **Management of products that retain a Chemical of Concern** – The end-of-life management section [69506.7(a)] seems to preclude the Department from requiring management of products that retain a Chemical of Concern during a long phase out period. Specifically, 69506.7(a) seems to conflict with 69506.1(a)(3). To clarify, we suggest the following language (page 62, starting on line 30): *(a) Applicability. A manufacturer of a selected alternative, a priority product that will remain in commerce in California pending development*

*and distribution of a selected alternative, or a Priority Product for which an alternative is not selected... shall comply with the requirements of subsection (c) except as otherwise provided under subsections (d) and (e).*

Section 69509. Assertion of a Claim of Trade Secret Protection:

- (8) **Trade Secret Protection** – This Chapter should not allow a manufacturer’s private non-disclosure agreement (e.g., an agreement between a chemical supplier and a manufacturer) to prevent disclosure of information to the Department. Allowing two private parties to agree to hide information from the State seems very inappropriate and sets a dangerous precedent. Therefore, we recommend the following changes (starting on page 72, line 41): *(c) Documentation. A person who asserts a claim of trade secret protection shall also at the time of submission provide the Department with both of the following: (1) Except where expressly prohibited by federal law, ~~or by a nondisclosure agreement whose relevant text is provided to the Department,~~ a complete copy of the documentation being submitted, which shall include the information for which trade secret protection is claimed; and (2) A redacted copy of the documentation being submitted, which shall exclude the information for which trade secret protection is claimed.*

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

Thank you for your consideration.

Sincerely,



California Product Stewardship Council

Enclosure: Who is CPSC Fact Sheet



February 28, 2012

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

**RE: SAFER CONSUMER PRODUCTS, R-2011-02: Comments on January 29, 2013 Draft Regulations**

Dear Ms. Von Burg:

The California Retailers Association submits the following comments in response to the January 29, 2013 draft of the proposed Safer Consumer Products Regulations.

**Definition of Manufacturer** (page 14, lines 17-20):

Unfortunately, the addition of a completely new phrase in the definition of "manufacturer" upends the foundation of the implementing statute and the regulatory framework by making all private label retailers de facto manufacturers. The proposed definition now reads: "*A manufacturer means any person that controls the manufacturing process, or has the capacity to specify the use of chemicals in such a product.*" By the use of the phrase "has the capacity to...", every retailer will by default become a manufacturer because *any* retailer "has the capacity to specify", yet most of them do not. Our Association has already agreed that a retailer that specifies use of a Chemical of Concern in a product should be deemed a manufacturer. But the Department's new language encompasses all retailers that private label as "manufacturers" because it includes those who *could possibly, might be able to, potentially could* specify a chemical but who do not do so.

Previous versions of the draft regulation, up until July 2012, defined "manufacturer" as: "*Manufacturer means any person who manufactures a product*". We had no issue with that definition. In the July 20, 2012 Initial Statement of Reasons, the Department explained it was changing the definition because "The private label retailer may wish to have more control over production and may dictate to the manufacturer specifications for raw material, ingredients or designs in a contract." The definition was changed to "*Manufacturer is any person who manufactures a product, or any person that controls the specifications and design of or use of materials in, a product*". We concurred with the Department's statement that, upon occasion, some private label retailers will want control over production and may direct use of specific chemicals, and that these retailers could legitimately be deemed "manufacturers", because of the combination of control and chemical specification. We argued that retailers normally instruct their private label manufacturers as to the general design parameters of their product--color, fit, style-- and that such design direction does not constitute control of the manufacturing

process nor specification of chemicals. The Department responded in the current draft with a new definition: "A manufacturer means any person that controls the manufacturing process, or has the capacity to specify the use of chemicals in such a product." The Department may, by removing the reference to "design or use of materials", have been attempting to resolve concern. However, it made the definition worse, in that it is now so broad that any retailer could be deemed a manufacturer, which was not the intent of the implementing statute. Nor is it consistent with the Department's tiered responsibility model as delineated in the Duty to Comply section of the regulation. The requirement that the retailer control the manufacturing process AND specify the affirmative use of certain chemicals, which is what we thought we had agreed to, is not evident in the current definition because of the use of "or" instead of "and", thereby removing the combination of control and chemical specification, and the addition of "has the capacity to specify chemicals", which is a completely different concept than actual specification of a chemical.

The new definition will have yet another negative result, one contrary to the Department's goal of reducing use of hazardous chemicals. As stated above, retailers who do not specify chemicals will become manufacturers, with all the responsibilities therein, because they had "the capacity to" specify a chemical even though they did not. Conversely, many retailers are beginning to specify chemicals they do NOT want in their private label products. More and more, responsible retailers are telling their suppliers that they want products without specified chemicals--bisphenol A, PBDEs, etc. Ironically, under the Department's new definition, retailers who tell their manufacturers they do not want candidate chemicals or chemicals of concern in their products will also be deemed manufacturers because they have "the capacity to specify chemicals"---even though they specified what they did NOT want to be included.

The phrase "controls the specification and design of, or use of, materials in a product..." was stricken from the proposed definition. Left alone, this would have resolved the problem, but the *addition* of the "capacity to specify" sabotaged the remediation. **We believe that the proposed definition fails the clarity standard, as well as conflicts with the Department's authority. The enabling statute clearly states that the regulations are to apply to manufacturers--and making another entity a manufacturer by virtue of their "capacity" do something they choose not to do, is completely confusing and inconsistent with the statute. We urge the Department in the strongest terms to clarify this definition.** To re-state, a definition that provides clarity, works operationally, is consistent with the statute and is consistent with the goal of the regulations would read: "Manufacturer means any person who manufactures a product subject to the requirements of this chapter, or any person that controls the manufacturing process and specifies the use of a chemical of concern to be included in such product."

Following are our remaining concerns with the proposed regulation:

**AA Threshold Notifications** (page 19, 69501.2(1)(B)):

The manufacturer is the only responsible entity permitted to file the Alternatives Analysis Threshold (69505.3) and Removal/Replacement (69505.2) notifications. That means importers, and potentially retailers, do not have the option to retain a product and opt out of the regulation by demonstrating that the chemical of concern may be a contaminant in negligible concentrations (below the PQL). Unfortunately, it is foreseeable that there will be failures to comply by foreign manufacturers. Some importers will do a better job than others in ensuring their manufacturers understand the regulation and fulfill their duties. But it is unduly restrictive to *preclude* importers/retailers from filing the AA Threshold exemption and confirmation, should they want to do so. Importers often actually do the testing that would support the AA threshold exemption. And it will be the importer, not the distant foreign manufacturer, who carries the liabilities for the various potential violations of federal and state safety, defect, consumer fraud, and unfair business practices laws. We recommend that the

importer and retailer be added as entities able to file AA Threshold Exemptions and Removal/Replacement Notifications, consistent with the Duty to comply tier of responsible entities.

**Replacement Parts** (page 11, lines 22-30):

The regulation will NOT apply to historic products, which we support. However, we believe an exemption from the regulation for *replacement parts* for historic products should be included in the regulation. Otherwise, the availability of replacement parts will shrink, causing financial hardship on replacement part manufacturers or retailers that still require replacement parts due to warranty or service agreements.

**Chemical and Product Information Gathering** (page 23, lines 29-31):

This section allows the Department to request chemical and product information from "manufacturers, importers, assemblers and retailers of any product or chemical not just those products or chemicals subject to the requirements of this chapter." We do not believe the Department has the authority to make information requests of retailers of ANY product, if not subject to these regulations.

**Priority Product Notifications** (page 40, lines 4-9):

Once the Department determines its Priority Products, within 60 days "each" responsible entity is supposed to notify the Department if it places those products into the stream of commerce. The Department has told us that they mean the responsible entity, beginning with manufacturers, and that retailers will only have to provide Priority Product Notifications if the manufacturer or importer doesn't. The Department indicated it did not want Priority Product Notifications from hundreds of thousands of retailers. However, "each" implies that manufacturers, importers and retailers are all *individually* responsible for the Notifications. On page 43, lines 3-42, "each" responsible entity is again referred to for Priority Product Notifications, requiring the "type, brand name and product names of Priority Products". This issue requires further clarification.

**Dispute Resolution** (page 90, lines 1-14):

This language specifies that decisions made under Articles 2, 4, or 9 (Process for Identifying Candidate Chemicals, Petition Process, and Trade Secret Protection) "are not subject to dispute resolution". It also specifies that the failure of a responsible entity to follow the dispute resolution procedures and timelines means the entity has lost its right to further contest the disputed issue. We do not believe the Department has the authority to eliminate a regulated entity's due process.

We do want to acknowledge the Department's actions to affirmatively respond to comments made by CRA. For example, we support the January 29, 2013 language that:

- Requires a public comment period and workshop for all proposed regulatory response determinations.
- Requires a manufacturer subject to creation of a product stewardship program as a Regulatory Response, to consult with stakeholders, with a minimum 30 days for public comments.
- Prohibits a manufacturer from proposing an EOL program that requires in-store take-back unless the manufacturer provides "evidence that a sufficient number of retailers have agreed in writing to participate to insure successful implementation of the plan."
- Adds a new statement that end of life requirements in the regulations can *only* apply to manufacturers, not importers or retailers, because the statute so requires.
- Adds new definitions of "assembly" and "component", and revises the definition of "importer" per our suggestion.

The Department has also clarified the timeframe for the retailer off-ramp; limited the Priority Products list to five initially; created a process for de-listing of a chemical; and added a priority products Work Plan that will allow for future planning. The Department's amended regulatory language has improved the Safer Consumer Products regulations in each subsequent draft, beginning with the "Straw Proposal", eight drafts and two years ago. We have made great progress, which unfortunately is threatened by a single revised definition, but which can be easily remedied.

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in cursive script that reads "Pamela B Williams". The signature is written in black ink and is positioned above the typed name.

Pamela Boyd Williams  
Executive Vice President  
California Retailers Association



## California Stormwater Quality Association<sup>®</sup>

*Dedicated to the Advancement of Stormwater Quality Management, Science and Regulation*

---

February 28, 2013

Debbie Raphael, Director  
California Department of Toxic Substances Control  
Office of Legislation & Regulatory Policy  
Attn: Krysia Von Burg, Regulations Section  
P.O. Box 806  
Sacramento, CA 95812-0806

**Subject: Comments on Proposed Safer Consumer Products Regulations  
(January 29, 2013; Ref No. R-2011-02)**

Dear Ms. Raphael:

The California Stormwater Quality Association (CASQA)<sup>1</sup> appreciates the opportunity to review and comment on the proposed Safer Consumer Products Regulations.

We view the regulations as an essential component of our efforts to comply with the federal Clean Water Act and the State Water Code. Controlling problem chemicals at the original source—in consumer products—is often the most cost-effective, and for some pollutants is the *only* effective method of ensuring they do not end up threatening aquatic life and human health. If problem chemicals are addressed in consumer products, then State and local agencies will not be forced to install, maintain, and operate expensive treatment facilities that have limited effectiveness for some pollutants in stormwater systems. Municipal costs savings could be significant – we have estimated the treatment cost for just one pollutant (copper) would be in the billions of dollars statewide. These costs are being partially addressed through implementation of SB 346, the brake pad bill. However, we expect that future regulation of pollutants associated with consumer products will need to be addressed through the Safer Consumer Products Regulations. In addition, reducing the pollutant load in urban runoff increases the viability of green technology projects that involve recharging the groundwater.

We appreciate the changes that have been made to earlier versions of these regulations, particularly changes to clarify and strengthen DTSC's ability to prevent water pollution. The substantial effort to incorporate water quality exemplifies DTSC's commitment to protecting the environment, especially water quality.

We strongly support adoption of the regulations and encourage DTSC to move forward with finalization of the rule. Timely implementation is important for California.

---

<sup>1</sup> CASQA is comprised of stormwater quality management organizations and individuals, including cities, counties, special districts, industries, and consulting firms throughout California. Our membership provides stormwater quality management services to more than 22 million people in California.

### ***Modifications to the regulations supported by CASQA***

We strongly support the inclusion of the 303(d) list in §69502.2 and consideration of public agency costs in the selection of regulatory remedies (§69506) and thank DTSC for making these additions. We also support the following revisions:

- **Threshold for alternatives analysis** – We support the use of the “practical quantification limit” and the Department’s discretion to set product-specific values.
- **“Ability” vs. “potential”** – We support changing the term “ability” to “potential” in the sections addressing adverse impacts or other negative effects (e.g., §69501.1. Definitions - *Adverse air quality impacts*).
- **Addition of factors for feasibility and practicality** – We support the changes to §69506. *Regulatory Response Selection Principles* that introduce factors related to practicality and the government’s interest in efficiency and cost containment.
- **Description of processes in the preliminary AA work plan** — We support the more detailed requirements of the work plan - see §69505.7(k)(1): “*The work plan must include a description of the process that will be used to identify the factors ...*”
- **Information for consumers regarding hazardous wastes** – We support the new provision in §69506.43 identifying the need to inform consumers if a product must be managed as hazardous waste at the end of its useful life.

### ***Recommended additional changes***

To ensure the regulatory program has the ability to provide timely protection to surface water quality while avoiding introducing new sources of water pollution, we recommend several modifications to the regulations, which we detail below.

1. **Increase AA comment periods** – As written, this comment period does not have a minimum length - meaning it could be as short as one day - and is currently limited to 45 days - see §69505.1(d)(2). We recommend that DTSC specify a minimum of 60 days because a shorter comment period may be inadequate for meaningful scientific input. A 90-day comment period is preferred; this could be the statutory maximum. Groups such as CASQA need to access scientific experts for these reviews and also require sufficient time to complete internal quality assurance and management reviews.
2. **Specify that engineering controls be allowed for environmental impacts** – We request the regulations allow the use of engineering controls not only for chemical releases that potentially harm human health, but also chemical releases that harm the environment during the life of the product – see §69506.6(b). This is consistent with other changes to the regulations that enable the program to effectively address adverse environmental impacts.

3. **Specify criteria for time extensions** – To ensure timely completion of the AA process, we propose that the Department identify specific criteria for its decisions on the acceptability of extensions - see §69505.7(k). Our experience with a related process, pesticide re-evaluation, with DTSC’s sister agency, the California Department of Pesticide Regulation, has demonstrated that, despite the best intentions, apparently straightforward questions commonly take more than a decade to answer. The criteria should provide for timely completion of scientific work.
4. **Provide for public comments on requests for exemption from regulatory response requirements** – We request the Department provide for public input on exemption requests – see §69506.9. In particular, it is important that affected public agencies and other parties have the opportunity to evaluate these requests.
5. **Modify requirement for matrix comparison of alternatives to increase readability of preliminary AA report** – This report should summarize and provide conclusions rather than “present” all the chemical information collected under Section 69505.5 in the matrix comparison of alternatives – see §69505.7(g)(1). Matrices could be rendered unreadable if they are the sole allowable format for presenting information, but would be useful for summary.

We support the recommendations of the California Product Stewardship Council (CPSC), including CPSC’s recommendations that DTSC establish end-of-life program performance goals (§69506.7(c)(2)(H)) and clarify the Department’s authority to require end-of-life management for products during a long phase-out of chemicals of concern (§69506.7(a)). CASQA also shares CPSC’s concern regarding the addition of language in §69509(c), referring to private confidentiality agreements. We ask that DTSC reconsider the language of §69509(c) to ensure that trade secret protections are maintained in a way that does not prevent agency review of information necessary to the program’s effectiveness.

To avoid misinterpretation of the provisions defining the relationship to other regulatory programs, we request that DTSC clarify for in the administrative record that the new text in §69501(b)(2)(A) does not in any manner interfere with the Department’s ability to regulate water pollutants that are currently addressed by the Clean Water Act and State Water Code.

***Include Water Polluting Product on Initial Priority Product List***

The Initial Proposed Priority Products List (§69503) will allow DTSC to address no more than five consumer products before January 1, 2016. We strongly request that at least one of the initial priority products be a product impacting California’s waterways. While human health is obviously top priority, it is also important to begin addressing products with strictly environmental impacts. Including a water-polluting product on the initial list will ensure that DTSC establishes the implementation processes necessary to address environmental impacts.

Once the initial restrictions on priority product selections are lifted in 2016, we anticipate needing DTSC’s assistance in addressing water-polluting products. For example, zinc is a toxic priority pollutant that has resulted in state waterways being classified as impaired. It is one of

## CASQA comments on Proposed Safer Consumer Products Regulations

the pollutants in urban stormwater runoff that frequently exceeds water quality standards at the point of discharge. A primary source in most urban runoff is tires, which we believe could be addressed by this program.

We believe these regulations will bring us much closer to the clean water and clean environment that is a basic right of the citizens of the state.

Thank you for the opportunity to provide comments. Please contact Geoff Brosseau, our Executive Director, at (650) 365-8620 if you have any questions or need additional information, or me at (714) 955-0670. We are also available to meet at your convenience to review the issues described in these comments

Very truly yours,



Richard Boon, Chair  
California Stormwater Quality Association

cc: Odette Madriago, Chief Deputy Director, DTSC  
Charles Hoppin, Chair, State Water Board  
Frances Spivy-Weber, Vice Chair, State Water Board  
Tam Doduc, Member, State Water Board  
Steven Moore, Member, State Water Board  
Felicia Marcus, Member, State Water Board  
Tom Howard, Executive Director, State Water Board  
Jonathan Bishop, Chief Deputy Director, State Water Board  
Darrin Polhemus, Deputy Director, State Water Board  
Victoria Whitney, Deputy Director, State Water Board  
Rik Rasmussen, Acting Assistant Deputy Director State Water Board  
Paul Hann, TMDL Section Chief, State Water Board  
Walt Shannon, Supervisor, Municipal Stormwater Section  
Greg Gearheart, Supervisor, Construction / Industrial Storm Water Section  
Alexis Strauss, Deputy Administrator, USEPA Region IX  
David Smith, Acting Director, Water Division, USEPA Region IX  
CASQA Board of Directors and Executive Program Committee

**COMMENTS ON THE  
CALIFORNIA SAFER CONSUMER PRODUCTS  
DRAFT REGULATIONS OF JANUARY 30, 2013**

**February 28, 2013**

**CHANGE Coalition  
Californians for a Healthy and Green Economy**

Californians for a Healthy and Green Economy (CHANGE) offers the following comments on DTSC's draft regulations to implement a Safer Consumer Products program under the authority of AB 1879. CHANGE is a statewide coalition of environmental and environmental justice groups, health organizations, labor advocates, community-based groups, parent organizations, faith groups, and others who are concerned with the impacts of toxic chemicals on human health and the environment.

We have closely tracked the development of the regulations by DTSC from the beginning. We appreciate that DTSC has provided CHANGE with the opportunity to provide the public interest perspective of our member organizations on this important effort.

Please let me know if you have any questions about these comments.

Sincerely,



Kathryn Alcántar  
CHANGE Coordinator

As we have observed before, CHANGE acknowledges that this is the first time a regulatory agency has set out to build a broad chemicals regulatory structure that has been mandated by statute to require analysis of alternatives to toxic chemicals. While other states may have programs that address certain classes of consumer products, California's program is unique in that it is required to examine a broad range of consumer products. This is the first time an agency has attempted to regulate chemicals, and the products that contain them, by focusing first on intrinsic hazard traits of chemicals rather than exclusively relying on risk assessment. This is the first time regulations of chemicals are attempting to incorporate cumulative exposures, which are a key public health concern as well as a long-standing demand from environmental justice communities. And, this is the first time manufacturers of consumer products will be required to formally answer the question, "Is the use of this hazardous chemical necessary in my product?"

This approach constitutes a long-overdue paradigm shift in how society should manage chemicals, and represents an effort to generate a process of continuous movement towards a green economy, which should include replacing toxic chemicals with non-chemical alternatives. Such an approach should have a focus on public, occupational, and environmental health, where the concept of primary prevention is essential.

This new draft represents both significant improvements and serious shortcomings in comparison to the previous draft released in October 2012. In particular, we are pleased to see that the standard of causation language has been addressed to reflect the statutory language of the law. We are also pleased to see that while the Alternatives Analysis Threshold process has been altered, it is still based in science and does not include a default level that would apply to all chemicals. We are also pleased to see that language exempting products that are made in California but not sold here will no longer be exempted from the regulations. Finally, we are pleased to see that the Alternatives Analysis process is much more transparent and open to the public.

Despite these improvements, the regulations contain significant shortcomings. First and foremost CHANGE vehemently opposes the alteration of the term "Chemical of Concern" and the introduction of the new term "Candidate Chemicals" to refer to the broad list of chemicals subject to this regulation. While we appreciate that the content of this list has been strengthened, we are dismayed at such a transparent capitulation to the demands of the chemical industry despite any basis in scientific fact. Moreover, we believe that this changing of the name intentionally deceives the public. In addition, other improvements that we and others in the public health, environmental, labor and sustainable business community have recommended have gone unheeded. Please see our detailed comments below.

Beyond these content issues, we wish to reiterate that this program will require a considerable investment in order for it to be successful in protecting the public and the environment. There is consensus among all stakeholders that DTSC does not have the resources to undertake implementation in a sustained way. DTSC has said that only 2-5 product categories will be identified in the first round, and a final alternative analysis report will take three years if all goes smoothly. The pace of work as outlined in the draft regulations will lead to very modest accomplishments. It would be impossible to argue that the program can generate any significant throughput without additional funding.

Providing DTSC with the means to implement this program should be a top priority for the Legislature. CHANGE intends to continue to communicate this priority to elected officials.

Furthermore, as we have consistently stated in the past, a "no data, no market" requirement must be developed to close the pervasive data gaps about chemical information and to put all chemicals, both new and old, on a

level playing field. DTSC's limited ability to create a requirement for a minimum data set for all chemicals in commerce under its existing authority is a critical shortcoming of the proposed program. Building a "no data, no market" mechanism into California's regulatory structure is a big job that remains to be undertaken. This is another key task for the Legislature: filling the data gaps outlined in the 2006 report "*Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*" which was commissioned by the Legislature in 2004.

These regulations are a product of four years of careful thought, consideration and advocacy on behalf of all stakeholders. We note that while we are pleased that this process is moving forward we must register our dismay at the pace of implementing this program. These regulations are now more than two years overdue. It is beyond time to start the work the legislature intended when the authorizing statute was passed in 2008. We hope that the length of time that has been used to create this program is not a preview for other important decisions that will be the result of these regulations.

CHANGE maintains its view that the draft regulations are in need of some important improvements in order to make the program as effective as possible. But it is vital for the program to be enacted quickly so that the Department may begin the important work outlined in the draft regulations.

---

**The regulations intentionally mislead the public with the term "Candidate Chemicals"**

Since the passage of the legislation authorizing the Safer Consumer Products program, the Department has consistently referred to the initial list of chemicals as "Chemicals of Concern." This was done not only because it was consistent with the legislation but it also reflected scientific consensus. The chemicals on the initial list are drawn from authoritative bodies around the world that have closely studied these chemicals and found them to be hazardous to human health or the environment.

The chemicals that are on this list are no longer in question. The debate on these chemicals has been settled—at some point in the production, use or disposal of the chemicals on this initial list, they harm human health or the environment. Context is, of course, important which is why the program is reviewing these chemicals in products and prioritizing them for action. However, we have always applauded the department's decision to call these chemicals "Chemicals of Concern."

The most recent draft of the regulations now refers to the initial list as "Candidate Chemicals," representing a departure from every previous version of the regulations and a departure from the intent of the authorizing legislation.

Referring to chemicals on the initial list as "Chemicals of Concern" is important for three reasons. First and foremost, it is intellectually and scientifically accurate. Renowned scientific bodies and experts have found enough data to place these chemicals on a list of known health or environmental hazards. Second, the legislature specifically used the term "chemical of concern" in order to provide the public with a frame of reference for the chemicals that would be examined as part of the program. Third, the department does not have the resources it needs to examine the hundreds of chemicals on this list in a timely manner. By labeling these chemicals as "of concern" to the state of California, it gives consumers the information they need to make choices about the products they buy, even if they are not a prioritized product.

The chemical industry and its allies have long lobbied against the term “Chemicals of Concern,” claiming that calling the initial list a “Chemicals of Concern” list will put the products that use these chemicals at a disadvantage over those that do not contain these chemicals. It should be noted that in most cases, the same industries and manufacturers were allowed to make their case to the authoritative bodies that are cited as part of the initial list. Their objections and rationales were heard and rejected and the chemicals that are represented on this initial list have met a high threshold and rigorous scientific debate has determined them to be toxic.

By the department acquiescing to the pressure exerted by those in industry seeking to change the name of the initial list, the administration is not only being scientifically inaccurate and bucking legislative intent, but most alarmingly it is aiding the chemical industry in their attempts to deceive the public about the true nature of these chemicals.

Changing the name of this list represents an attempt to allay the public’s well-placed concerns about these chemicals. If chemicals that have been identified by scientific experts across the world as toxic aren’t “of concern” to the state of California, then what are?

This change is a serious misstep by the Department and the Brown Administration and puts a cloud over the entire program. We strongly recommend that these regulations be modified and that the initial list of chemicals is referred to again as “Chemicals of Concern.”

---

### **Improvements to the Candidate List**

Despite our strong objections to the name of the Candidate list, CHANGE strongly supports DTSC's plan to post a robust list of Candidate Chemicals that relies on the work of authoritative science bodies within 30 days of the effective date of the regulations. The proposed list contains chemicals for which there is already sufficient cause for concern for human and environmental health. Relying on authoritative bodies, which have listed chemicals after comprehensive and peer-reviewed scientific processes, constitutes a thoughtful and reasonable process for the identification and prioritization of Chemicals of Concern.

A large Candidate Chemicals list will support, encourage, and stimulate efforts by forward-thinking entrepreneurs and businesses to voluntarily act before subsequent regulation compels them to do so. This will create jobs for California's green economic development. The size of this list will, as DTSC intends, help reduce the problem of regrettable substitutions. A large list will enable DTSC to use scarce resources for other important program activities.

While some may claim that the estimated 1,200 chemicals which will be listed is too large a number to be meaningful, it represents, in fact, only a small fraction of the more than 80,000 industrial chemicals currently registered for use in the U.S., most of which are not adequately tested for safety before reaching the market.

CHANGE also strongly supports DTSC’s intent not to rank chemicals on the Candidate Chemicals list in what would be a misguided effort to identify and prioritize the "worst" chemicals. We believe such an effort is inherently impossible because of the pervasive data gaps and difficult judgments that would be required to compare and rank different kinds of harm. It would result in an endless paralysis by analysis and lead to fruitless litigation over the resulting prioritization. Moreover, such ranking is not required by AB 1879. An

unranked list is consistent with the approach used by other states with similar programs. Chemicals on the list have made it through prioritization processes of a variety of reputable scientific bodies and legislative authorities. An unranked list also provides strong market signals so that manufacturers and others can begin looking for alternatives before products are prioritized.

We are dismayed, however, that the regulations do not explicitly state that the Candidate Chemicals list is automatically updated when any of the lists it relies upon are updated. We recommend that this change be made to the final version of the regulations to prevent the Department from using outdated scientific information.

We support the addition of the list of respiratory sensitizers identified under Category 1 in Annex VI to Regulation (European Commission) 1272/2008.

We also support the addition of chemicals identified as pollutants by California or the US Environmental Protection Agency pursuant to section 303(d) of the federal Clean Water Act and section 130.7 of title 40 of the code of Federal Regulations. This is the central list by which to identify water pollutants impairing the state's waters to the degree that they violate water quality standards as specified by the federal Clean Water Act and California's Porter Cologne Water Quality Control Act. It is necessary to include the contaminants on the 303(d) list in order to ensure that water quality is given the priority it deserves when identifying Priority Products.

Despite some improvements, the list still contains some shortcomings.

First, DTSC should ensure that all hazard traits identified by OEHHA are captured in its Candidate Chemicals list, including neuro-developmental hazard traits.

Second, the proposed Candidate Chemicals list needs some additions. While we are pleased that DTSC has added respiratory sensitizers to the list, we note that certain health endpoints of particular relevance to workers have been excluded yet again. Asthmagens and skin irritants/ sensitizers should be added to the list of Candidate Chemicals. OEHHA lists these hazard traits already (e.g., Chapter 54, s. 69403.16 Respiratory Toxicity) and there are lists available from both North America and Europe. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) also includes these hazard traits, which the US federal Hazard Communication Standard will require to be considered on "safety data sheets" in the next few years.

For asthmagens and other sensitizers, see:

- <http://www.cdc.gov/niosh/topics/skin> (NIOSH information about skin irritants and sensitizers);
- <http://www.aoecdata.org/ExpCodeLookup.aspx> (Association of Occupational and Environmental Clinics -- AOEC);
- <http://esis.jrc.ec.europa.eu/index.php?PGM=cla> (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction --

Other lists CHANGE recommends including are the following:

Washington State Department of Ecology *Reporting List of Chemicals of High Concern to Children* - <http://www.ecy.wa.gov/programs/swfa/cspa/chcc.html>

Minnesota's list of 1,700 chemicals of high concern in 2010 under the Minnesota Toxic Free Kids Act.

Maine's list of 1,700 chemicals of high concern in 2009 under the Maine Toxic Chemicals in Children's Products Law.

The Skin Disease portion of the Haz-Map database:

U.S. National Library of Medicine, Specialized Information Services

National Institutes of Health

Haz-Mat, Skin Disease

<http://hazmap.nlm.nih.gov/types-of-diseases>

Green Chemistry & Commerce Council, An Analysis of Corporate Restricted Substance Lists (RSLs) and Their Implications for Green Chemistry and Design for Environment, November 2008 (chemicals listed in Appendix 1)

<http://www.greenchemistryandcommerce.org/publications.php>

**§ 69502.2(b)**

CHANGE maintains its support for DTSC's ability to identify new Candidate Chemicals based on their hazard traits or environmental or toxicological endpoints. It is critical to provide this mechanism for additions to the Candidate Chemicals list that do not appear on existing authoritative body lists. New peer-reviewed science, for example, can point to health or environmental concerns before authoritative bodies can act. This is an important avenue for new chemicals of concern to be identified as soon as possible, and it further distinguishes the Safer Consumer Products program as forward-looking.

**§ 69502.2(b)(1)(D)**

CHANGE strongly supports the additional language allowing DTSC to consider "structurally or mechanistically similar chemicals for which there is a known toxicity profile" to be added to the Candidate List. Many chemicals are similar in structure and while data may not be as robust as to warrant being included on lists from authoritative bodies, nevertheless, structural activity can signal early warnings of harm and DTSC should be able to act on these warnings.

**§ 69502.3(a)**

DTSC needs to specify how often the Candidate Chemicals list will be formally updated. As currently written, DTSC will do this "periodically." CHANGE urges that the list be updated at least every two years.

**§ 69502.3(c)**

CHANGE supports the opportunity for formal public input on proposed revisions to the Candidate Chemicals list.

**§ 69504.(a)**

CHANGE supports the petition process whereby a person may petition DTSC to add or remove a chemical or the entirety of an existing chemical list to the SCP Candidate Chemicals list. However, we are alarmed that this petition process now includes a provision whereby entire authoritative bodies' lists may be removed. Despite DTSC's attempts to ensure that an entire list would only be removed in the case that the body's scientific standards were not rigorous, this leaves much to interpretation and potential mischief. CHANGE recommends that this portion be deleted.

---

**CHANGE strongly supports the definition of alternative analysis threshold as the practical quantification limit, and the removal of default alternative analysis (*de minimis*) threshold exemptions**

One of the most important improvements in the previous draft proposed regulations was the removal of the default alternative analysis threshold (AAT), or what had also been termed a “*de minimis*” level. CHANGE, along with many from the scientific community, members of the Green Ribbon Science Panel, a coalition of 44 wastewater agencies, and many other environmental and public health groups pointed out the serious problems inherent within the proposed default alternative analysis threshold. We were gratified to see that DTSC has addressed these serious concerns and eliminated default AAT thresholds from the proposed regulations.

While we recognize that the previously proposed default thresholds of 0.01 percent and 0.1 percent (depending on the health endpoint in question) was somewhat more protective than *de minimis* thresholds in other programs and that it was an improvement over the original proposed 0.1 percent threshold for all health endpoints, these default thresholds nevertheless lacked scientific justification and would have posed significant public health hazards.

For example, a consumer product could have contained 20 times more lead or arsenic, 100 times more cadmium, 200 times more benzene, and 500 times more mercury than what would be considered a hazardous waste under federal Environmental Protection Agency regulations, but be exempted *a priori* from undergoing alternative analysis under DTSC’s previous proposed regulations. Given that DTSC is the California agency that enforces EPA hazardous waste regulations, this provision of the regulations was simply unsupportable.

We also know from peer-reviewed research that some chemicals, previously thought to be harmless, can in fact have adverse impacts at extremely low doses. For the endocrine disruptor bisphenol A, for instance, effects can be observed in the parts-per-trillion range. A threshold of 0.01 percent would have failed to be protective by several orders of magnitude. Endocrine disruptors in general would have been under-recognized within DTSC’s proposed structure.

Moreover, the previously proposed default AAT exemption would have created perverse incentives than ran counter to the intent of the program. For example, product manufacturers would have been motivated to continue to use chemicals of concern (and other dangerous chemicals) as long as they were below the default AAT threshold.

Manufacturers would also have been motivated to replace a chemical of concern used at levels above the threshold with multiple chemicals of concern each at levels below the threshold. These counter-productive incentives would have undermined the intent and central goal of AB 1879, to prompt a search for safer alternatives.

We commend DTSC for its decision to affirm scientific integrity and define alternative analysis thresholds as the practical quantification limit for each product category/chemical combination the agency prioritizes for review. This approach is vastly preferable to a one-size-fits-all approach that lacks scientific integrity and undermines the intent of the Safer Consumer Products program.

CHANGE does have one concern about this approach, however. Our reading of the revised draft regulations

indicates that it is the product manufacturers themselves that will be defining what the practical quantification limit will be for each product category/chemical combination. This is certainly true in the case of “Alternatives Analysis Threshold Notification,” which is essentially a process whereby companies can be exempted from completing alternatives analysis. In our experience, product manufacturers have often claimed that detection limits for certain chemicals were much higher than what was actually the case. For this reason, it is important that the public be able to challenge companies’ claims about practical quantification limits when exemptions from the AA process are in question.

---

**Standard of causation language restored to reflect statute**

CHANGE strongly supports the change to the regulation that conforms to the authorizing statute’s burden of proof for causation. The most recent draft adds the word “potential” when discussing a chemical’s ability to contribute to or cause harm and properly defines “potential” as “reasonably foreseeable based on reliable information.

In making this change, this program has given itself the necessary authority to take action on chemicals with the potential to cause harm. The word “potential” was used very purposefully in the authorizing statute and we are pleased to see that the regulations are using the same terminology.

However, we do see some areas that still require attention.

First, the use of the term “potential” should be harmonized in §69502.2, which governs Candidate Chemicals Identification.

In particular, §69502.2(a) should recite that “a chemical is identified as a Candidate Chemical if it exhibits **the potential for** a hazard trait . . .” (emphasized material added). Since what follows are two very restrictive criteria, there is no need to impose the further restriction of being required to actually exhibit a hazard trait or endpoint rather than have the potential to do so. Indeed, we question why this phrase is needed at all and why the Regulations could not simply rely on the recited criteria without qualification.

Similarly, and for the same reasons, 69502.2(b) should recite “the Department may identify as Candidate Chemicals those chemicals that exhibit **the potential for** one or more hazard traits . . .” (emphasized material added). There is no reason to require a higher standard of proof for a chemical to be listed as a Candidate Chemical than the standard that applies to PP/COC determinations, Alternatives Assessments or Regulatory Responses – indeed just the opposite. Also, use of “potential” here would conform to the use of the word “potential” in 69502.2(b)(1)(B).

Second, 69505.2(b)(D) should recite that hazard traits and endpoints “with the potential to be associated” be disclosed rather than those “known to be associated.” The “potential” standard of evidence should apply in this situation so that DTSC can consider whether the replacement is indeed a better alternative or perhaps should even be listed as a Candidate Chemical. DTSC should also consider asking for studies and information on this issue to be submitted.

---

**Minimize regrettable substitutions**

The draft regulations include a new section that was not previously discussed in any manner in stakeholder meetings. Section 69505.2 allows for manufacturers that immediately replace a chemical of concern with another chemical to be exempted from performing an alternatives analysis provided that the replacement chemical is not a candidate chemical or that if the replacement chemical is a candidate chemical, the manufacturer can demonstrate that it is used by other manufacturers for the same purpose. While we understand manufacturers' desire to avoid a cumbersome alternatives assessment process and understand that moving from one chemical to another may be easily accomplished, we are confused as to why a program that is built on the principle of ensuring safe alternatives would allow manufactures to use chemicals that may be untested or that may not have yet been added to the candidate list. The entire purpose of this regulation is to avoid regrettable substitutes and this section almost ensures that regrettable substitutes will happen. For example, CHANGE can easily envision a scenario in which Polybrominated Diphenyl Ethers (PBDEs) were prioritized and the popular replacement, chlorinated Tris (Tris (1,3-dichloro-2-propyl) phosphate), was not. Both have negative health and environmental effects and neither should be used to replace the other. However, under this scenario, a manufacturer would be able to switch from PBDEs to chlorinated Tris without having to disclose this fact to consumers and without having to conduct an alternatives analysis to determine if there were safer alternatives. This section is all but guaranteeing the continuation of the "whack-a-mole" approach of the past. At a minimum, we recommend that any manufacturer seeking this exemption under this section be required to disclose the identity of this chemical to the public so as to increase transparency and allow consumers to make informed decisions.

While the above concerns may be alleviated through ensuring that all Candidate Chemicals used for a similar purpose in a product be prioritized at the same time, DTSC will not be able to do anything if a manufacturer moves from a candidate chemical to one that is not yet on the candidate list but has a large body of evidence demonstrating its negative impact on human health or the environment. While we appreciate and support the efforts DTSC is making to gather information on the replacement chemical by requiring the identity of the chemical and the hazard traits associated with it (see §69505.2 (b)(9)(D)), merely having this information does not allow DTSC to put any regulatory response in place to limit exposure to this chemical. Additionally, without an AA, DTSC and the public will not know if there were safer alternatives available to the replacement chemical. As such, we recommend that §69505.2 (b)(9)(F)(2) be removed.

CHANGE has previously recommended prioritizing classes or groups of chemicals or products rather than taking them up individually. Since many chemicals are structurally similar, it is easy to envision a scenario in which manufacturers will slightly alter a molecule so that it is technically a different chemical but in practice performs the same function and exhibits similar health impacts. Phthalates and PBDEs are examples of classes of chemicals where the above scenario has already played out in the market place. While these technically new chemicals may not have the body of data as their sister chemicals on a candidate list, it is important to note that absence of data does not equate to absence of harm.

---

**Cumulative exposures/impacts is an important component of the program.**

CHANGE strongly supports DTSC's efforts to build in cumulative exposure. Addressing this regulatory challenge is long overdue and is a fundamental concern for many environmental justice communities and public health experts. It is important and appropriate because emerging science shows that many of our environmental and public health problems stem from the cumulative impact of many diverse stressors, often including, but not limited to, numerous chemicals. The European Commission, for example, has recognized that multiple exposures from combinations of chemicals have not been adequately addressed in existing regulatory structures and has taken steps to develop new approaches – see <http://ec.europa.eu/environment/chemicals/effects.htm> .

California EPA is engaged in an ongoing process that is studying cumulative impacts (OEHHA’s Cumulative Impacts and Precautionary Approaches Workgroup). As OEHHA continues its work to develop tools to address this, we encourage DTSC to maintain its commitment to this issue.

What is important to consider is the impact of chemicals as they accumulate with other broadly defined environmental factors, not just “other chemicals with the same or similar hazard traits.” Therefore, as before, we recommend that the regulations include language that commit DTSC to examining cumulative effects not just with other chemicals but “with other environmental factors” which include, but are not limited to nutrition, the built environment, and socioeconomic status.

We recognize that cumulative impacts are difficult to quantify, and yet it is also important to not restrict the scope of inquiry. Qualitative or semi-quantitative analysis of the real scope of impacts is more likely to be useful than greater quantitative analysis of a small portion of impacts.

**§ 69502.2(b)(1)(A)(3)**

Current language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors.**

**§ 69503.2(a)(1)(c)**

Current language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors.**

---

**Environmental Endpoints**

CHANGE supports a number of revisions to the draft regulations that strengthen their potential to address the impacts of chemicals- and the products that contain them- on the environment, as well as human health. Most notable are the clarification that air quality refers to both indoor and outdoor air and the inclusion of the 303 (d)

list to the list of lists from which Candidate Chemicals and Chemicals of Concern will be chosen. This addition will help ensure that water quality is given the priority it deserves when identifying CoC/Priority Product combinations. We recommend that the regulations explicitly indicate that DTSC will review the list each time it is updated by the California State Water Resources Control Board.

There continues to be confusion and concern about the issue of overlapping regulations that could lead to DTSC not regulating water and other environmental pollutants. There is in fact a potential contradiction between sections 69501 (b) (2)(A) and 69503.2 (b) (2). In the first case, it appears that water and other environmental pollutants could be exempted from SCP regulation based on existing regulations of the pollutant in emissions or discharges, rather than regulation of the product that contains such a chemical.

When CHANGE asked for clarification about this very issue in the last iteration of the regulations, we were assured that if a chemical that is regulated by such laws as the Clean Water Act, the Safe Drinking Water Act, and the Clean Air Act is finding its way into the environment because of its presence in a product or products, DTSC would consider these other regulatory structures to be inadequately protective of public health and the environment and could regulate those product/chemical combinations through the SCP program. If, as we hope, this continues to be DTSC's intention, this needs to be made explicitly clear so that there is not any ambiguity for the public, environmental agencies, as well as chemical and product manufacturers.

CHANGE members are very disappointed that the language describing the initial list of Priority Products (§69503.6) continues to set restrictions on the chemicals to be considered in the first few years, requiring environmental toxins to also demonstrate a threat to human health. As an example, this restriction automatically leaves out products the use of which disperses substances such as zinc or copper to waterways, causing severe damage to the aquatic environment without demonstrable human exposure.

While CHANGE does not oppose regulating chemicals in products that have both health and environmental endpoints, explicitly stating this restriction sends a troublesome message about how the Department prioritizes environmental endpoints and what can be expected after this first pilot process. Consequently, we would again urge DTSC to eliminate this explicit restriction. Most importantly, we strongly urge the Department to consider input from other environmental agencies (including air boards, water boards, and waste, storm, and drinking water entities), as well as the environmental and environmental justice communities, to ensure that product/chemical combinations that demonstrate clear environmental endpoints are included in the first round of the SCP regulations

---

**Occupational health and worker protection has improved but more changes need to be made to give workers equal protection.**

CHANGE has consistently stated that workers must be included as part of this program and must not be assumed to be protected by other laws that may be outdated or may not address the hazards this program is attempting to address. We appreciate that significant changes have been made to address our previous concerns and we acknowledge that more can still be done to ensure workers are given adequate consideration in this program. These proposals are detailed below.

**§ 69501(b)(2)**

DTSC has deleted a problematic provision that would have illegally limited the definition of consumer product in the regulation. We understand that while products placed into the stream of commerce for the sole purpose of

manufacturing an exempted product may not be first on the priority list, we nevertheless appreciate the removal of this provision as it was inconsistent with the authorizing statute.

**§ 69501 (b)(3)**

CHANGE also notes that the language exempting products produced or transported through the state but not sold here has been removed. Again, we appreciate this deletion as it was inconsistent with the statutory definition of consumer product. While these products also may not be prioritized for action in the early days of the program, it is vital to not exempt these products when they do not have to be. Products manufactured in the state, whether sold here or not, have an impact on the environment and public health. Deleting this clause ensures that the workers who make these products and communities that live near manufacturing facilities will be protected.

**§ 69501.1(a)(2)**

CHANGE supports the inclusion of indoor air quality in the definition of adverse air quality impacts. Indoor air can sometimes be more toxic than the air outdoors and explicitly including this language will capture a number of indoor air pollutants that had not been captured by the old definition.

**§ 69501.1(a)(6)**

CHANGE supports the language that states, "Public health includes occupational health." This is consistent with the definition and understanding of public health within the Occupational Safety and Health Section of the American Public Health Association.

**§ 69501.1(a)(58)(A)(2)**

We support this section where "reliable information demonstrating the occurrence of exposures to a chemical" includes monitoring data that shows the chemical to be "present in, or released from, products used in or present in homes, schools or places of employment."

**§ 69501.5**

We support this section that will make information available on DTSC's website, which will enhance workers' right to know about the hazards of products they use, and the Injury and Illness Prevention Programs their employers must prepare.

Unfortunately, the information will only be available in English. This does little for the many people in the state with literacy issues in that language. We recommend that the list of chemicals of concern and priority products should be available at least in Spanish. Other government agencies do this (e.g., Cal/OSHA, DLSE).

**§69503.3(b)(3)**

CHANGE supports the inclusion of the workplace in DTSC prioritization deliberations since chemicals are used both in the home and in the workplace.

**§69505.7 (e)(4)**

CHANGE supports the inclusion of Material Safety Data Sheets relating to a priority product in an Alternatives Analysis Report. We recommend that this language be altered, however, to reflect that MSDSs will soon be known as Safety Data Sheets or SDSs under the upcoming Globally Harmonized System/GHS rules in the state's Hazard Communication Standard, and elsewhere in the world.

**§ 69505.7(g)(2)(B)**

CHANGE supports the requirement that the preliminary AA reports include information about which “relevant safeguards” in other regulatory programs were considered.

**§ 69506.3**

Product information for consumers, as specified in this section, also needs to be made available to workplaces. “Consumer products” are used in workplaces and by workers every day. As members of the public, they have as much right to know about hazardous chemicals and products as others, including consumers.

---

**Workers are appropriately included in the definition of “sensitive sub-populations”.**

**§ 69501.1(a)(58)**

CHANGE supports the inclusion of language in this definition that identifies workers as a sensitive sub-population when they experience greater chemical exposures due to the nature of their occupation. It recognizes that occupational hazards often lead to greater and longer exposures than those encountered in other settings (e.g., someone cleaning their own home). The exposures can be both higher and more frequent, making the hazard significant. There are many examples where workers are at greater risk for adverse health effects when exposed to chemicals that exhibit certain hazard traits.

The wording in this section could and should be improved, however, since workers face increased hazards not only because of the “nature of their occupation” but also because of the specific tasks or activities they perform at work. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. It’s what they actually do that matters.

Accordingly, CHANGE recommends changing the last sentence of the definition of sensitive sub-population (page 13, lines 23-25) as follows:

Current language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures or workers with greater exposures due to the nature of their occupation.

Suggested language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures, or workers with greater exposures than the general population, due to the nature of their occupation and specific duties.

---

**The definition of “sensitive sub-populations” should be expanded to include women of reproductive age.**

CHANGE is disappointed to see that women of child-bearing age have not been added as a sensitive sub-population. If we are concerned about exposure to chemicals at vulnerable windows of development (as we should be), then we must protect the woman who may become pregnant. The first weeks of gestation are a time of rapid development for the fetus and therefore also a time of critical vulnerability to harm. Consequently,

many hazards to normal development threaten the fetus *in utero* early in pregnancy including before a woman may know she is pregnant. To protect the fetus, women of reproductive age must also be protected in addition to women who already know they are pregnant.

It should also be noted that children who are fathered by men who work in certain occupations with high chemical exposure are at higher risk for birth defects. See Desrosiers, T.A., et al. (2012) "Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study", *Occupational and Environmental Medicine*, 69(8): 534 – 542; and also Olshan, A.F., Teschke, K., & Baird, P.A. (1991) "Paternal occupation and congenital anomalies in offspring", *American Journal of Industrial Medicine*, 20(4):447 – 475.

---

**DTSC actions, as well as innovation, will be hampered  
by dependence on “available information.”**

We support DTSC’s decision to eliminate the requirement in §69502.2 (b)(2)(B) that would have given more weight to chemicals with a greater amount of reliable information and chemicals for which a safer alternative is already available. While the goal of these provisions was likely to encourage DTSC to prioritize “low hanging fruit,” it nevertheless created legal issues that the department may not have been able to surmount. In addition, language such as this could have been interpreted to mean that no information implies a chemical is "safe."

Much of what we are learning about potential harmful effects from chemical exposure is based on science that has emerged (and is emerging) quickly in recent years. New chemicals, and existing chemicals that have not been sufficiently studied, will frequently lack the data sets that the definition of "safer alternative" could be interpreted to require.

However, despite the deletion mentioned above, these regulations still contain instances where DTSC’s decisions and regulatory actions will be limited by the lack of available information. By giving preference to, and relying on, the current availability of chemical data, instead of exercising the Department’s authority to request new information, DTSC will find itself in the position of promulgating the data gap that continues to limit innovation or the development of green chemistry based alternatives. It also ensures that the burden of proof remains on the regulatory agency to demonstrate a chemical’s harmful effects and not on the companies making the chemical or product containing the chemical to demonstrate its safety.

Chemicals for which there is little or no information demonstrating reasonable safety should be formally identified by the SCP program as lacking adequate safety data. Furthermore, DTSC should exert its call-in authority under AB 1879 to require the generation of new health and environmental impact data in order to accurately identify Candidate Chemicals and safer alternatives and to make appropriate regulatory responses. DTSC should exercise this authority as early as possible in the program’s implementation.

CHANGE believes that chemicals for which there is little or no information that demonstrates reasonable safety should be formally identified by the SCP program as lacking adequate safety data. This would give DTSC authority to request further information about them.

**§ 69501.4(a)**

Much of the information about chemicals that is needed by DTSC and the public is already known by manufacturers in-house, and should be required to be submitted to DTSC. While the effort by DTSC to obtain existing or new information is a good one, the language should be strengthened so it’s not simply an

option for responsible entities, but a requirement. Throughout these sections, “request” should be replaced with “require.”

### **§ 69506.2**

CHANGE strongly supports the language in this section that gives DTSC authority to require the provision or development of needed additional information. We also applaud the ability for DTSC to modify its regulatory response based on new information that would be generated under this section.

---

**The regulations are silent about how to treat chemicals for which we have insufficient or no information.**

CHANGE continues to contend that chemicals for which there is little or no information demonstrating whether they are safe can reasonably be considered Candidate Chemicals under AB 1879, giving DTSC the authority to request further information so these chemicals can be assessed.

In the absence of such a minimum data requirement, the regulations should at the very least create a mechanism to identify these chemicals – a “yellow flag” that sends a message to the market and the public that they are under-studied and not necessarily safe.

---

**The draft regulations too often over-rely on simply reducing or containing chemical exposures instead of preventing their use**

We recognize that exposure data will be considered in the SCP implementation, but the innovative intent of AB 1879 is to base decisions on reducing hazard as the highest priority. That is, a substance deemed dangerous, should be reason enough to act to restrict its use. Otherwise, it is far too easy to fall into a strategy of “containment” whereby exposures continue to be allowed based on a plan of containing a chemical to reduce or contain exposure. This approach unfortunately fails too often; for example, this can be easily seen in the occupational setting where “containment” and limit standards are generally inadequate and often out of date.

Moreover, containment fails to drive the development and use of safer, less toxic chemicals, which is one of the overarching goals of both the SCP regulations and California's broader Green Chemistry Initiative.

For these reasons, CHANGE has consistently advocated that engineered safety measures or administrative controls should be viewed as *interim actions* and not permanent solutions to reduce danger to the public and the environment while inherently safer alternatives are developed. At the same time, CHANGE recognizes that restricting exposure by confining a chemical within a product may be an improvement and is in keeping with DTSC's approach of not prescribing how manufacturers address the CoCs in their products.

### **§ 69506.6**

CHANGE recommends that any Engineered Safety Measures or Administrative Controls imposed by DTSC in this section be considered ***an interim action*** until a more sustainable solution is found.

We suggest the following addition to § 69506.7 (a)

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, to reduce the potential for adverse as an interim action while a solution to eliminate the hazard from the Chemical(s) of Concern is found.

**§ 69501.1 (a)(10)(D)**

We suggest the following addition to this subsection: If Removal, Reformulation, or Redesign is not feasible, a secondary strategy of another any other change to a Priority Product or a manufacturing process that reduces the adverse impacts and/ or potential exposure associated with the Chemical(s) of Concern in the Priority Product, and/or the potential adverse waste and end-of-life effects associated with the Priority Product.

---

**Definitions of "technically and economically feasible alternative" have been appropriately separated**

CHANGE strongly supports DTSC's decision to create separate definitions for "economically feasible" and "technologically feasible".

**§69501.1 (a)(29)**

The definition of economically feasible is an improvement over the previous draft in that it does not refer to meeting consumer demand after a phase in period. The previous language was not defined and relied solely on manufacturer's data which could have been easily manipulated.

However, we are dismayed that the definition solely relies on a manufacturer's operating margin to determine economic feasibility. While a manufacturers operating margin may increase initially, over time, it may decrease. These variances in operating costs over time are not taken into account. We recommend that DTSC add to this definition language to address this concern.

**§69501.1(65)**

CHANGE supports the current definition of "technologically feasible."

---

**Definition of "functionally acceptable"**

CHANGE is disappointed to see that the definition of functionally acceptable has not been altered. We reiterate our concern that the current definition would enable a responsible entity to cite its impacted operating margin as a reason to be exempted from pursuing safer products because "consumers have not been reasonably accepting of the alternative in the marketplace." This is a vague and undeterminable indicator that would be essentially impossible to define and measure. Who will judge what "consumers can be reasonably anticipated" to accept?

**§ 69501.1(a)(35)(B)**

We recommend the following language for the definition of "functionally acceptable": (B) "The product performs the functions of the original product sufficiently well that the product's goals are reasonably well attained."

## **Definitions of "Chemical" and "Chemical Ingredient"**

CHANGE has worked hard with the Department to ensure these definitions enable the Department to reach nanomaterials and other kinds of chemicals and chemical ingredients in consumer products, should a basis for concern be established. We appreciate the Department's attention to this issue, and believe the current definitions address our concerns, follow our suggestions and are entirely appropriate. We hope the Department will advise us if further changes are considered.

---

## **Trade Secret Protections**

CHANGE has consistently been uncomfortable with the trade secret provisions in the authorizing statute. Rampant abuse of trade secrecy claims in the past has frustrated consumers and regulators alike when trying to protect public health. We do see enormous potential for trade secret abuse in this statute and appreciate some of the steps DTSC has taken to limit this abuse. While DTSC does not have the authority to change the trade secret provisions in the statute, we do see ways in which DTSC can incentivize transparency. We applaud DTSC for some of the most recent changes as outlined below but are dismayed that some of the suggestions we have made in the past have not been heeded. We reiterate these suggestions below as well.

### *a. Trade Secret Protection for Chemical Identity*

#### **§ 69510 (f)**

The regulations provide in § 69510(f) that “. . . trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission.” We believe this provision is not discretionary but is mandated by AB 1879, HSC § 25257(f), including as applied to chemical identity in hazard trait submission. The reason chemical identity should not be claimed as a trade secret in a hazard trait submission is that doing so would disconnect the remaining disclosure of health, safety or environmental information from any particular chemical and thereby render it meaningless, useless and immune from any oversight by the public or market. It would defeat the obvious intent of the law to make the health, safety and environmental information about particular chemicals contained in hazard trait submissions available to the public and the market. Accordingly, CHANGE strongly supports this provision.

### *b. Hazard Trait Submissions*

#### **§69501.1(37)**

CHANGE has provided numerous comments on the various iterations of the “hazard trait submission” definition. We appreciate that DTSC has incorporated our suggestion that “hazard trait submission” not be restricted to instances where the submission shows a chemical poses a hazard, but will now apply to any study or information regardless of its results. Studies purporting to exonerate a chemical are just as important, if not more important, for the public to review as those purporting to demonstrate a hazard.

We suggest one further refinement to the current definition in §69501.1(37). It currently applies to any “study . . . or . . . information . . . submitted to the Department . . .” We suggest that this definition should include any “study . . . or . . . information . . . submitted to the Department or relied upon or referenced in any submission to

the Department . . .” It seems very possible that a health, safety or environmental study might be relied upon or referenced in an AA or other submission without the study itself being submitted. The purpose of this definition and the exception from trade secret protection that it confers makes it reasonable to include within the definition of “Hazard Trait Submission” studies that are relied on or referenced in submissions to the Department under this chapter even if they are not themselves “submitted.”

**§69509(g)**

CHANGE notes that the new proposed Regulations contain a very substantial modification to the exemption from the Hazard Trait Submission exclusion from trade secret protection, now contained in §69509(g). Now chemical identity may be masked from a Hazard Trait Submission if a patent application has been filed on a chemical or its use in a product if it is considered or proposed in an AA. We consider this an appropriate way to protect confidential information that the owner believes is important enough to file a patent application on. It is also an inherently time-limited exemption.

The comment we offer is with respect to the event that terminates the authorization to mask this information from the public: the Regulations provide termination upon “grant or denial” of the patent application. CHANGE believes this is inappropriate, and that authorization of masking should terminate when the patent application or a foreign counterpart disclosing the chemical or use is published anywhere in the world. At this time, that period is now harmonized for new applications at 18 months after filing in both the US and the EU and other countries as well. (Former US patent practice did not entail publication of US patent applications, but EU counterparts have been published 18 months after the filing date for decades, thus revealing to the global public the content of counterpart US patent applications.) Once a patent application is published anywhere in the world, its contents are no longer fairly considered a trade secret, and there is no longer any basis for withholding chemical identity from hazard trait submissions.

Moreover, the terms “grant or denial” are quite vague in patent practice: patent claims are routinely “rejected” during patent prosecution but then allowed after modification by patentees; both allowance and final rejection of claims can be appealed within the patent office and then to federal court under various procedures, sometimes involving third parties, in processes that can literally take decades; it is very possible that some claims could be allowed in a patent application that discloses a chemical considered in an AA, but not cover that chemical – if DTSC means to condition the right to mask a chemical identity on the final allowance of a claim covering that chemical identity or its use, the current Regulations do not make that at all clear; and there are many other complications as well. We suggest that DTSC not pursue this approach, for the real issue is whether the subject matter of chemical identity or use is disclosed to the public, not whether it is covered by an allowed claim in an issued patent. Our suggestion focuses on just that issue by terminating the temporary authorization of masking when the subject patent application or a foreign counterpart is published.

We suggest DTSC adopt the following language in §69509(g)(1):

“...Such masking shall be authorized only until the information subject to the trade secret claim is made public through any means, including through publication of the patent application, a foreign counterpart or issued patent. The person claiming the trade secret shall notify the Department within thirty (30) days after the information is made public.”

**§ 69501.1(a)(66)**

The definition of “Trade Secret” should provide that “Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient” as specified in 69510(f), Page 76, lines 32-34.

**§ 69505.4 and 69505.7**

CHANGE strongly supports this language whereby if an AA Report contains information "claimed by the responsible entity to be a trade secret, a separate, publicly available AA Report shall be submitted to the Department that masks claimed trade secret information only to the extent necessary to protect its confidential nature." This would protect valid trade secret claims, but at the same time provide a useful range of data so the material basis for the decision is explained in some way. We believe many industries are already familiar with such masking strategies, such as preparing disclosures to comply with securities laws, or voluntarily describing confidential technology in initial approaches to prospective business partners, even under confidentiality agreements.

**§ 69505.7 (d)**

CHANGE strongly supports the requirements that compel the responsible entity to provide information in their AA reports on the Supply Chain (d); Facility Description and Location (e); and the identification of unavailable reliable information (h)(2). This information will help the market operate more efficiently.

**§ 69505.8(e)**

All notices issued by the Department should also be posted on DTSC website.

**§69509(a)**

We support the requirement in the regulations that responsible entities must provide adequate justification for trade secret claims. We believe these requirements will discourage trade secret claims that are not warranted or of little value to the responsible entity, and we urge DTSC to retain these requirements.

**§ 69509(c)(2)**

CHANGE is disappointed that the department has stricken language that would allow it to make redacted copies of documentation available to the public at its discretion. We are unclear as to why this language has been removed as it would allow the public, local agencies, and end-users to gauge the degree to which information is being kept confidential and allow them to make better consumer, business, or regulatory decisions accordingly. Since no trade secret information will be included, CHANGE recommends that DTSC not only reinstate this language but also to make the documentation available in all cases, rather than "at DTSC's discretion."

**§ 69509.1**

CHANGE recommends that DTSC should add language here that the public shall be informed when companies' trade secret claims have been approved by DTSC so that the public knows that complete information about the chemical is not available.

---

**A strong firewall is necessary between Responsible Entities and those who complete Alternative Assessments**

CHANGE has long maintained that Alternatives Assessments should not be conducted by the makers or users of toxic chemicals. Since AAs contain both quantitative and qualitative data, the assessment can be easily “gamed” to arrive at a pre-determined outcome. We maintain that the best, non-biased way to conduct AAs would be for manufacturers to pay into a fund that is then administered by the department to hire one or more AA experts to conduct the AA or for DTSC to conduct the AAs itself. Such a system would eliminate conflicts of interest and would provide DTSC with unbiased information prior to issuing a regulatory response. It would build expertise at the state in conducting AAs for following and developing best practices. And it would be more cost effective for DTSC to manage the program itself instead of the vast oversight responsibilities that present themselves under the current draft regulations: develop detailed procedures about conducting AA; develop criteria for accreditation bodies; monitor and re-certify accreditation bodies; review each Preliminary AA and Final AA report; manage extension requests; and issue individual regulatory response for each AA.

An alternative method to provide more assurances of an unbiased AA would be to require manufacturers to work with outside, certified AA experts who could conduct the AA. Yet another method would be to require independent third party verification of AA reports performed by industry. CHANGE has suggested that industries that conduct AAs with no trade secret claims and make the reports public could be exempt from 3<sup>rd</sup> party oversight. None of these suggestions is reflected in the formal draft regulations.

Since there will be no independent third party verification, the entirety of review will fall to the public which will have incomplete information, as stated above, and DTSC which is underfunded. CHANGE can easily envision a scenario in which the department limits the number of priority products due to the limitations it faces in reviewing AAs. We are disappointed that DTSC has consistently ignored these calls for independent review and verification.

**§69505.7(k)(1)(A)**

CHANGE supports the additional language in this subsection requiring yearly progress reports for responsible entities that receive an extended due date for a Final AA Report.

**§69505.8**

Despite our misgivings, we appreciate the language addition clarifying the scope of DTSC’s review of AAs. This criteria is appropriate and will help to ensure that each AA receives a meaningful review.

---

**Transparency must be maximized in Alternatives Assessment Reports**

In our previous comments, CHANGE asserted that “transparency in how the program is managed is important both for accountability of decision-making and for the ability of the program to correct the market failure caused by lack of publicly available information in the market. Moreover, without transparency, there is a substantial risk that the program won’t be seen as credible by the people of California.” Understanding that

DTSC believes it does not have the authority to limit trade secrets as permitted under current law, the Coalition supported the strategy of masking trade secret information in a manner that protects its confidential nature while providing the public with enough information to have an accurate *sense* of the validity of the redacted alternative analyses and the associated decisions that they led to.

Because of the sole reliance on the public's oversight in this version of the proposed regulations, however, transparency of both the alternatives analysis process, the final analysis, and the DTSC's regulatory response is even more critical. Without any third party input and the limitations of DTSC itself to analyze the quality and content of the AAs they receive, the process relies on 45 day public comment periods for oversight of analyses done by the regulated community itself. However, the public is expected to do this with one arm tied behind its back since companies can and will claim trade secrets for the most essential aspects of the AAs, including chemical identities. In the absence of any third party review by outside experts without a specific interest in the outcome the public needs to have full access to the AAs in order to provide greater oversight. This relates to preliminary and final AA reports or any allowable alternatives as described in the regulations, requests for extensions to comply with regulatory requirements, chemical and/or product removal/replacement notifications, alternatives analysis threshold notifications, and DTSC's determinations of exemption eligibility. CHANGE supports the process laid out in the draft regulations by which the public can provide comment on regulatory decisions, but once again, adequate information must be made available on which to base those comments.

#### **§69505.7(a)(4)(A)**

The language in this subsection relating to trade secret masking continues to be vague. It is not clear what information is subject to masking and what it means to ensure that the public has a substantive understanding of a company's workplan, the actual AA, and the ultimate conclusions of the AA. Furthermore, there are no clear steps that companies should take to ensure that they are meeting the requirements of these provisions.

We therefore strongly recommend that the department develop specific guidelines for masking strategies as part of the Alternative Assessment guidance that it will publish subsequent to the adoption of these regulations. This guidance should clarify the types of information for which masking is acceptable and provide recommendations by which companies can comply, including but not limited to using ranges to obscure specific formulations.

While there is a growing number of companies who recognize that full public disclosure about their products actually creates competitive advantage, there is nothing in the regulations that encourages this. While requiring companies to mask trade secret information in a way that promotes the public's understanding of AAs is a positive step, DTSC should provide incentives for voluntary full public transparency. For example, DTSC could add language that would give manufactures a streamlined review process in exchange for forgoing trade secrecy claims altogether.

Ultimately, CHANGE believes that while companies have the right to assert trade secrecy claims, when it comes to potentially toxic chemicals in a consumer product, public, worker, and environmental health trumps an individual manufacturer's desire for confidentiality. We appreciate the Department's recognition of this and its attempts to facilitate a balance between the public good and legitimate business concerns. However, in order for such a balance to be successful, there needs to be proper guidance, a variety of options, and public input so that both businesses and the general public can have confidence in the program.

---

**Some timelines can be shortened to avoid unnecessary delays in program implementation.**

In places, the draft regulations are overly generous to responsible entities in the allowed timelines and the granting of extensions. In addition, the regulations allow all DTSC actions to be stayed during a dispute until resolved. We are concerned that allowing disputes at any stage of the process can lead to frivolous delay tactics by those entities that are regulated. It's clear that DTSC will focus on chemical/product combinations that have enough evidence to suggest a high hazard to the public, and the public has a right to know which of these product/combinations are of sufficient concern to warrant DTSC's request for an AA.

**§69503.4 (a)**

In CHANGE's previous comments, we stated our concern that a priority products list would not be established until 6 months after the effective date of the regulation. The current draft lengthens this process to a full year after implementation. This timeline is far too long. These regulations have been in development for over four years. By the time the regulation is implemented, stakeholders and DTSC will have had almost five years to plan for priority products. In fact, DTSC is currently in the process of soliciting feedback on which products should be prioritized first. The department does not need an additional year to create a work plan. We reiterate our strong support for issuing the initial work plan 90 days after adoption of this regulation. Consumers have been waiting for too long for action on this program. In the years since the authorizing statute has passed, chemical regulation has virtually stopped at the legislative level. DTSC should not force consumers to wait yet another year before any products are even prioritized for action. This new development is highly disappointing and disillusioning for consumers and public health advocates.

**§69505.7(k)(1)(A)**

CHANGE appreciates the effort by DTSC to ensure that manufacturers who are granted an extension under section 69505.8(b)(4)(A) are required to submit yearly progress reports. However, this new section does not indicate if this progress report will be available to the public. We urge that these progress reports be made readily available to the public.

**§69507.6 (d)**

This section of the draft states: "The Department shall issue an order specifying its decision on the merits of the Request for Review within one hundred and eighty (180) days from the date it grants the Request for Review." CHANGE believes 180 days is much too long a time period for DTSC to make this kind of decision, especially since DTSC will have already had 60 days to consider whether to grant a Review or not. A total of 90 days should be more than adequate for DTSC to act in this regard.

---

**"Economic Impacts" must capture all appropriate costs, including to public health, occupational health, and the environment.- KATHRYN**

CHANGE is pleased with some of the changes that have been made to address the externalities associated with economic impacts during an AA. Economic impacts must address not only costs to a manufacturer or responsible entity but to society as well. Currently, consumers and taxpayers are bearing the financial burden of a chemicals management system that causes increased illnesses, increased pollution and increased waste.

While we appreciate some of the changes that have been made and note them below, more can be done to address the true costs of toxic chemicals in consumer products.

**§ 69501.1**

We continue to recommend inserting a definition of "Economic Impacts" using the following language: "Economic Impacts means internalized and externalized costs to the public, public health, workers, government agencies, businesses, consumers, and the taxpayer."

**§ 69505.6(a)(2)(A)**

Too often, extraction is left out of a life cycle analysis. "Extraction of raw materials" should be added to the life cycle impacts listed in 1.-7. This is an often significant life cycle impact that should not be ignored.

**§ 69505.6(a)(2)(C)**

CHANGE supports the new language in this section that explicitly states that the manufacturer must evaluate, monetize and compare the costs to public health, the environment, government agencies and non-profit organizations for each potential alternative. This language ensures that when evaluating economic impacts, the manufacturer or responsible entity will look beyond its own balance sheet and look as well to the costs to society for their decision.

---

**A key principle driving Regulatory Responses by DTSC gives preference to responses providing the greatest level of inherent protection**

**§ 69506 (b)**

*"In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection."*

CHANGE strongly supports this important principle that will guide DTSC regulatory responses. Preventing harm is easier, cheaper, and more effective than managing harm after it has occurred. This key language clarifies that the ultimate goal of the Safer Consumer Product regulations is the elimination of toxic chemicals and the development of safer, green chemistry-based alternatives.

---

**Enforcement must include significant penalties.**

**§ 69501.2(c)**

If the most stringent or only punitive measure to address "Failure to Comply" is a DTSC website listing, this is an inadequate effort by DTSC to compel compliance by responsible entities. "Failure to Comply" and "Failure to Respond" should trigger more meaningful penalties, including significant fines.

Furthermore, warning responsible parties that they are not in compliance and will be so listed on DTSC's web site takes up department resources and time. We would suggest that it is up to those parties to comply with the regulation and that not doing so should result in listing without warning, until they rectify the situation. In our view, this is not only fair, given that companies have the responsibility to be familiar with the law and

heed it, but also appropriate given the current economic burden on public agencies and DTSC's limited funding and resources.

**§ 69501.3 (a) – (c)**

We strongly supported the previous draft's provisions requiring all information submitted to DTSC to be signed by the person who has prepared the information as well as the owner of the company or official or authorized representative under the penalty of perjury. It was an effective method to ensure the company's responsibilities under these regulations are integrated into the company's activities. This was consistent with requirements for California's Injury and Illness Prevention Program and studies showing that programs are more effective with written management commitment that comes from the top. We are dismayed to see that the phrases "under penalty of perjury" and "punishable offence" have been removed. DTSC is yet again placing itself in a position of weakness in its ability to uphold the law. Since there will be no independent verification of any of the documents given to DTSC, it is imperative that there be a threat of serious punishment and penalties for providing false information. By removing this phrase, yet another impediment to providing false information is removed and consumers and the department will be forced to merely trust manufacturers at their word. We strongly urge that these changes be deleted and that the original language be reinserted prior to final implementation of this regulation.

In addition, CHANGE recommends that responsible entities should be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

---

**A robust end-of-life management program is important and will contribute to positive changes in the marketplace.**

**§ 69506.7(a)(2)**

Concerning the End-of-Life Management Requirements in regulatory responses, CHANGE strongly supports the language that requires the responsible entity to "fund, establish, and maintain an end-of-life management program" including a detailed plan and financial guarantee mechanism, as well as compensation to retailers and other persons who agree to administer or participate in the collection program.

In addition, CHANGE believes responsible parties should also be required to estimate the lifetime of the applicable products they are managing; and they should be required to provide DTSC a copy of the product stewardship plan they develop to enhance oversight.

**§ 69506.8(e)**

CHANGE reiterates our objection to the provision which would permit a responsible entity to request an exemption from end-of-life management program requirements by demonstrating to DTSC that such end-of-life program "cannot be feasibly implemented for the product." Such an off-ramp will surely lead to claims that end-of-life programs are in fact not feasible. DTSC would then be giving itself the job of deciding whether or not the responsible entity had adequately "demonstrated" its claim. It would be better for the end-of-life management program to be required in all cases, with limitations and mitigating factors detailed by the responsible entity in the end-of-life management plan.

**An inventory recall mechanism should be included in Regulatory Reponses.**

**§ 69506.6**

We are again disappointed that there is no provision for an inventory recall in the Product Sales Prohibition section. Additional language should be added here to ensure that phased-out products, with a consumer label or not, are not dumped into discount stores and low-income areas.

---

**Advancement of Green Chemistry and Green Engineering**

**§ 69506.9**

CHANGE supports the draft regulations that give the Department the ability to require responsible entities to initiate a research /development project or fund a green chemistry challenge grant. We especially appreciate the new language in the draft that authorizes this regulatory response if a manufacturer chooses an alternative that does not eliminate the use of the Candidate Chemical in the product.

---

**Dispute Resolution**

**§ 69507**

CHANGE supports the language in the draft regulations that require responsible entities pursuing a dispute to follow the specified procedures or forfeit the right to further contest the dispute administratively.

CHANGE recommends that when a dispute is filed, DTSC make public the reason the dispute is being filed, as well as continue to inform the public as to where the matter stands. In other words, there should not be a blanket silence when a dispute is filed; rather there should be a summary of why the chemical/product combination has been prioritized, and a current update on how the dispute is being resolved. Without provisions like this, industry will have a green light to pursue frivolous disputes, wasting scarce DTSC resources and undermining the public's confidence in the entire process.

If a dispute process is going to be considered, it should include short timelines to minimize costs to both sides. The current draft allows for far too much delay in the process by the responsible entity in what should be a straightforward task.

---

###



February 28, 2013

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

**Re: Safer Consumer Products – Proposed Regulations of January 13, 2013**

Dear Ms. Von Burg:

The Chemical Industry Council of California<sup>1</sup> (CICC) once again appreciates this opportunity to comment on the Proposed Safer Consumer Products regulation. CICC was among the industry organizations that supported the enabling statutes of these Proposed regulations, AB 1879 and SB 509, when they were passed in 2008. Since that time we have actively engaged both directly with the Department and with the Green Chemistry Alliance, the industry coalition through which detailed comments have been provided regarding the various iterations of possible regulations.

As we noted in our comments on the last draft set of regulations (comments of October 11, 2012), that experience and investment carries with it a special sensitivity to the evolutionary history of these regulations. In that context, we find this latest – perhaps final – proposal to be significantly improved over the prior draft, but still falling short of being fully implementable and, of greatest concern, still far removed from the incentive-, and innovation-driven instrument that we believe was originally intended. That history, of course, also makes us very sensitive to the time and effort already expended in pursuit of final regulations, and the myriad of pages of comments and proposals already in the record in this context. We will therefore offer the following as a high-level summary of our conclusions at this very late stage.

**KEY AREAS OF CONCERN**

**Chemicals of Concern (69501.1, 69502)**

The Department's decision to recast the larger universe of chemicals under consideration for prioritization to designate them as "candidate chemicals" is a major step toward a more rationale approach to these laws, and we applaud that. As noted in our October, 2012 comments, we believe the aim of these laws was not to ignite a feeding frenzy of public interest attacks on a broad universe of

---

<sup>1</sup> The Chemical Industry Council of California is a voluntary trade association comprised of large and small chemical manufacturers, distributors and allied businesses throughout California representing 105 facilities, with annual sales in excess of \$3 billion; employing more than 5700 workers with combined annual payroll \$283 million. An additional 11,000 indirect jobs are created by CICC member companies, with a combined annual payroll of some \$360 million.

chemicals, but to leverage the combined insight of hazard traits of chemicals and potential exposure via applications to zero-in on those chemical/product combinations that pose the greatest threat to Californians.

By confining the designation of “chemicals of concern” to those prioritized substances that have been targeted along with potentially problematic applications, restores to a significant degree the intent of the front-end process called for in the laws. We still expect the decision to cite such a large universe of candidate chemicals and to require “alternatives” to be judged against them will invite that larger list to be used as a “blacklist” by public interests targeting particular products or manufacturers with challenges that may not be worthy from a scientific perspective. Such abuse of the list is perhaps to be expected, however, but is certainly likely to be less extreme, given this more rationale delineation of California’s “chemicals of concern.”

### **Reliable Information (69501.1)**

“Reliable information” is a concept crucial to operation of these proposed regulations. It is cited repeatedly in a number of different contexts as potential grounds for critical DTSC decisions ranging from whether a chemical has a particular hazard trait to the adequacy of engineering controls. Given the potential impact of decisions grounded on “reliable information,” the standards proposed for such information are woefully inadequate. In the extreme, merely being mentioned in a publication of a governmental agency (at any level) could be grounds for California initiating major regulatory action. This is simply not commensurate with either the capacity of this state to make well-informed scientific judgments.

At a minimum, reliable information must meet a weight-of-the-evidence test that assures the integrity of these critical decisions. DTSC has an obligation to take responsibility for the science behind these complex but important matters. That was the whole purpose of the 2008 laws – to put these evolving issues around chemicals in products in the hands of the State’s competent scientists, rather than leaving them to the whims of the Legislature. If DTSC fails to exercise measured judgment in evaluating that science, it will have effectively abdicated on that responsibility.

### **Exemption - Conflict with Existing Regulations (69503.2, 69506.9)**

Once again we must note that the standard being imposed to justify deference to other regulatory programs is seriously flawed and effectively could allow the Department’s interpretation to ride roughshod over whole programs administered by other departments. As we pointed out in our comments on the last draft, there are two distinct elements of the laws’ directives relating to exemption on grounds of conflicting regulations: this regulation cannot 1) limit or supersede the authority of any other department, or 2) duplicate or adopt conflicting regulations for categories already regulated “for purposes consistent with this article.” Both of these must be taken into account in judging the extent to which this proposed regulation would conflict. Clearly the standard cited as an exemption from the processes of the proposed regulation responds only to the first: *“the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.”*

The more reasonable (and legally defensible) interpretation must also take into account the first prohibition, regarding limiting or superseding other authorities. In this regard the proposed regulatory interpretation falls far short. Consider, for example, the authority over the workplace under both CalOSHA and its federal counterpart. They are charged with worker protection, including from harmful exposure to toxic substances. That mandate, however, is coupled with recognition of the workplace as a unique environment – one which often includes potential exposure to conditions inherently hazardous, but one which recognizes the necessity of moderating risk associated with those conditions by expert training and safety management, rather than total avoidance. If DTSC inserts itself in an

arena in which the established regulatory authority does take into account the use of specific chemicals (including those DTSC deems to be Chemicals of Concern) in that overall risk-management balance, then DTSC is clearly encroaching on the authority of that agency.

It is curious that this proposed regulation does seem to recognize either of the two grounds for exemption later in the draft, in allowing a claim of conflict to exempt from a particular regulatory remedy. The inconsistency between the two is a problem, particularly since the limitation on the initial exemption could force a product manufacturer (and DTSC) into a long, expensive and complex AA process, only to find at the end that the regulatory remedy is exempt.

### **Bulk chemicals and chemicals destined for exempt products or for use outside of the State (69503.3)**

We are conscious of the fact that DTSC has opted to advance an expansive conception of “consumer product” in this proposal, which represents a significant distortion of the intent of the laws and potentially a significant misallocation of resources. This stems from the fact that there is no exemption for bulk chemicals, chemicals destined solely for the manufacture of categorically exempt products, or chemicals destined solely for use outside the State. All of these have been viewed as categorically exempt in earlier iterations of these proposed regulations, but none are exempt under this proposal.

The aim of these laws is to target the particular chemical/product combinations that pose the greatest threat to the citizens of California, and initiate a process to systematically reduce that risk. It is difficult to foresee any circumstance where these categories of chemicals could conceivably constitute the greatest “threats” to the citizens of California. Further, it is the case that each of these categories of chemical use are already extensively regulated by agencies of the Federal and State governments, for precisely the purpose of safeguarding against their risk (e.g. Cal OSHA). To the extent DTSC would presume to intercede in these chemical uses, it would be superimposing its limited program authority and direction over the broader authorities already applicable, and would be channeling both public and private resources to deal with risks already being addressed systematically by public bodies. In so doing, it would be diverting necessary attention and resources from chemical/product combinations that may pose unique risk that is not being systematically addressed. There simply is no legitimate reason for inclusion of these categories of chemical use as targets of these regulations.

### **Use of Administrative Procedures Act (69503.5, 69502.2)**

We also applaud greater reliance upon the California Administrative Procedures Act, particularly in identifying chemical/product combinations of priority concern. We’ve always respected this as a significant force in ensuring responsible administrative practices in the state, and believe it is entirely appropriate to bring apply it liberally in the context of the present regulations. These are path-breaking and there is great potential for abuse if administrative disciplines are not adhered to.

For that reason, though, we are also a bit concerned that Department seems to have chosen not to be bound by such disciplines in the critical initial stages of the regulation’s implementation. Given the appropriate emphasis on APA adherence, it is ironic and concerning that the Department has exempted such recourse from being available to the first round of chemicals/products to be reviewed. Logically, this would seem to be a point where such review would be most appropriate, given the pioneer nature of these path-breaking reviews. Again, their exemption from APA protections raises uncomfortable questions about the possible motivations of the Department.

In a related concern, the decision to exempt from challenge the lists from which the initial Candidate Chemicals list is drawn seems shadowy, at best. This is particularly so given that at least two of these lists would seem to violate standards of curation which the Department deems appropriate for future list-additions (the Oslo Paris Convention list, for example, is no longer used or maintained by that Convention). This raises the concern that the underlying motivation of the Department may well have

been to ensure against challenge the inclusion of certain chemicals from those lists that would otherwise surely be questioned vs the standards elsewhere in the regulation.

### **De Minimis/Alternatives Analysis Threshold Exemption (69505.3)**

We remain very concerned about the Department's steadfast refusal to consider establishing reasonable *de minimis* standards. This would render the regulation far more predictable and render the Department's task of administration far more manageable. Instead, the Department has chosen the route of a standard driven by the ever-decreasing level of detection, qualified even further by applying it only to trace contaminants.

This amounts to very little, indeed – for most chemicals and products, nothing. The cost of uncertainty for the potential regulated community is significant. The reason for this resistance is unclear at best. Certainly it stimulates suspicion that this is driven entirely by the handful of more extreme advocates – including several of prominence in the California debates – who regard there to be no safe levels of exposure, regardless of what established science and international norms are telling us to the contrary. This hardly befits a measured approach to identifying to greatest threats to Californians.

### **Public Comment on AAs (969505.1, 69505.7)**

The AA process for targeted chemical/product combinations is intimately tied to the world of R&D – perhaps the most closely guarded territory in corporate enterprise. The decision – completely novel in this decision, having had no prior discussion at all – poses serious threat to the integrity of that process – to the heart of innovation. This is particularly so with the terribly compromised CBI standard that denies protection to anything other than patented CBI. The threats are simply that 1) competitors would have a field day interpreting and exploiting now non-protectable information integral to the processes underlying innovation relating to the targeted chemical/product combination; and 2) the mandate of completely open public review and obligations to respond to any and all public comments raises the specter of CEQA-type manipulation of the process to the end of inferring complex legal obligations, and leaving an opening for harassing civil litigation aimed at little more than delay and pressure to alight on specific outcomes, regardless of where science and innovation may otherwise lead. It is baldly an abdication of DTSC responsibility to oversee this process – a responsibility attended also by the obligation to respect the integrity of the effort being undertaken and the intellectual property that will necessarily play a role in virtually any successful outcome.

### **Trade Secrets/Patent Restriction (69509)**

The decision to restrict trade secret protection only to patented materials is short-sighted and at odds with the State's long-established practices, to say nothing of long-established norms of intellectual property protection at the global level. The reality is that the patent system has a critical role to play in protection of intellectual property, but it applies only to limited circumstances where the interests of the innovator coincide with making the innovation systematically available (that is the role of patents). In many, perhaps most cases involving chemical formulations and processes, benefit derive from maintaining the competitive advantage of a unique formulation or process and the choice is to protect the innovation via other CBI routes. This option would be foreclosed under this proposal, seriously compromising its compatibility with genuine innovation in chemical development and application.

This is a very serious undermining of incentives for innovation, as it effectively denies a preferred route of CBI protection that is relied upon across the industry to provide an effective probability of securing return-on-R&D investment. Again, as with the limitations compromising other aspects of this proposal, it is unclear what the motivation may be for such a severe restriction of traditional CBI protections. Even less clear is how this restriction could possibly fit with the aim of stimulating innovation and green chemistry that is ostensibly the aim of the original laws.

**CONCLUSION: A DISINCENTIVE TO INNOVATE**

Cumulatively, the changes outlined above seriously undermine not only the ability to comply with this proposed regulation, but with the incentive toward green chemistry innovation that was supposed to be at the heart of these laws. They leave a regulatory landscape driven by a myriad of potential chemical targets (some of dubious origin), with virtually no ability to effectively anticipate prioritization to genuine chemicals of concern, let alone to priority products. The process completely disregards decisions driven by other regulations for broader purposes, and offers no “off-ramp” for products or materials no matter how minute the chemical presence.

At the same time, it weakens dramatically protection for intellectual property associated with any solutions to priority chemical/product combinations. The result will actively discourage investment pursuant to this regulatory regime, rather than stimulating such investment to spur innovation. This seems to fly completely in the face of the intent of the laws passed in 2008. It breeds the cynical conclusion that this administration within DTSC is openly denying the original intent of the laws and merely leveraging them to broaden the frontier of traditional command-and-control – substituting the meat-ax for the scalpel that we all thought we were investing in.

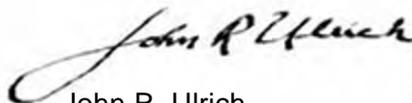
It is with sincere regret that we again offer such critical comments regarding what we have always hoped could be a fully-embraced process, providing genuine incentives to target and eliminate the greatest real risks faced by Californians through products. We’ve recognized this as a truly pioneering effort in which we would all have to work collaboratively to develop truly workable solutions. We have endeavored to do that consistently, and are sorry that has not proven to be worthy. We all stand to lose if this pioneering suite of laws proves to be unworkable in their implementation.

We appreciate your consideration of our concerns. For further information or questions regarding the Chemical Industry Council of California, its members, or the attached comments contact Thomas R. Jacob (916) 782-1266 or John Ulrich (916) 989-9692. You may also visit the CICC website at [www.cicc.org](http://www.cicc.org). Thank you!

Sincerely,



Thomas R. Jacob  
Sr. Consultant/ Lobbyist  
Chemical Industry Council of California



John R. Ulrich  
Executive Director  
Chemical Industry Council of California

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



**Matthew Rodriguez**  
Secretary for  
Environmental Protection



## Department of Toxic Substances Control

Deborah O. Raphael, Director  
1001 "I" Street  
P.O. Box 806  
Sacramento, California 95812-0806



**Edmund G. Brown Jr.**  
Governor

TO: Scientific Peer Reviewer

FROM: Jeff Wong, Ph.D.  
Office of Pollution Prevention and Green Technology  
Department of Toxic Substances Control

DATE: January 30, 2012

SUBJECT: NOTICE TO PROCEED WITH SCIENTIFIC PEER REVIEW FOR SAFER  
CONSUMER PRODUCT REGULATIONS

Thank you for your participation as a scientific peer reviewer for the California Safer Consumer Product Alternative Regulations. Attached you will find:

- Attachment 1: Summary of Proposed Regulations and Changes. Attachment 1 provides a brief background that has led the Department of Toxic Substances Control (DTSC) to propose regulations for Safer Consumer Products regulations and the revisions that were made.
- Attachment 2: Scientific Factors: Peer Review Topics. Attachment 2 contains the topics that DTSC is requesting the peer reviewers to comment on.
- Attachment 3: Revised Proposed Regulations for Safer Consumer Products. Attachment 3 contains the revised proposed regulations that are the subject of this peer review request, which can also be found at:  
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf>

The unofficial version, without underline and strikeout, of the Revised Proposed Regulations can also be found at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text-NU.pdf>

Please complete your review by **March 4, 2013** and send your written comments to Daphne Molin at [daphne.molin@dtsc.ca.gov](mailto:daphne.molin@dtsc.ca.gov). If you require clarification of this communication, please contact Dr. Jeff Wong at [jeff.wong@dtsc.ca.gov](mailto:jeff.wong@dtsc.ca.gov) or (916) 322-0504 or Daphne Molin at [daphne.molin@dtsc.ca.gov](mailto:daphne.molin@dtsc.ca.gov) or (916) 445-6130.

## **Attachment 1**

### **Summary of Proposed and Revised Regulations**

#### Background

On July 27, 2012, DTSC entered the rulemaking process for [The Safer Consumer Products Regulations](#) to fulfill the mandate of [AB 1879](#), which became Chapter 559 (stats. of 2008). This law directs DTSC to adopt regulations to establish a process to reach an aspirational goal that encourages the manufacture of safer consumer products through innovation and the use of safer or less hazardous chemicals. DTSC is proposing a four step regulatory process that:

- (1) Yields an informational list of chemicals that have been identified by an authoritative organization or reliable information to exhibit a hazard trait or shown by reliable information to demonstrate the occurrence of the chemical in the public or environment. These chemicals are referred to as Candidate Chemicals after they have been identified, subjected to stakeholder input, and finalized by DTSC.
- (2) Allows DTSC to evaluate product-chemical combinations and nominate products for the proposed Priority Products list and finalize the list following public review and stakeholder input.
- (3) Requires manufacturers to examine their Priority Products and their potential alternative products through an Alternatives Analysis and identify the selected alternative product, if any. Copies of the completed Alternatives Analysis Reports, excluding trade secret information, will be made publically available.
- (4) Designates Regulatory Response options for DTSC to impose on to manufacturers based on their product selection in the Alternatives Analysis process.

In the July proposal, a product that would be listed as a Priority Product and that meets the criteria for an alternatives analysis threshold exemption was exempt from the requirement to perform an Alternatives Analysis if a responsible entity for the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC. Peer reviewers were asked to review and provide comment on the scientific nature of four topics points. The previous request can be found at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Revised-Request-Memo.pdf>

After considering public comments, Departmental resources, and various practical and policy issues, DTSC revised the proposed regulations and asks the reviewers to review the revised proposed regulation, and comment on the scientific nature of the same four points (Attachment 2). To provide the peer reviewer the context of these revised regulations, please refer to the Summary of Significant Changes in January 2013 Revised Proposed Regulations at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Summary-of-Changes.pdf>

## **Attachment 2 Scientific Factors: Peer Review Topics**

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

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

### Topics:

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

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

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

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

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

***Christensen response: These changes are consistent with our scientific understanding of the potential impacts of these chemicals on the human and ecosystem health.***

## **Attachment 2**

### **Scientific Factors: Peer Review Topics**

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

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

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

***Christensen response: These changes are important and founded in sound science. Replacing “a significant ability” with “potential” is especially important. “Significant ability” is an imprecise phrase open to a variety of interpretations. “Potential” is much clearer and consistent with the intent to protect human and ecosystem health.***

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

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

**Attachment 2**  
**Scientific Factors: Peer Review Topics**

***Christensen response: The Practical Quantification Limit is scientifically sound. Furthermore, it is logical that that Alternative Analysis Threshold would apply only to contaminant chemicals and not to chemicals intentionally added to a product.***

**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.*

***Christensen response: These changes seem appropriate. The terms “impact” and “effect” are often used as synonyms and the difference between them is subtle (impact perhaps being a generally negative effect).***



February 28, 2013

Ms. Debbie Raphael, Director  
c/o Krysia Von Burg  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
*Submitted via email to gcregs@dtsc.ca.gov*

350 Frank H. Ogawa Plaza, Ste. 200  
Oakland, CA 94612  
415-369-9160 (P) 415-369-9180 (F)  
[www.cleanwateraction.org](http://www.cleanwateraction.org)

**Re: Safer Consumer Products Regulations**

Dear Ms. Raphael,

On behalf of Clean Water Action, I am pleased to submit these comments on the version of the Safer Consumer Products (SCP) regulations dated January 2013.

Clean Water Action's role is to represent the voices of our one million members -- 50,000 of whom live in California -- who are calling for a clean, safe environment to live, work, and raise their families in. They also want to ensure an equitable and robust economy, which does not transfer the price of polluting and health threatening practices away from responsible businesses and onto the public, especially when those businesses defend themselves under the guise of protecting jobs and the economy. Instead, we support embracing the opportunities that innovation based on sustainability and environmental health provide as a means of building that equitable and sustainable economy.

Clean Water Action's participation over the years in the SCP regulations' development has been based on these priorities. While this letter makes recommendations to correct flaws that we see in the current draft, we continue to believe that they are an important step forward in protecting California's environmental future while building our economy and protecting our place in the world marketplace. The state is already two years behind the date mandated by law for the regulations to go into effect. While we accept that some of that time was necessary to ensure they are developed properly, it is clearly time to finalize them without further delay.

Environmental Endpoints

Our review of the current draft certainly uncovered some major improvements that we thank DTSC for making, particularly in regard to addressing environmental endpoints. In particular, we fully support the addition of the 303 (d) list to the lists of chemicals covered by the regulations. This was essential in ensuring that chemical impacts on our water resources are addressed. We feel that wastewater, stormwater, and other end of life impacts, including the costs of pollution are appropriately recognized throughout, including as part of the criteria for selection of regulatory responses. We remain very concerned, however, with the lack of clarity regarding how DTSC will consider other regulatory programs and determine if they provide adequate protection related to chemicals used in products. As we have stated in the past, we are concerned that substances that are regulated under such laws as the Clean Water Act, the Safe Drinking Water Act, and the Clean Air Act, though included as candidate chemicals, will not be prioritized given that our ultimate goal is to ensure that their use in products does not result in their entry into the environment and necessary remedial actions under these laws. We

therefore ask the Department to clarify Sections 69501 (b) (2) (A) and 69503.2 (b) (2), to better state DTSC's intent and make it clear to the public and to the regulated community that chemicals used in products that are regulated under other laws are still subject to this regulation.

#### "Candidate" Chemicals

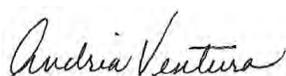
Clean Water Action strenuously opposes changing the name of what was formerly called Chemicals of Concern to "Candidate" Chemicals. While we recognize that the size of the list, which we support, has not changed, this revision is nothing less than a means of misleading the public as to the potential threat of these chemicals. We have heard industry arguments in favor for this change that make this explicitly clear – that they don't want the public to think these such chemicals are necessarily a threat. However, they are chemicals of concern, which is why they are on the various authoritative lists in the regulations and this is an accepted term that is well understood by regulators around the world, the regulated community, and the public. While some industry members may choose in their private marketing efforts to mislead the public by "soft-soaping" the potential impacts of the chemicals they use, it is inappropriate for DTSC to place itself in the position of doing the same. For this reason, we strongly urge the Department to go back to its original Chemicals of Concern and Priority Products language.

#### Transparency/Oversight of Alternatives Analysis

As we have expressed in the past, one of Clean Water Action's core values is the public's right to know about what is in their environment and what they are being exposed to. While we are pleased to see that Alternatives Analyses (AAs) will be made publicly available and open to comment, and that there is language requiring companies to ensure that in the case of trade secret claims, the public has a general sense of how decisions are made, this has become all the more inadequate given that there is fundamentally no assured oversight of AAs. While DTSC states its intention of providing necessary review of the AAs, there is a lack of public trust that this will be viable given the Department's limited resources. At minimum, it is expected that such a structure will ensure that the program will never grow to more than a handful of chemical/products at a time. While the public can provide some input to ensure AAs meet the necessary requirements and the intent of the regulations, without knowing what chemicals are actually involved or full transparency of the AA process, this too will be limited. Consequently, we once again repeat our belief that a process allowing for at minimum an independent 3<sup>rd</sup> party review of AAs produced by regulated companies themselves is important for the success of this program.

There are many other issues that Clean Water Action has taken an interest in related to the SCP regulations, and for this reason we recommend the letter submitted by the CHANGE coalition to DTSC's attention. We have focused here on some of the key items of particular interest to our members. Once again, we wish to state that we believe that on a whole, the SCP regulations are a positive step for California and that their implementation should not be delayed further. We look forward, in the years to come, to working with DTSC and with the industries striving to ensure that their products *safely* provide the benefits to society for which they are developed.

Sincerely,



Andria Ventura  
Toxics Program Manager



27 February 2013

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

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

RE: Revised Draft Regulations for Safer Consumer Products (SCP), January 2013

Dear Ms. Von Burg:

The Clorox Company, with headquarters in Oakland, California, is a manufacturer and distributor of many well-known and trusted consumer products. In addition to our namesake bleach and cleaning and disinfecting products, we have a stable of recognized brands including GLAD® wraps, bags and containers; Green Works® home care products; Pine-Sol cleaners; Fresh Step® cat litter; Kingsford® Charcoal; Hidden Valley® and KC Masterpiece® dressings and sauces; Brita® water-filtration products; and Burt's Bees® natural personal care products.

As we noted in the comments we submitted in response to the July 2012 draft, The Clorox Company is committed to providing our consumers with the safest, most efficacious product to meet their needs AND is protective of human health as well as the natural environment. We support the broad goals of the Green Chemistry Initiative and are committed to working with the Department and other stakeholders to spur "green chemical" innovation while providing a safe, efficacious consumer experience.

We would also reiterate that the Clorox family of products meets or exceeds safety requirements of those state, provincial or federal agencies charged with regulating those products, including, but not limited to the Environmental Protection Agency (U.S.), the Consumer Product Safety Commission (U.S.), the Occupational Safety and Health Administration (U.S.), the Food & Drug Administration (U.S.), Health Canada, Environment Canada, the California Air Resources Board, and the California Department of Pesticide Regulation. This robust regulatory backdrop does provide essential human health and natural resource protection. In fact, that is a key obligation of their activities and should be looked to for guidance in establishing a workable regulatory framework in meeting the Department's obligations under the Safer Consumer Products Act.

The Clorox Company appreciates the opportunity to review and provide comments on the Safer Consumer Products proposed regulations (“the regulations”). Through our association with the American Cleaning Institute (ACI), the Consumer Specialty Products Association (CSPA) as well as other industry efforts, we have been actively reviewing and providing our perspective to both the authorizing legislation and the years-long regulatory development process. In that vein, we align ourselves with the comments submitted by our industry representatives which provide a more comprehensive review of the points of concern as well as incorporate by reference our earlier comments, dated 11 October 2012.

With respect to the current revised SCP proposed regulations, we appreciate the Department’s modifications as it relates to:

- Elimination of the Certified Assessor process;
- Express recognition of the primacy of existing California and/or federal regulatory programs and their requirements affecting chemical management;
- Following the APA process in the future development of “Priority Products lists”;
- Improved measure of reliability of information received by including a specified standard before being “accepted”; and
- Including science-based prioritization factors and requirement rather than Governor’s executive order, general petition or specific legislative directive.

With respect to areas of ongoing concern, we have the following:

- The provisions addressing adverse air quality impacts now explicitly includes INDOOR as well as and outdoor air emissions that create a potential to adversely affect public health and the environment. As noted in our prior comments, consumer products are already subject to the California Air Resources Control Board requirements regarding indoor air quality and this provision is problematic to the extent that it captures degradents emitted by a suite of antimicrobial products. Furthermore, with the addition of the word “potential” (vs. ability) to degrade, etc., the provision broadens the sweep of DTSC’s ability to make a determination regarding this category of products.
- The “*de minimis*” question is “addressed” through the introduction of a “Practical Quantitation Limit” (PQL), is limited to contaminants. Not only does this introduce a new concept with limited utility re: addressing “*de minimis*” concerns, it does not harmonize with actions taken by two other states in this area: Washington state and Maine. We would encourage the Department to reconsider inclusion of a commonly understood, international standard of 0.01% for chemicals with particular hazard traits; and 0.1% for all other chemicals.
- The timelines associated with the Alternative Analysis provisions, as noted previously, are aggressive and do not comport with industry’s experience involving the development of alternative formulations (i.e. U.S. EPA’s Design for the Environment program).
- Regulatory Response as proposed continues to limit opportunity for development of additional mitigation measures and/or additional data. In addition, it also raises data compensation issues.
- The provisions surrounding the protection of “Trade Secrets” continue to undermine the confidentiality of business information (CBI). The provision now relies on protection under PATENT statutes, essentially eliminating CSF type approach and not providing significant improvement around CBI concerns.

The following areas have introduced new concerns and warrant calling out:

- Article 3: Process for Identifying & Prioritizing Product Chemical Combinations
  - Safer alternative language now predisposes DTSC to list if there is a “readily available safer alternative” (area of concern in the prior version as well, more explicit in the current version).
  - New language capturing product that is manufactured, stored, transported through California EVEN when destined for use OUTSIDE of California.
  - Presence of the product/releases now includes homes, schools, workplace and other locations; again, it raises the question of how this aligns with authorities of other regulatory agencies, i.e. CalOSHA/OSHA.
  - Section 69503.2: Other Regulatory Programs: The Department grants itself the authority to assess the adequacy of other state and federal programs as well as international agreements to provide adequate protections with respect to specified adverse effects. To the extent that in earlier provisions of the proposal deference was paid to other state/federal/international programs, this provision would seem to pierce that primacy and/or “fire wall”. This places the regulated community in a position both “double jeopardy” and obligated to meet what may be mutually exclusive criteria.
- Article 5: Alternatives Analysis
  - All relevant information pertaining to the AA report will be available on the department’s web site and all responses will be summarized in either the final AA or the abridged AA report. This places a significant burden on the regulated entity, to wit: AA development now resembles CEQA-like process, including a public review requirement. Under this requirement, it is unclear to what extent the manufacturer must circulate a proposal and the comments received. The most conservative reading suggests that this requirement applies at each stage of the process, i.e. Preliminary AA report; draft abridged AA Report; and the alternate process AA work plan. If this is the correct interpretation, the time requirement increases substantially as does the draw on resources to manage the public review process.
    - Related to this exercise, there is no guidance regarding how public comments should be evaluated: is the opinion of the commenter held in the same regard as a scientifically peer-reviewed journal article? How much data, if any is sufficient to support a commenter’s position?
  - Section 69505.6(a)(2)(C)(1)(b) Economic Impacts: The calculation of costs (public goods) now includes “non-profit organizations that manage waste, oversee environmental cleanup, et seq.” This is in addition to government agencies. The inclusion of this language has the power to greatly expand the universe of entities that would need to be considered in the calculation of public good costs and argues for deletion of the reference to “non-profit” organizations. Absent that, at a minimum, the “non-profit” should be contractually or otherwise obligated to a public agency (local/state/federal) to manage for environmental outcomes or otherwise obligated to a public agency to manage to measureable outcomes; e.g. the Nature Conservancy’s contracts to manage public lands for BLM, local conservancies and the like.
  - Section 69505.7: AA Reports: a change of some concern relates to the increased visibility given AA reports; namely, a separate, publically available AA must be submitted with the information of concern “masked”. However, if this version is rejected by the Department, a non-redacted version will have submitted/made publically available which is contrary to the regulated community’s best interest as it

relates to confidential business information, including the affirmative obligation to actively manage the availability of the information in order to assert trade secret status.

Clorox appreciates the opportunity to comment on the Department's revised proposed regulations. We remain committed to working for a regulatory scheme that is legally defensible; allows for practical implementation; and is meaningful in meeting the spirit behind the authorizing statutes.

Please contact me if you have any questions regarding our comments.

Sincerely,

A handwritten signature in purple ink that reads "MaryAnn Warmerdam". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Mary-Ann Warmerdam  
Regulatory Affairs Leader  
Global Stewardship

Albany  
Atlanta  
Brussels  
Denver  
Los Angeles

**McKenna Long  
& Aldridge** LLP  
Attorneys at Law

101 California Street • 41st Floor • San Francisco, CA 94111  
Tel: 415.267.4000 • Fax: 415.267.4198  
www.mckennalong.com

New York  
Philadelphia  
San Diego  
San Francisco  
Washington, D.C.

ANN G. GRIMALDI  
(415) 267-4104

EMAIL ADDRESS  
agrimaldi@mckennalong.com

February 28, 2013

**VIA E-MAIL ([DRAPHAEL@DTSC.CA.GOV](mailto:DRAPHAEL@DTSC.CA.GOV)) AND  
BY FEDERAL EXPRESS**

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

Re: Comments of the Complex Durable Goods Coalition on Revised Proposed Safer  
Consumer Products Regulations

Dear Ms. Raphael:

I am pleased to submit the comments of the Complex Durable Goods Coalition (the "Coalition") on the Revised proposed Safer Consumer Products Regulations (the "Revised SCP Regulations"), released by the Department of Toxic Substances Control ("DTSC") on January 29, 2013 for public comment. As described further in this letter, the Coalition is pleased to see some of the revisions made by DTSC. Nevertheless, many of the revisions are so substantial and unexpected that the Revised SCP Regulations should be released as a new regulatory proposal with a Statement of Reasons, a new 45-day comment period and a public hearing pursuant to the California Administrative Procedures Act ("APA"), Government Code sections 11340 *et seq.* In addition to this overarching issue, the Coalition remains extremely concerned that the overall regulatory scheme remains unworkable and unpredictable.

The Coalition is a group of trade organizations representing broad and diverse industry interests. Its mission is to engage in strategic planning, and regulatory and technical advocacy, regarding state and federal chemical initiatives that may impact the manufacturers of complex durable goods, their suppliers and other related entities such as those that may distribute or sell such goods and/or sell or use their replacement parts. For the Coalition's purposes, "complex durable goods" are manufactured goods composed of 100 or more manufactured components, with an intended useful life of five or more years, where the product is typically not consumed, destroyed, or discarded after a single use. For purposes of this comment letter, the Coalition consists of the following members: the Aerospace Industries Association, the Alliance of Automobile Manufacturers, the Association of Global Automakers, the Automotive Aftermarket Industry Association and the Motor and Equipment Manufacturers Association.

The Coalition appreciates the efforts made by DTSC to respond to a wide spectrum of concerns raised by DTSC's July 2012 version of the proposed SCP Regulations (the "2012 SCP Regulations"). The Coalition is gratified to see some of the revisions that DTSC has made, including the elimination of the certified assessor requirement, the introduction of the concept of economic feasibility in key provisions, and the introduction of "assembler" as a new category of responsible entities.

However, many of the problems in the 2012 SCP Regulations remain, and many new problems and uncertainties are introduced, in DTSC's revisions. In order for the SCP Regulations to achieve the goal of a workable, consistent and fair chemical/product regulatory program, these problems must be fixed and the uncertainties must be eliminated. And, as discussed further in this letter, the broad and unanticipated nature of many of the revisions requires DTSC to release these revised regulations as a new regulatory proposal subject to another formal public participation process under Government Code sections 11346.4 and 11346.5 of the APA.

Many of the remaining problems in the Revised SCP Regulations present particularly difficult obstacles to manufacturers of complex durable goods and to the entities that manufacture or sell replacement parts for such goods. The Coalition's comments to the 2012 SCP Regulations, which the Coalition attaches and incorporates herein by reference, described in detail the unique aspects of complex durable goods.<sup>1</sup> Because these unique aspects have a great impact on the application of the SCP Regulations, we repeat them here:

- The global supply chain for these goods is multi-tiered and multi-faceted, from foundational raw materials to finished systems' components for final assembly and installation.
- The lead-time necessary for product design, development and validation is on the order of years, not months or weeks.
- These products are designed to be in service for several years, or in many cases, decades.
- Because these products are designed to last for years, replacement parts to support their repair and maintenance likewise must be available for years.

<sup>1</sup> See Attachment 1 hereto. The Coalition's comments also may be found at [http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP\\_Comments\\_A\\_J.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP_Comments_A_J.pdf). Although the Coalition does not physically include with this letter the attachments to its October 10, 2012 comments, it incorporates those attachments herein by reference.

- These products already are subject to stringent legal, governmental and industry requirements, including safety, environmental, product performance and other certification standards.
- Changes in design and/or chemical composition nearly always require significant analysis, validation and performance testing. Such requirements can range from failure-mode analysis to actual field testing to specific methodologies of testing mandated by any number of regulatory outlets in the global markets in which products are sold. Timing, especially when prior regulatory approval is required, is unpredictable, potentially unachievable, and often in the magnitude of years, assuming that the chemical substitute even meets the performance criteria originally intended.
- These products must perform and function reliably in very specific ways.
- Consumers and customers have specific expectations and requirements for these products.

The Coalition discusses below its primary concerns with the Revised SCP Regulations. We observe here that the absence of any Statement of Reasons accompanying DTSC's revisions creates difficulties in understanding their basis; if the Coalition's comments are based on misunderstandings of the revisions discussed below, we ask that DTSC provide clarification in its Final Statement of Reasons.

**I. THE NEW TERMS "ASSEMBLE" AND "ASSEMBLER" CREATE CONFUSION IN THE CONTEXT OF MANUFACTURING COMPLEX DURABLE GOODS.**

**A. Explanation of concern**

The Coalition and many of its individual members previously provided detailed comments and recommendations to DTSC outlining the challenges imposed by the proposed SCP Regulations on the manufacturers of complex durable goods. DTSC has taken this input to mean that such manufacturers fundamentally only assemble many components when they manufacture such goods. The Revised SCP Regulations now include "assemblers" as responsible entities, allocating to them a role similar to that of retailers. The Coalition appreciates DTSC's revision in this regard, in that it is an attempt to appropriately allocate the regulatory burdens of DTSC's proposed program.

However, the complex global supply chain inherent in the assembly of complex durable goods means that many of these entities nevertheless will fall under the category of "importer" and be subject to the complex and burdensome aspects of the regulatory program. That is because these entities sometimes may import the components that they assemble and/or in some cases import the assembled product. In these importing contexts, these entities have little access to information pertaining to the components' constituents and have little control over the

components' composition, in order to fulfill the regulatory obligations imposed by DTSC's proposed program.

In short, it appears that in some cases assemblers of complex durable goods would be deemed to be covered by the higher tier of responsible entity, *i.e.*, importer. To promote DTSC's goal in creating the new "assembler" category, DTSC should revise the definition of "importer" as the Coalition proposes below, and thereby appropriately allocate the regulatory obligations among responsible entities.

In addition, the terms "assembly" and "subassembly" in the definition of "component" renders the new terms "assemble" and "assembler," and their respective definitions, unnecessarily confusing. This is particularly troublesome because of the prominent role played by components in the assembly of complex durable goods; indeed, complex durable goods fundamentally are complex assemblies of components. These two terms should be removed from the "component" definition and the definition should clarify that it pertains to components in assembled consumer products.

**B. Proposed revisions to regulatory language (additions in underline; deletions in strikethrough)**

The Coalition proposes that DTSC adopt all of the following revisions.

1. *Move the definition of "complex durable product" now contained in Section 69503.5 (c)(2) to new Section 69501.1(a)(23), and renumber subsequent sections accordingly.*
2. *Revise Section 69501.1(a)(23)(A):*

"Component" means a uniquely identifiable homogeneous material, part, or piece, ~~assembly, or subassembly~~ that is a necessary or intended element of an assembled consumer product.

3. *Revise Section 69501.1(a)(39):*

"Importer" means a person who imports a product that is subject to the requirements of this chapter. "Importer" does not include:

A. A person that imports a product solely for use in that person's workplace if that product is not sold or distributed by that person to others; or

B. A complex durable product assembler.

## **II. DTSC'S REVISIONS FAIL TO ADDRESS REPAIR, REFURBISHMENT AND PRODUCT MAINTENANCE ACTIVITIES AND FAIL TO ADDRESS REPLACEMENT PARTS.**

### **A. Explanation of concern**

Complex durable goods typically are intended to last several years, even decades. As a result, such goods require repair, refurbishment and/or maintenance services – and replacement parts with which to provide such services. Replacement parts may be associated with products that are no longer being manufactured. Frequently such parts must meet specific legal requirements and/or regulatory approvals or certifications.

The Coalition previously commented on the 2012 SCP Regulations' definition of "manufacture" and those Regulations' treatment of replacement parts. The Coalition urged DTSC to exclude repair, refurbishment and maintenance activities from the definition of "manufacture" because persons and entities conducting such activities are ill-positioned to conduct the complex and costly alternatives assessments ("AAs") required under the proposed program. The Coalition also urged DTSC to exclude replacement parts from the definition of "consumer product." The Revised SCP Regulations fail to address the Coalitions' concerns.

DTSC previously has stated its position that repair, refurbishment and maintenance activities are not considered "manufacture" activities within the meaning of these regulations. *See, e.g.*, Revised Statement of Reasons ("SOR") at 31 ("...activities such as replacing worn, or depleted parts, repairing defective or nonworking components, or restoring or rebuilding a product would not represent the manufacture of a product. A "manufacturer" would not include persons engaged in these restoration activities."). Yet, the new definition of "manufacture" now contains no exclusion for repair, refurbishment or maintenance activities in any form. DTSC may have intended the "assemble" exclusion, contained in that definition, to encompass such activities. However, the definition of "assemble" does not achieve that goal for two primary reasons. First, by referencing the *creation* of a consumer product, that definition could be interpreted as not reaching repair, refurbishment or maintenance activities for *existing* products. Second, the term "responsible entity" under the Revised SCP Regulations includes assemblers – a definition that would thwart the goal of excluding altogether from the AA process those persons and entities merely conducting repair and maintenance services.

We recognize that DTSC has included new language under the Regulatory Response section that allows DTSC to consider replacement parts in establishing the scope of a regulatory response. *See* Section 69506.1(f)(4) (referencing "Priority Products ordered by a retailer prior to the effective date of the Priority Product listing, and still for sale..." and "Priority Products manufactured after the effective date of the Priority Product listing, but before the date of the final regulatory response determination notice."). But this provision does not go far enough. First, it is too narrow in scope, in that: (1) it seems designed to allow retailers to exhaust existing inventory, and not necessarily to allow continued manufacture of replacement parts; and (2)

insofar as it relates to manufacture of replacement parts, it covers a very narrow time window of manufacture.

Second, while this revision allows DTSC to select how to address these types of products, which may – or may not – include replacement parts, there is no certainty that replacement parts actually will be excluded. As the Coalition explained in its previous comments, replacement parts are a necessary and critical aspect of ensuring the full useful life of complex durable goods and there must be certainty that these replacement parts can continue to be offered as needed. We continue to urge DTSC to explicitly exclude from this regulation replacement parts used to repair and maintain products.

**B. Proposed revisions to regulatory language (additions in underline; deletions in strikethrough)**

The Coalition proposes that DTSC adopt all of the following revisions.

1. *Revise Section 69501.1(a)(43):*

“Manufacture” means to make or produce. “Manufacture” does not include:

(A) acts that meet the definition of “assemble;” or

(B) repair or refurbishment of an existing consumer product; or

(C) installation of components to an existing consumer product; or

(D) making non-material alterations to an existing consumer product.

2. *Revise Section 69501.1(a)(24) to add:*

(D) “Consumer product” does not mean replacement parts used to repair, refurbish or maintain existing consumer products.

**III. THE ALTERNATIVES ANALYSIS THRESHOLD EXEMPTION IS OVERLY NARROW.**

**A. Explanation of concern**

DTSC previously has acknowledged that an AA should not be required for all Priority Products, and that appropriate criteria must be established for those circumstances in which a responsible entity is relieved of the obligation to conduct an AA. *See, e.g.*, Revised SOR at 112-116 (describing the Alternatives Analysis Threshold Exemption). This is consistent with

DTSC's legislative mandate to "identify and *prioritize*" chemicals in consumer products. Health & Safety Code § 25252(a) (emphasis added).

In establishing the Alternatives Analysis Threshold Exemption (the "AAT Exemption"), DTSC recognized that an "off-ramp" from the AA process, based on the amount of the chemical of concern ("COC") in the Priority Product, is necessary for a workable and scientifically defensible regulatory program. DTSC further has explained that the criteria for such an "off-ramp" must be "scientifically appropriate." Revised SOR at 114. Significantly, DTSC previously has stated that any exemption based on the amount of the COC in the Priority Product should encompass both intentionally added chemicals and contaminants because the "risk to public health and the environment are the *same* for intentionally and unintentionally added chemicals." Revised SOR at 112-113 (emphasis added).

This concept is hardly new. Numerous federal and California environmental programs, such as the California Drinking Water Program, establish specific levels for chemicals, above which a regulated entity must take specific action, and below which it need not, in accordance with the relevant law and regulations. These specific levels are calculated using standard risk assessment methods and in many cases (such as for Maximum Contaminant Levels) also incorporate technical and economic feasibility concepts.

But DTSC's proposed revisions associated with the AAT Exemption fail to achieve the goal of creating a reasonable, scientifically well-founded "off-ramp" from the AA process for those Priority Products that contain minimal amounts of COCs and present little or no risk to human health or the environment. Two key deficiencies of DTSC's AAT Exemption proposal undermine its intent: (1) the failure to include intentionally-added chemicals and (2) reliance on the "Practical Quantitation Limit" ("PQL") as the sole scientific measure to trigger the exemption.

These deficiencies must be cured. They are inconsistent with legislative intent, which makes clear that AB 1879 is intended to address chemical-product combinations that pose significant risk:

AB 1879 represents a balanced, *science-based approach* to addressing the *danger* of hazardous chemicals contained in consumer products....The bill provides an open and transparent process for identifying and prioritizing the *most dangerous chemicals* and for determining what the department should do about these chemicals contained in products.

Report of Senate Committee on Environmental Quality dated August 20, 2008 ([http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab\\_1851-1900/ab\\_1879\\_cfa\\_20080821\\_111017\\_sen\\_comm.html](http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080821_111017_sen_comm.html)) at 6 (emphasis added).

There is no scientifically justifiable reason to exclude intentionally added chemicals from the AAT. DTSC itself has acknowledged that the exemption should not differentiate between the two categories of chemicals, as the 2012 SCP Regulations and the Revised Statement of Reasons demonstrate. Yet, in a complete reversal of its prior position, DTSC inexplicably has narrowed the AAT Exemption in an artificial distinction between contaminants and intentionally added chemicals that yields no benefit to public health or the environment.

DTSC's AAT Exemption proposal also suffers because of its exclusive reliance on the PQL. The proposed definition of the PQL is too vague to provide sufficient guidance to the regulated community.<sup>2</sup> PQLs depend on the analytical method, the instrumentation, and even the laboratory in which a PQL is developed. At a minimum, the PQL must incorporate statistical rigor in order for it to have practical meaning in DTSC's proposed program.

Thus, the AAT Exemption must be revised in at least two important ways: (1) it must encompass intentionally added chemicals and (2) the PQL definition must incorporate statistical rigor.

Finally, DTSC's use of the PQL in the proposed regulation also fails to account for the potential for risk to human health or the environment resulting from the presence of a COC in a Priority Product. This means that responsible entities will invest substantial resources to conduct complex and burdensome AAs for products that have little or no potential for adverse impacts. This similarly means that DTSC will be inundated with AA reports for products presenting little or no risk of adverse impacts. Such a result does not seem to be a wise investment of resources, and is contrary to the Legislature's intent that DTSC "*prioritize*" chemicals in consumer products and target "*the most dangerous*" chemicals. The Coalition urges DTSC to adopt a risk-based AAT Exemption.

**B. Proposed revisions to regulatory language (additions in underline; deletions in strikethrough)**

The Coalition proposes that DTSC adopt all of the following revisions.

1. *Revise Section 69501.1(a)(12):*

"Alternatives Analysis Threshold" means the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product ~~solely as a contaminant~~.

<sup>2</sup> PQLs also may change over time. That is because a PQL depends on the particular analytical method, which itself may change over time. Thus, an exemption based exclusively on a PQL offers no consistency or certainty in application, even for the same COC in the same Priority Product.

2. *Revise Section 69501.1(a)(52):*

“Practical Quantitation Limit” or “PQL” means the lowest concentration of a chemical that can be precisely quantified (percent relative standard deviation within  $\pm 10$  percent) with an acceptable bias (percent recovery within 90-110 percent) reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.

3. *Revise Section 69505.3(a)(4):*

A statement certifying that ~~the Chemical(s) of Concern are present in the manufacturer’s Priority Product only as contaminants and~~ the concentration of each Chemical of Concern in the manufacturer’s Priority Product does not exceed the Alternatives Analysis Threshold for that chemical;

**IV. SUBJECTING THE PRELIMINARY AA REPORT, THE DRAFT ABRIDGED AA REPORT AND THE ALTERNATE PROCESS AA WORK PLAN TO PUBLIC COMMENT, TO WHICH THE RESPONSIBLE ENTITY MUST RESPOND, IS AN UNNECESSARILY BURDENSOME METHOD OF ENSURING TRANSPARENCY.**

**A. Explanation of concern**

The Coalition appreciates that DTSC intends the AA process to be as transparent as possible. However, subjecting the Preliminary AA Report, the draft Abridged AA Report and the Alternate Process AA Work Plan to public comment, with the requirement that the responsible entity (rather than DTSC) collect and respond to such comments, is an unprecedented and unnecessarily burdensome method of achieving that goal. This provision must be eliminated.

DTSC’s proposal would require the responsible entity to invest substantial resources in establishing the necessary infrastructure for this public process and in responding to an as-yet-unknowable, but likely large, number of public comments. By thrusting on the regulated community’s shoulder the responsibility to engage the public in a formal public participation process, DTSC’s proposal ironically threatens the integrity of public participation in the AA process altogether. Such a radical revision of the 2012 SCP Regulations could not possibly have been anticipated by the public.

The AA process is a highly technical and complex one. DTSC itself has conducted numerous workshops to identify appropriate technical approaches for conducting AAs, inviting experts in academia and in the regulated community to provide input. DTSC also is working on developing guidelines for conducting AAs, which presumably will provide significant assistance to responsible entities. Yet, this proposed provision in the Revised SCP Regulations would invite any comment, no matter how scientifically ill-founded, and require the responsible entity to invest the resources necessary to respond. DTSC’s proposal fails to establish specific criteria

for public comments to ensure the scientific integrity of the AA and to minimize the use of the responsible entity's resources to respond to irrelevant and scientifically unfounded comments.

The Revised SCP Regulations also fail to establish any criteria for the method by which the responsible entity is to collect public comments. This failure may subject even the most well-intentioned responsible entity to claims that the method of submitting public comments for a particular AA document is inadequate. Such issues will distract from the goal of ensuring that the AA process is transparent and that the AA document at issue is grounded in scientific integrity.

DTSC's proposal also may exceed the agency's authority under AB 1879, in violation of the APA. Regulations promulgated under AB 1879 must be "consistent and not in conflict" with the authorizing statute. Gov't Code §11324.2. AB 1879 requires DTSC to "ensure that the tools available are in a form that allows for ease of use...." Health & Safety Code § 25253(c). As already described above, the proposed public review process is not a tool that "allows for ease of use," as AB 1879 requires, and therefore DTSC's proposed regulation may violate the APA.

Regulations promulgated under AB 1879 also must be "reasonably necessary" to effectuate its purpose. Gov't Code §11342.2. As is relevant here, AB 1879 requires DTSC to "establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." Health & Safety Code § 25253. Requiring private entities to lead formal public participation proceedings, collecting and responding to public comments on the AA documents required by DTSC's own regulatory program, is not "reasonably necessary" to effectuate this purpose. In this round of the regulatory process, DTSC has provided the public with no rationale that may otherwise establish the "reasonably necessary" prong for validity of this regulation under the APA.

Ultimately, DTSC's proposal subverts DTSC's role in implementing the SCP Regulations. It is DTSC, not the responsible entity, that should be the lead in collecting and responding to comments pertaining to reports required under DTSC's own regulatory program. It is DTSC, not the responsible entity, that possesses the existing infrastructure and experience to collect and respond to comments. Indeed, the Revised SCP Regulations already require DTSC to post a notice on its website regarding the availability of the particular AA document for public review and comment, reflecting the agency's acknowledgement of its own role in the public participation process. The SCP Regulations must eliminate the proposed regulation requiring the responsible entity preparing the subject AA documents to collect and respond to public comment.

The Coalition observes that this proposed regulation is not necessary to achieve DTSC's apparent goal. If DTSC's motivation for its proposal is the conservation of agency resources, then DTSC may request the responsible entity submitting the AA document to assist DTSC in preparing responses to public comments, rather than abdicating this regulatory role. There is

precedent for this collaborative approach, insofar as under other regulatory programs it is not uncommon for state agencies (including DTSC) to work with regulated entities in responding to public comments. For example, Remedial Action Plans (“RAPs”) for contaminated property cleanups are required to be published for public notice and comment under Health & Safety Code section 25356.1. RAPs frequently are prepared, under DTSC’s oversight, by the private entity conducting the cleanup. In these circumstances, such private entities also frequently work with DTSC in responding to public comments. Similarly, draft Environmental Impact Reports (“EIRs”) under the California Environmental Quality Act frequently are prepared by the project proponent under the oversight of the lead agency. Draft EIRs are required to be published for public notice and comment and, again, it is not uncommon for the project proponent to assist the lead agency in the preparation of responses to public comments.

**B. Proposed revisions to regulatory language (additions in underline; deletions in strikethrough)**

The Coalition proposes that DTSC make the following revision.

*Revise Section 69505.1(d):*

(d) Consideration of information ~~and public comments~~.

(1) A responsible entity conducting an AA shall consider all relevant information made available on the Department’s website, ~~including any relevant public comments~~, and any additional information or technical assistance the Department may provide regarding alternatives analysis. The responsible entity shall summarize these efforts in the Final AA Report or final Abridged AA Report, whichever is applicable.

~~(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 Workplan submitted to the Department. The notice shall include the time period, not to exceed forty five (45) days, during which the public may submit comments, and the methods 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.~~

**V. THE AA GUIDELINES ARE REGULATIONS SUBJECT TO THE FORMAL PUBLIC PARTICIPATION PROCESS OF THE APA.**

Section 69505 of the proposed regulations requires DTSC to make AA guidelines available prior to the initial list of Priority Products. These guidelines are intended to assist persons in performing AAs “in accordance with this article.” DTSC’s Revised SOR for this section further explains that “Since this is a new endeavor for most regulated entities, DTSC’s guidance is *essential* to ensuring that the AAs are performed and reported in a manner that is timely and *in compliance with the regulations*.” Revised SOR at 130 (emphasis added).

These guidelines must be promulgated in accordance with the APA's requirements because the guidelines effectively are regulations. Failure to comply with the APA's public participation requirements will render the "guidelines" invalid underground regulations.<sup>3</sup> Yet, nothing in the proposed regulations states or even suggests that the guidelines will be subject to public notice and comment.

Under Government Code section 11342.600, a "regulation" means "every rule, regulation order or standard of general application ... adopted by any state agency to implement, interpret or make specific the law enforced or administered by it, or to govern its procedure." All regulations are subject to the public participation requirements of the APA.

The guidelines described in Section 69505 of the proposed regulations are standards to be applied to entities regulated under AB 1879 and DTSC's proposed program implementing the law; they are to be adopted by DTSC, a state agency; and they will be promulgated to make specific AB 1879 – *i.e.*, the law administered and enforced by DTSC – as well as to govern the AA process imposed by DTSC's regulatory program. The guidelines are therefore "regulations" within the meaning of the APA. DTSC's reference to them as "guidelines" cannot change the fact that they must be adopted pursuant to the procedure calling for notice and opportunity to be heard. *See Union of American Physicians and Dentists v. Kizer* (1990) 223 Cal.App.3d 490. Failure to subject the guidelines to formal public participation under the APA will render them invalid underground regulations.

DTSC must issue the AA guidelines as regulations subject to the formal public participation requirements of the APA, and DTSC must clarify, in the current proposed regulations, that the guidelines shall be posted on DTSC's website after the public participation proceeding has been completed in accordance with the APA.

<sup>3</sup> The Office of Administrative Law's regulations define the term "underground regulation" as:

any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, including a rule governing a state agency procedure, that is a regulation as defined in Section 11342.600 of the Government Code, but has not been adopted as a regulation and filed with the Secretary of State pursuant to the APA and is not subject to an express statutory exemption from adoption pursuant to the APA.

<sup>1</sup> Cal.Code Regs. § 250(a).

**VI. THE BROAD AND UNANTICIPATED NATURE OF DTSC'S REVISIONS REQUIRES DTSC TO RELEASE THE REVISED REGULATIONS AS A NEW REGULATORY PROPOSAL WITH A STATEMENT OF REASONS, A NEW 45-DAY COMMENT PERIOD AND A PUBLIC HEARING UNDER GOVERNMENT CODE SECTIONS 11346.4 AND 11346.5.**

DTSC's extensive revisions of the proposed SCP Regulations render them subject to a new round of formal public participation proceedings under the APA. Contrary to Government Code section 11346.8(c), the revisions are neither "nonsubstantial or solely grammatical in nature," nor "sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action." Among these changes:

- The requirement for the responsible entity, rather than DTSC, to receive and respond to public comments on a Preliminary AA, a draft Abridged AA or an Alternate Process AA Work Plan completely turns on its head the agency's statutorily mandated responsibility to inform and engage the public in regulatory decision-making. Aside from the improper abdication of a public agency's duty to solicit, receive and respond to public comments, this provision places significant burdens on the responsible entity, especially in terms of establishing a clear and reliable method for the public to submit comments to it, all in the complete absence of any criteria for the method for such communication. Nothing in the July 2012 version of the SCP regulations could have put the public on notice of this unprecedented shift, to the regulated community, of DTSC's responsibility to solicit, receive and respond to public comments.
- DTSC's apparent current position on whether "manufacture" includes repair, maintenance and refurbishment activities is an unprecedented reversal of its former position.
- Trade secret protection under Article 9 appears to have been narrowed substantially, with, *e.g.*, protection now tied to a patent application and only temporarily masked.
- The expansion of the information call-in subject matter to include even products not encompassed by Health and Safety Code section 25251 is unprecedented and likely unlawful.

Accordingly, the Revised SCP Regulations are not revisions subject to Government Code section 11346.8(c). Rather, they constitute a new regulatory proposal required to comply with Government Code sections 11346.4 and 11346.5. The Coalition therefore asks that DTSC release the Revised SCP Regulations as a new regulatory proposal with an accompanying Statement of Reasons for a full public notice and comment proceeding with a hearing.

Debbie Raphael, Director  
February 28, 2013  
Page 14

Thank you again for this opportunity for the Coalition to comment on the Revised SCP Regulations.

Very truly yours,



Ann G. Grimaldi

cc: Matthew Rodriquez, Cal/EPA Secretary (via first class mail and email:  
matthew.rodriquez@calepa.ca.gov)  
Cliff Rechtschaffen, Senior Advisor to Governor Brown (via first class mail)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor  
(via first class mail)  
Odette Madriago, Deputy Director (via email: omadriago@dtsc.ca.gov)  
Jeff Wong, Chief Scientist (via email: jwong@dtsc.ca.gov)  
Kryisia von Burg, Regulations Coordinator (via first class mail and email:  
gcregs@dtsc.ca.gov)

SF:27562451.5

# **ATTACHMENT 1**

Albany  
Atlanta  
Brussels  
Denver  
Los Angeles

**McKenna Long  
& Aldridge**<sup>LLP</sup>  
Attorneys at Law

101 California Street • 41st Floor • San Francisco, CA 94111  
Tel: 415.267.4000 • Fax: 415.267.4198  
www.mckennalong.com

New York  
Philadelphia  
San Diego  
San Francisco  
Washington, D.C.

ANN G. GRIMALDI  
(415) 267-4104

EMAIL ADDRESS  
agrimaldi@mckennalong.com

October 10, 2012

**VIA E-MAIL ([DRAPHAEL@DTSC.CA.GOV](mailto:DRAPHAEL@DTSC.CA.GOV)) AND  
BY FEDERAL EXPRESS**

Debbie Raphael, Director  
California Department of Toxic Substances Control  
1001 "T" Street  
Sacramento, CA 95812

Re: Comments of the Complex Durable Goods Coalition on Proposed Safer  
Consumer Products Regulations

Dear Ms. Raphael:

I am pleased to submit the comments of the Complex Durable Goods Coalition (the "Coalition") on the proposed Safer Consumer Products Regulations released by the Department of Toxic Substances Control ("DTSC") on July 27, 2012 (the "Regulations"). We appreciate the extension of time DTSC granted to submit comments.

The Coalition is a group of trade organizations representing broad and diverse industry interests. Its mission is to engage in strategic planning, and regulatory and technical advocacy, regarding state and federal chemical initiatives, as such initiatives may impact the manufacturers of complex durable goods, their suppliers and other related entities such as those that may distribute or sell such goods and/or sell or use their service parts. For the Coalition's purposes, "complex durable goods" are manufactured goods composed of 100 or more manufactured components, with an intended useful life of five or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

Ten trade organizations comprise the Coalition, and membership continues to expand. Current members include the Aerospace Industries Association, the California Building Industry Association, the California Automotive Wholesalers Association, the Association of Home Appliance Manufacturers, the Outdoor Power Equipment Institute, the Truck and Engine Manufacturers Association, the Alliance of Automobile Manufacturers, the Association of Global Automakers, the Automotive Aftermarket Industry Association and the Motor and Equipment Manufacturers Association.

The companies represented by the Coalition are crucial to the economy of California and the nation. Aside from the economic contributions that flow from the sale and purchase of their goods, these companies in the aggregate directly provide hundreds of thousands of jobs in California and nationwide, and indirectly support the employment of millions of other individuals.

Notwithstanding the diversity of the Coalition's membership, Coalition members are uniform in their concern that the Regulations are overbroad, impractical and unworkable for manufacturers of complex durable goods, their suppliers and other entities which distribute, sell or use them and/or their service parts. Stated in the simplest way, the Regulations do not adequately account for the unique characteristics of complex durable goods. Among these unique characteristics:

- The global supply chain for these goods is multi-tiered and multi-faceted, from foundational raw materials to finished systems' components for final assembly and installation.
- The lead-time necessary for product design, development and validation is on the order of years, not months or weeks.
- These products are designed to last for several years, or in many cases, decades.
- Because these products are designed to last for years, service parts to support their repair and maintenance likewise must be available for years.
- These products already are subject to stringent legal, governmental and industry requirements, including safety standards.
- Changes in design and/or chemical composition nearly always require significant analysis, validation and performance testing. Such requirements can range from failure-mode analysis to actual field testing to specific methodologies of testing mandated by any number of regulatory outlets in the global markets in which products are sold. Timing, especially when prior regulatory approval is required, is unpredictable, potentially unachievable, and often in the magnitude of months and years, assuming that the chemical substitute even meets the performance criteria originally intended.
- These products must perform and function reliably in very specific ways.
- Consumers have specific expectations and requirements for these products.

Below I describe the Coalition's top concerns regarding the Regulations, and set forth the Coalition's proposed revised regulatory language and other recommendations to address those concerns.

Before turning to those top concerns, however, the Coalition joins in the comments of other entities pointing out the deficiencies in DTSC's economic impact analysis required under the California Administrative Procedures Act, and in DTSC's attempt to comply with the California Environmental Quality Act ("CEQA"). The Coalition agrees with those commenters that DTSC's analyses do not meet the legal requirements of those respective laws. The Coalition also points out that CEQA requires, among other things, an analysis of alternatives to the Regulations, yet despite the fact that DTSC has drafted numerous informal iterations of the Safer Consumer Products Regulations, DTSC has failed to analyze any of these. In these comments, the Coalition attaches and incorporates herein by reference two reports that discuss these analyses' shortcomings in greater detail: "The Consumer Impact of California's Green Chemistry Initiative," authored by the California Foundation for Commerce and Education and dated October 3, 2012; and the October 11, 2012 letter from Jim Lyons of Sierra Research.

The Coalition also joins in the concerns expressed by the Enterprise and Industry Directorate-General of the European Commission in the September 11, 2012 email communication from Mr. Giuseppe Casella to the TBT Enquiry Point of the United States (the "EU Comments"). That communication is attached and is incorporated herein by reference. As the EU comments point out, the Regulations are not even-handed and will not establish a level playing field among and within regulated industries. The Coalition agrees with the EU Comments regarding the inadequacy of DTSC's economic analysis, the limited time frame provided to responsible entities for conducting the complex alternatives analyses required, and the potential for conflict with the Technical Barriers to Trade Agreement.

## **I. TIME FRAMES FOR COMPLIANCE ARE WHOLLY INADEQUATE.**

### **A. Explanation of concern**

Complex durable goods require years of design, research and development, testing and validation. Changes in design and/or chemical composition affect each phase of the product lifecycle and require substantial lead-time: materials development alone can require five or more years, with design and development an additional four or more years, and potentially longer for aerospace products. Changes in design and/or chemical composition often require prior regulatory approval from other state and federal agencies. The timelines for such prior regulatory approvals are unpredictable, and potentially unattainable. Further, the supply chains for these products' raw materials and components are extremely complex. The Regulations must build in sufficient time to accommodate these challenges.

The time required to determine, for example, if the Priority Product contains the Chemicals of Concern ("COCs") at the Alternatives Analysis ("AA") Threshold (or, indeed, *any* level) will depend on whether the necessary information exists at the time the Priority Product is listed. If the necessary information is not available at that time, it could take several months to navigate through the complex supply chain network to obtain the necessary information. Even more challenging is the ability to make a decision regarding Priority Product removal or

replacement in the 60-day time frame established by the Regulations, for such decisions necessarily require the foundational knowledge, which takes time to obtain, that a Priority Product contains the COC. It would be virtually impossible for a manufacturer of a complex durable good to make a decision about Priority Product removal or replacement in that 60-day time period.

Further, the time to complete the extremely complex AA process is much too short. The EU Comments identify this problem in their comparison of the Regulations to the EU's REACH program. See EU Comments at p. 8. In addition, the time to complete an AA depends in significant part on how many alternatives are being analyzed. It takes little prognosticative ability to predict that the more alternatives are analyzed, the longer the analysis will take. Arbitrarily compressing the time frame to conduct the analysis could mean that alternatives that otherwise may be beneficial to human health and the environment will be discarded early in the process, to the detriment of the goals of AB 1879 and SB 509.

Regulated entities that manufacture complex durable goods also must be given sufficient time to build, test and validate prototypes. This process is time-consuming and resource intensive, and cannot feasibly be conducted on numerous alternatives. Moreover, entities must establish a reliable supply chain for the manufacture of complex durable goods; with new designs and/or chemical composition, establishing the necessary supply chain may require substantial time. The Regulations must accommodate the need for the prototype process and its timelines. The Regulations also must build in time to obtain necessary regulatory approvals following the prototype build, testing and validation process, so that the manufacturer may lawfully produce the final alternative. And, as part of implementing this prototype process, the Regulations must allow the Final AA report to make a recommendation regarding what alternative(s) will go through the prototype build, test and validate process, along with a recommendation regarding the time frame for such work, before any regulatory response is imposed.

DTSC can find an example of a regulatory approach that addresses the need for this post-AA process by looking to Washington State. Washington's brake friction material law requires a reduction of copper in brake friction materials, since the copper is released from the material during use and enters waterways, with the potential to harm aquatic organisms. Under the law, if Washington's Department of Ecology concludes that an alternative brake friction material may be available, it must convene a brake friction material advisory committee, consisting of representatives from industry, regulators and non-government organizations, and consult with that committee regarding the potential alternative. Revised Code of Washington ("RCW") section 70.285.040. Notably, and in obvious recognition of the lead-time necessary to test, validate and implement a change in brake friction material design and chemical composition, the law requires full implementation of the alternative *eight years* after the Washington's Department of Ecology concludes that a viable alternative exists, following its consultation with the advisory committee. RCW section 70.285.050.

The time frames for compliance under the Regulations are insufficient to accommodate the challenges described here. The Regulations must provide additional time for the initial notifications required to be submitted to DTSC, must build in more flexibility for the preparation and submission of the AA reports and work plans and must include a post-AA prototype testing and validation period prior to the imposition of any regulatory response, if one is to be imposed.

If, indeed, the goal of green chemistry is the design of new and “better” chemistries, the complex durable goods industry must be afforded sufficient time to develop them. And, as important as it is to avoid regrettable chemical substitutions that may adversely impact human health and the environment -- one of DTSC’s oft-stated concerns -- it is equally important to avoid regrettable *products* that do not provide the necessary functionality, durability, safety and other characteristics upon which users rely. The Coalition therefore urges DTSC to adopt its recommendations.

**B. Proposed revisions to regulatory language and timeframe recommendations  
(additions in underline; deletions in strikethrough)**

1. *Revise Section 69503.4(g) as follows, with consistent changes in Sections 69503.7, 69503.6, 69501.2(b) and 69505.1(g):*

(g) Each responsible entity for a product listed on the Priority Product list shall provide to the Department one of the following notifications within ~~sixty (60)~~ one hundred eighty (180) days after the product is listed as a Priority Product, or ~~sixty (60)~~ one hundred eighty (180) days after the product is first placed into the stream of commerce in California, whichever is later:

\* \* \* \* \*

2. *Revise Section 69505.2(c)(3)(C) as follows:*

(C) The work plan must be submitted to the Department no later than ~~sixty (60)~~ one hundred eighty (180) days after the product is included on the Priority Products list. Upon receipt of a work plan under this subsection, the Department shall follow the steps specified for the review of Preliminary AA reports in section 69505.6(a).

3. *Decouple the deadline for submitting the Preliminary AA Report, the Abridged AA Report and the Chemical of Concern Removal Notification, from the date the Priority Product list is published:*
  - a. The deadline for submitting the Preliminary AA report, the Abridged AA Report or the Chemical of Concern Removal Notification should be eighteen (18) months after the responsible entity submits the Priority Product Notification.
  - b. An extension of up to ninety (90) days should be made available as per Section 69505.1(d)(1).
4. *Revise the deadline for the Final AA Report:*
  - a. Section 69505.1(c)(3)(B):

Except as provided in subsection (d)(1), the responsible entity shall submit the Final AA Report no later than ~~twelve (12)~~ thirty-six (36) months after the Department issues a notice of compliance for the Preliminary AA Report....

- b. Section 69595.5(k)(1)(A):

The work plan and implementation schedule must specify the proposed submission date for the Final AA Report, and must ensure that the Final AA Report will be submitted to the Department no later than ~~twelve (12)~~ thirty-six (36) months after the Department issues a notice of compliance for the Preliminary AA Report.

- c. Section 69505.1(d)(1):

A responsible entity may request, and the Department may grant, a one-time extension of up to ninety (90) days to the submission deadline for ~~either~~ the Preliminary AA Report or up to thirty-six (36) months to the submission deadline for the Final AA Report, ~~or both~~....

- d. Section 69505.2(c)(3)(D):

The due date for the Final AA Report shall be ~~eighteen (18)~~ thirty-six (36) months after the date the Department issues a notice of compliance for the work plan, unless the responsible entity requests, under Section 69505.5(k)(1), and the Department approves, under Section 69505.6(a)(3), a longer period of time. ~~The additional time shall not exceed thirty (30) months after the Department issues a notice of compliance for the work plan.~~

5. *Establish a post-AA prototype process:*
  - a. The Regulations must allow responsible entities to identify, in the Final AA Report, one or more alternatives that will undergo prototype building, testing and validation. In the Final AA Report, the responsible entity also would identify what other regulatory approvals are necessary for a successful prototype to be rolled out commercially.
  - b. DTSC would issue a Compliance Notification Regarding Prototype, and the deadline to complete the prototype process would be based on the date of the notification.
  - c. At least twenty-four (24) months must be provided for completion of the prototype process. In some cases, further development time may be required.
  - d. At the end of the prototype process, the responsible entity shall submit a Notification Regarding Prototype which identifies which alternative, if any, will be rolled out commercially and makes recommendations regarding regulatory responses, if any.
6. *Add new subsection in Section 69506:*

(d) No regulatory response shall be imposed on any product for which prototype building, testing and validation has not been completed and for which necessary regulatory approvals have not been obtained.

## II. THE TERM "HISTORIC PRODUCT" IS TOO NARROW.

### A. Explanation of concern

The Regulations' current definition of "historic product" suggests that industry will be forced to make difficult choices regarding a limited amount of financial and human resources. Ultimately, AB 1879 requires DTSC to develop a prioritization process that adequately accounts for the risk and liability of products. The prioritization process should be transparent, objective and focused on the intent of the regulations, which includes economic feasibility.

As applied to the concept underlying the definition of "historic products," service parts represent, in large part, components that are no longer being manufactured or distributed in significant quantities. Further, such service parts are predominantly associated with products that are no longer being actively manufactured. In essence, industry can either be forward-

looking and dedicate funds and human resources on research and development and making future products better, or it can go back and reinvent products that have little impact on human health or the environment. The latter is contrary to DTSC's oft-stated intentions.

The Regulations already, and appropriately, embrace the concept of exempting existing products by the definition of "historic products." However, the definition is too narrow to accommodate the regulatory realities of complex durable goods. In addition, the Regulations do not explicitly exempt spare parts for repair and maintenance of existing products. It is entirely consistent to include an exemption for service parts in the same spirit as "historic products" and for the same reasons. The definition of "historic" products therefore must be broadened, and service parts for such products must be explicitly included within the exemption.

**B. Proposed revision to regulatory language**

Revise definition of "historic product" in Section 69501.1(a)(22)(B)2 as follows (additions in underline; deletion in strikethrough):

"Historic product" means ~~a product that ceased to be manufactured prior to the date the product is listed as a Priority Product~~ one of the following:

(i) A product that ceased to be manufactured prior to the date the product is listed as a Priority Product; or

(ii) A product manufactured in accordance with a certification or approval by a federal or state regulatory agency or the Department of Defense prior to the date the product is listed as a Priority Product; or

(iii) A product that is used as a spare part or component for repair or maintenance of a product identified in (i) or (ii) regardless of when it was manufactured.

**III. THE DEFINITION OF COMPONENT IS VAGUE AND UNCERTAIN AS APPLIED TO COMPLEX DURABLE GOODS.**

**A. Explanation of concern**

Complex durable goods are composed of hundreds, even thousands of components, which themselves may be composed of many other components. In their current form, the Regulations acknowledge the difficulty in undertaking alternatives analysis on an entire complex durable good like a washing machine or a car. See Section 69503.4(a)(1)(B). But in order for the Regulations to be workable and provide predictability, the Regulations must be much more precise in defining what "components" may be identified in a Priority Product that is a complex durable product.

The Regulations also must be more specific about, and must limit the number of, “components” that may be identified in a Priority Product in a given time period, and must account for the cumulative impact, on the responsible entities charged with conducting AAs, of multiple component or materials listings. Alternatives analyses will be extremely complex, costly and time-consuming to undertake. DTSC’s proposed limit of ten components every three years is unworkable.

**B. Proposed revision to regulatory language**

1. *Revise Section 69503.4(a)(2)(B) to add new subsection 4 (addition in underline; with subsequent subsections renumbered accordingly):*

4. For purposes of subparagraph 2, “component” means a uniquely identifiable material within a single identifiable part or piece, not comprised of subparts, of a highly durable product.

2. *Revise second sentence of Section 69503.4(a)(2)(B)2 (addition in underline; deletions in strikethrough):*

For each listed highly durable product, the Department shall specify no more than ~~ten (10)~~ three (3) components ~~and/or homogeneous materials~~ per product every three (3) years.

3. *Strike the definition of “homogeneous material” in Section 69505.1, and remove all references to “homogeneous material” throughout the Regulations.*

**IV. ANY REGULATORY RESPONSE TO BE IMPOSED MUST APPLY ONLY TO PRODUCTS MANUFACTURED DURING THE NORMAL MANUFACTURING CYCLE THAT BEGINS AFTER THE EFFECTIVE DATE OF THE REGULATORY RESPONSE.**

**A. Explanation of concern**

Products identified as Priority Products may continue to be manufactured as they undergo the alternatives assessment process. Service parts for such products necessarily also must be manufactured -- not only during this interim period before the effective date of a regulatory response, if any, but also after the effective date of any regulatory response. That is because Priority Products that are complex durable goods will continue to be used, and will require service and maintenance, for years after their manufacture. The Regulations, however, fail to explain how regulatory responses will apply to such interim products and their service parts, thereby generating uncertainty in the regulated community.

The Regulations also fail to account for product manufacturing cycles, which typically manifest themselves as model years (for vehicles) or equivalents in other industries. Disruptions of normal manufacturing cycles are economically detrimental to the affected manufacturing entities and, ultimately, to the consumer.

Regulatory responses must be forward-looking and must not interfere with normal product manufacturing cycles. If DTSC expects regulatory responses to apply after-the-fact to such products and their service parts, DTSC will create a cumbersome, expensive and unworkable regulatory approach that will lead to substantial economic harm with no countervailing public benefit. Accordingly, the Regulations must ensure that regulatory responses will apply only to products, and the service parts of such products, manufactured during a product manufacturing cycle that begins after the effective date of the regulatory response, taking into account the necessary lead-time that manufacturers will require to implement any regulatory response.

**B. Proposed revisions to regulatory language**

Revise Section 69506.1 to add new subsection (b) (with subsequent subsections renumbered accordingly):

(b) Regulatory responses shall be imposed only on products, and the service parts of products, manufactured during the course of the manufacturer's normal product manufacturing cycle (e.g., model or model year) that begins after the effective date of the regulatory response, taking into account lead-time necessary for manufacturers to implement the regulatory response(s).

**V. THE DEFINITION OF "MANUFACTURE" IS OVERBROAD.**

**A. Explanation of concern**

The current definition of "manufacture" exempts repair, refurbishing and alteration activities, but unnecessarily narrows the exemption. The qualifying phrase in the definition that begins with the word "unless" will capture entities that have not been considered "manufacturer" in any other regulatory context and that very likely are ill-equipped to manage manufacturer responsibilities. This unnecessary narrowing of the "manufacture" exemption will result in confusion and uncertainty in the marketplace, ultimately to the detriment of California's economy by encouraging businesses, both large and small, to exit California for a more predictable business climate. At the same time, the Coalition sees no counterbalancing benefit to human health or the environment resulting from this expansive definition. The definition of "manufacture" should retain the exemption for repairs, refurbishment and alterations of consumer products, but DTSC must eliminate that qualifying phrase.

**B. Proposed revision to regulatory language**

Revise the definition of “manufacture” in Section 69501.1(a)(40) as follows (proposed deletion in strikethrough):

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

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

**VI. THE REGULATIONS IMPERMISSIBLY ATTEMPT TO SUPERSEDE AND/OR DUPLICATE OTHER REGULATIONS.**

**A. Explanation of concern**

Health & Safety Code section 25257.1(b) prohibits DTSC from superseding the regulatory authority of *any* other department or agency. This section contains no other qualifying language. Health & Safety Code section 25257.1(c) separately prohibits DTSC from duplicating or adopting conflicting regulations for product categories already “regulated or subject to pending regulation consistent with the purpose of this article.” By separating the two concepts of superseding “any” other regulatory authority, on the one hand, and duplication/conflicting regulations, on the other, in Section 25257.1, the Legislature clearly expressed different concerns, and clearly intended any implementing regulations to account for these separate concerns.

But the Regulations gloss over this distinction and violate both of these prohibitions. The result is unnecessary and duplicative regulation that interferes with industry compliance with other regulatory schemes.

By focusing exclusively on Health & Safety Code section 25257.1(c), the Regulations do not adequately account for the existence of “the regulatory authority of any other department or agency” as required by Health & Safety Code section 25257.1(b). Further, the Regulations do not adequately address the prohibition contained in Health & Safety Code section 25257.1(c). These prohibitions should not be merely factors in Priority Product prioritization or in regulatory responses. Rather, in order to effectuate legislative intent, they explicitly should frame the applicability of the Regulations to exclude consumer products over which “any other department or agency” exercises authority and/or for which regulations already exist.

DTSC appeared to incorporate at least some aspects of this concept in its October 31, 2011 draft informal regulations. However, it is now far from clear that DTSC intends to abide by the prohibitions set forth in the authorizing statute. The Initial Statement of Reasons (“ISOR”) identifies an example of a “component” that DTSC may regulate: catalytic converters due to their ability to release nitrous oxide. ISOR at p. 22. This subject matter falls squarely in the realm of federal regulation under the Clean Air Act. Only the California Air Resources Board has been delegated authority in this area in California, and only to the extent allowed by federal law. Yet, the ISOR makes clear DTSC’s intent to regulate – impermissibly – in this area.

Absent clear language regarding the limits of DTSC’s authority, there is no reason to believe that DTSC would not improperly invade other areas of regulation. The Coalition urges DTSC to revisit its approach and adopt the revision set forth below.

**B. Proposed revision to regulatory language**

Revise to add new Section 69501(b)(4) (addition in underline):

(b)(4) This chapter does not apply to a consumer product that is regulated by one or more federal and/or other California regulatory program(s), and/or applicable international trade agreement(s) ratified by the United States Senate, to the extent that such other regulatory program(s) or international trade agreement(s) address(es) any of the factors identified in Health & Safety Code section 25253(a)(2)(A)-(M).

**VII. THE DEFINITION OF “FUNCTIONALLY ACCEPTABLE” IS INADEQUATE.**

**A. Explanation of concern**

The Regulations’ definition of “functionally acceptable” does not adequately address the unique nature of complex durable goods. As the Coalition explained in its testimony at the September 10, 2012 public hearing, complex durable goods are not the proverbial widget. Characteristics such as durability; safety (stemming from legal requirements and industry and company standards); performance consistent with product brand; consumer expectations with respect to the product brand; functional performance with respect to the product’s designated use; and aesthetics, including “look and feel” aspects of the product -- these all must be accounted for in the Regulations. Because the term “functionally acceptable” is critical in the prioritization of products, in evaluating alternatives and in the imposition of product sales prohibitions, the Regulations must be more comprehensive to be workable.

**B. Proposed revision of regulatory language**

Revise Section 69501.1(a)(31) as follows:

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

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

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

(B) The product complies with all applicable safety standards in the relevant industry and with all internal safety standards implemented by the manufacturer of the product; and

(C) The product meets other applicable product criteria, taking into account the specific nature of the product and other relevant factors.

**VIII. THE TERM “EXPOSURE” IN SECTION 69503.2 IS INCONSISTENT WITH THE SCIENTIFIC DEFINITION OF “EXPOSURE”**

**A. Explanation of concern**

The Coalition is concerned that the criteria used in proposed Section 69503.2, to evaluate “exposure” in prioritizing products, erode the scientific concept of exposure to the detriment of the goals of AB 1879 and SB 509. The Regulations’ criteria of market presence, statewide sales and the like are inadequate surrogates for the scientific concept of “exposure.” Thus, the criteria in Section 69503.2 effectively break the link between the COC and the consumer product -- the link that is at the very core of what AB 1879 and SB 509 intend to target. Instead, the Regulations must incorporate the scientific concept of exposure -- *i.e.*, the fact that exposure requires the chemical to come into contact with, and be absorbed by, the body in some way.

**B. Proposed revision to regulatory language**

Revise Section 69503.2(a)(1)(B) to delete current subsection 1.a - b, and replace with the following (additions in underline; deletions in strikethrough):

~~1. Market presence information for the product, including all of the following:~~

~~a. Statewide sales by volume;~~

~~b. Statewide sales by number of units; and~~

1. Human exposures to the Chemical(s) of Concern in the product, considering:

a. The amount(s) of the Chemical(s) of Concern in the product;

b. The ability of the Chemical(s) of Concern in the product to come into contact with, and be absorbed by, the body of the intended user during reasonably foreseeable use of the product;

c. The amount of time that the Chemical(s) of Concern in the product is/are in contact with the body of the intended user during reasonably foreseeable use of the product; and

d. Intended product use(s), and types and age groups of targeted customer base(s).

In their final form, the Safer Consumer Products Regulations must be forward-looking in order to provide industry consistency with global regulations and implementation timing -- and, ultimately, in order to achieve the goals of AB 1879, SB 509 and, more broadly, the Green Chemistry Initiative. But in an attempt to craft a comprehensive chemical/product regulatory mechanism, California has pursued a course that not only makes compliance and enforcement unworkable, but also hinders other global efforts whose outcome would surely provide ancillary benefit to the State. Creating rules that make real-world compliance virtually impossible, combined setting with unrealistic expectations, perpetuates industry uncertainty and expenditure of resources that, in the end, fail to benefit the environment or the people of California. The Coalition urges DTSC to heed the Coalition's concerns and to incorporate the proposed revisions described above.

Debbie Raphael, Director  
October 10, 2012  
Page 15

Thank you again for this opportunity for the Coalition to comment on the Regulations.

Very truly yours,



Ann G. Grimaldi

**Attachments**

cc: Matthew Rodriguez, Cal/EPA Secretary (w/ attachments, via first class mail and email: [matthew.rodriquez@calepa.ca.gov](mailto:matthew.rodriquez@calepa.ca.gov))  
Cliff Rechtschaffen, Senior Advisor to Governor Brown (w/ attachments, via first class mail)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor (w/ attachments, via first class mail)  
The Honorable Michael Rubio, California State Senate (w/ attachments, via first class mail)  
Odette Madriago, Deputy Director (with attachments, via email: [omadriago@dtsc.ca.gov](mailto:omadriago@dtsc.ca.gov))  
Jeff Wong, Chief Scientist (with attachments, via email: [jwong@dtsc.ca.gov](mailto:jwong@dtsc.ca.gov))  
Krysia von Burg, Regulations Coordinator (with attachments, via first class mail and email: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov))



*founded 1881*

February 28, 2013

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

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

Dear Ms. Von Burg:

On behalf of the Consumer Healthcare Products Association (CHPA), a 131 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers, I'd like to thank you for the opportunity to comment on the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Products Regulations (R-2011-02) ("proposal" or "regulation") of January 2013 (post-hearing changes).

As a Green Chemistry Alliance (GCA) Coalition member, CHPA reiterates the improvements included in the latest draft proposal and appreciates the considerable effort DTSC has invested to develop an efficient and effective regulatory environment which strikes a balance between concern for the environment and California consumers.

We, in concurrence with GCA, strongly recommend DTSC consider a program concentrating on the true risks for human health and the environment based on hazard, exposure and the likelihood of harm. Ultimately, CHPA strongly requests that OTCs be exempt from the regulations entirely.

**Consumer Healthcare  
Products Association**  
900 19<sup>th</sup> Street, NW, Suite 700  
Washington, DC 20006  
T 202.429.9260 F 202.223.6835  
[www.chpa-info.org](http://www.chpa-info.org)

## **OTCs should be exempt entirely from regulation.**

The regulation of OTC medicines under the proposal is preempted by the federal Food, Drug, and Cosmetic Act (FDCA) and under regulations of the U.S. Food and Drug Administration (FDA).

Section 751 of the FDCA clearly preempts states from imposing additional regulation on OTC drugs, stating “no state may establish... any requirement (1) that relates to the regulation of a [nonprescription] drug...; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter...”<sup>1</sup>

Furthermore, the language in the proposal is narrower than what is provided for in the implementing statute. Section 25257.1(c) of the California Health and Safety Code provides that “[t]he department shall not duplicate or adopt conflicting regulations for product categories already subject to pending regulation consistent with the purposes of this article.” Therefore, OTCs, which are regulated by the FDA and FDCA for the same risk being addressed under DTSC’s proposal, should *automatically* be exempted from regulation.

Applied to the OTC industry, the proposed regulation is clearly duplicative and conflicting. The safety of chemicals used in OTC medicines is regulated by the FDA through the approval of either a new drug application (NDA) or by conforming to a monograph issued by FDA. Through both processes, FDA approves a drug if, and only if, it proves to be safe and effective. Each monograph outlines detailed conditions to which the drug product must conform in order to be legally marketed, including identifying active ingredients, labeling statements, warning statements, and the like. Active ingredients that are included in a monograph have undergone extensive review for human health effects by experts in what is known as the OTC Drug Review. Through this assessment, FDA sets non-hazardous chemical levels and determines what is acceptable for use; any chemical formulation that does not meet this standard will not be approved.

As with all human drugs, the FDA already has authority to require an environmental assessment for OTC drugs (See 21 C.F.R. Part 25). Environmental assessments are part of the FDA’s

---

<sup>1</sup> 21 U.S.C. § 379r(a). Section 751 permits state enforcement of requirements identical to those imposed under the FDCA. See 21 U.S.C § 379r(f).

implementation of the National Environmental Policy Act, which ensures responsible stewardship of the environment for present and future generations, and enables the FDA to determine whether the proposed action may significantly affect the quality of the human environment.

Furthermore, the proposed regulation specifically requires the Department to consider the above mentioned laws when designating Priority Products. Since these laws undoubtedly ensure “adequate protections with respect to the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product,” as required by Section 69503.2(a)(3) of the proposed regulation, OTCs should not be considered for Priority Product identification.

While Section 69506.9, “Exemption from Regulatory Response Requirements,” permits a regulatory exemption from a requirement if it is in conflict with a federal program and the responsible entity could not reasonably be expected to comply with both, the FDA’s NDA process and monograph requirements should obviate the need for inclusion in the regulation and subsequent burden of the exemption process.

Similarly, under the Dietary Supplements Health and Education Act, the FDA has several post-marketing responsibilities to ensure the safety of dietary supplements, including enforcement of the final rule on dietary supplement Good Manufacturing Practices (GMPs), released on June 25, 2007. This rule establishes uniform standards needed to ensure quality throughout the manufacturing, packaging, labeling, and holding of dietary supplement products.

OTC and dietary supplement manufacturers request regulatory certainty to ensure consistent product development and maintain quality and safety standards. These products provide real and significant health benefits to consumers at minimal costs. They are formulated and manufactured under extremely controlled environments that are also governed by FDA. Manufacturers of OTCs need the confidence that they will not be subjected to a patchwork of state requirements that could conflict with already existing federal obligations.

Subjecting these products to additional regulation could result in restrictions on ingredient use that is inconsistent with the federal determination. Thus, at a minimum, OTC drugs should be excluded from the scope of the proposed regulation for purposes of human health and

environmental health issues. In addition, dietary supplements should also be excluded from the scope of the regulation.

**Recommendation:**

In order to explicitly exempt products already regulated by state and federal laws and prevent regulatory duplication and to remove the laborious, one-by-one exemption process, CHPA recommends adding the following section to the regulation:

§69501(b)(5): This chapter does not apply to product categories for which a Federal agency or another State agency has in place or pending regulations consistent with the purposes of §25251 through §25257.1 of the Health and Safety Code.

**End-of-Life Management Requirements are Unnecessary and OTCs are Exempt under California Law**

CHPA disagrees with the requirements laid out in Section 69506.7, End-of-Life Management Requirements. The vast majority of pharmaceuticals in the environment are from human use and metabolites of medicines – not from the improper disposal of medicines.<sup>2</sup> Consumers have more effective means of ensuring safe medicine disposal which not only protect the environment, but also prevent illegitimate access to drugs, decrease potential of abuse, and limit accidental poisonings.

Furthermore, the requirement pertains to products “required to be managed as hazardous waste in California,” which OTC products, under certain circumstances, were exempted from under AB 1442<sup>3</sup> which was signed by Governor Jerry Brown on September 27, 2012.

Disposal in household trash is the most convenient and environmentally responsible way to dispose of unused medicines. Proper disposal in household trash is environmentally responsible and more convenient for consumers than a product stewardship program.

---

<sup>2</sup> Tischler, L. 2007. *Potential Contribution of Unused Medicines to Environmental Concentrations of Pharmaceuticals*, report to Pharmaceutical Research and Manufacturers of America, Tischler/Kocurek, Round Rock, TX.

<sup>3</sup> California Assembly Bill 1442, sponsored by Assemblymember Bob Wieckowski. Chapter Number 689 of the 2012 Legislative Session. Effective January 1, 2013.

**Trade Secret Protection must be Less Arbitrary.**

CHPA supports the inclusion of Trade Secret Protection in Article 9 Section 69509 as OTC and dietary supplement formulations are frequently trade secrets. The proposal requires a producer or responsible entity to provide a significant amount of chemical and product data and information, as well as the quantity of intentionally-added chemical ingredients that CHPA believes is unnecessary and exceeds the scope of the statutory authority.

CHPA opposes the submission of redacted copies required by this Article. The regulation must include stronger safeguards and assurances that product formulations and trade secret information will be adequately protected. In addition, the regulation would benefit from clarification that intellectual property under patent (either pending or once issued) is protected since, in some instances, OTC and dietary supplement formulations are patented. While this protection is implicit, the regulations would benefit from an explicit reference to patent protection.

In sum, CHPA believes that the proposal conflicts with and is largely duplicative of federal regulation of OTCs and should, therefore, exempt OTCs entirely. We urge DTSC to give serious review and consideration to these comments, as well as the comments submitted by the Green Chemistry Alliance.

CHPA appreciates the opportunity to contribute to the development of the Safer Consumer Product Alternatives Regulation. I am more than happy to speak to you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,



Carlos I. Gutiérrez  
Director, State Government Relations



Representing Household & Institutional Products

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

February 28, 2013

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

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

**Re: Revised Safer Consumer Products Regulation**

Dear Ms. Von Burg:

The Consumer Specialty Products Association (CSPA)<sup>1</sup> appreciates the opportunity to review and provide comments on the revised Safer Consumer Products Regulation. CSPA and our member companies have been actively engaged in the advancement of California's green chemistry program over the past five years, from the announcement of the Green Chemistry Initiative, through the adoption of the 2008 legislation (SB 509 and AB 1879) which provides the statutory basis for this regulation, and through the years-long regulatory development process.

CSPA members are committed to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. As stated in previous submissions regarding the Safer Consumer Products Regulation, CSPA and our members support the broad goals of the Green Chemistry Initiative and look forward to continuing to work with the Department and other stakeholders in the state to help spur green chemical innovation and continue to ensure that products are safe.

---

<sup>1</sup> The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$80 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. CSPA member companies employ hundreds of thousands of people globally. Products CSPA represents include disinfectants that kill germs in homes, hospitals and restaurants; candles, and fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care<sup>®</sup>, and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety and sustainability of their products.

We appreciate the efforts of the Department of Toxic Substances Control (DTSC) to review the voluminous public comments on the previous draft and the efforts to address concerns identified with previous drafts, particularly:

- Clear indication DTSC will follow the Administrative Procedures Act (APA) process on future Priority Products lists;
- Creation of a “candidate chemicals list” and changes in product-chemical combinations being listed as a Priority Product with a designated “chemical of concern”;
- Elimination of the certified assessor process;
- Upfront applicability exemption for products regulated under other statutes/regulations as well as recognizing primacy of requirements of other California or federal regulatory program(s);
- Improved measure of reliability of information received by including a specified standard before being “accepted”; and
- Science-based prioritization factors and requirements rather than Governor’s executive order, general petition or specific legislative directive.

However, as this proposed rulemaking approaches conclusion, we remain gravely concerned about a number of provisions, many of which have been raised regarding each successive iteration. We incorporate by reference our comments submitted on previous drafts, but specifically draw to your attention the following points which are either critical in terms of implementation or are significant changes from the previous draft:

- Lack of an internationally harmonized *de minimis* threshold;
- Significant concerns with exemption and regulatory overlap;
- Fundamental misunderstanding by DTSC of confidential business information and trade secret protection and the critical necessity of protecting such, and
- Significant concerns with the Alternatives Analysis process.

CSPA offers the following comments on the revised proposed Safer Consumer Products Regulation and respectfully requests DTSC address the concerns raised to provide a regulatory process that is workable for the regulated community.

#### **Failure to Comply with the California Administrative Procedures Act.**

CSPA believes that DTSC’s Revised SCP Regulation fails to meet the requirements of the California Administrative Procedures Act (“APA”), California Government Code Sections 11340 *et seq.*, and requests DTSC to withdraw the regulations, perform an adequate economic analysis, and republish the draft regulations for a full comment period with a concurrent statement of reasons for the new rule.

In promulgating a regulation, DTSC must comply with the APA. An agency must give the public notice of its proposed regulatory action (Gov’t. Code §§ 11346.4, 11346.5) and give interested parties an opportunity to comment on the proposed regulation (§ 11346.8). Any regulation that substantially fails to comply with these requirements may be judicially declared invalid. *Morning Star Co. v. State Board of Equalization* (2006) 38 Cal.4th 324, 333; *Naturist*

*Action Committee, et al. v. Department of Parks & Recreation* (2009) 175 Cal.App.4th 1244, 1250-51.

The APA's procedures are "exacting." *California Advocates for Nursing Home Reform v. Bonta* (2003) 106 Cal.App.4th 498, 507. They are designed to promote meaningful public participation and effective judicial review, *California Assn. of Nursing Homes v. Williams* (1970) 4 Cal.App.3d 810-12. These objectives are as binding as the APA's itemized procedures themselves. *California Optometric Assn. v. Lackner* (1976) 60 Cal.App.3d 500, 509. To meet these objectives, an agency must provide meaningful notice and meaningful opportunity for public comment.

To that end, a court will set aside regulations if facts in the rulemaking record are inadequate in critical degree, if the agency has failed to respond to vital comments, and if affected persons have had insufficient opportunity to know and to meet important facts that the agency has considered. *California Hotel and Motel Ass'n v. Industrial Welfare Commission* (1979) 25 Cal.3d 200, 222 (concurring opinion). Without such support, it is impossible for a court to determine whether the regulation is adequately supported. *Id.*

Applying these principles, the procedure used by DTSC to issue its revised proposed rule violates the spirit, if not the letter, of the APA's notice and comment requirements in at least the following ways:

***The Department Has Issued "New" Regulations Without Soliciting Required Notice and Comment.***

DTSC published the proposed regulations on July 27, 2012. A public hearing was held on September 10, 2012, and the public comment period ended October 11, 2012. Despite making significant changes to the regulation, DTSC considers these new changes to the rulemaking to be "sufficiently related changes" as defined in Title 1, California Code of Regulations, Section 42. The regulations define "sufficiently related changes" as those changes which "a reasonable member of the directly affected public could have determined from the notice that [such] changes to the regulation could have resulted." If post-hearing changes are not sufficiently related to the original regulation, however, the rule must be republished in accordance with the requirements of Government Code section 11346.5. Cal. Gov. Code § 11346.8(c).

CSPA and its members, who are an important and vital part of the directly-regulated community, respectfully disagree that the many changes to the draft regulation are sufficiently related to the original draft so as to avoid republication of the proposed rule. The draft rule was changed substantially. The new draft incorporates new definitions, including key concepts such as "alternatives analysis threshold," "molecular identity," and "contaminant." Trade secret protection was narrowed substantially in new Article 9. Moreover, whole sections have been newly inserted or completely revamped: e.g., § 69503.2, "Priority Products Product-Chemical Identification and Prioritization Factors"; § 69503.3, "Adverse Impact and Exposure Factors"; § 69503.4, "Priority Products List";

§ 69503.6, ~~–“Alternatives Analysis Threshold Exemption Notification”~~; § 69505.1, ~~–“Alternatives Analysis: General Provisions”~~; § 69505.2, ~~–“Removal/Replacement Notifications in Lieu of Alternatives Analysis”~~; and § 69505.3, ~~–“Alternatives Analysis Threshold Notification in Lieu of Alternatives.”~~

These changes are so broad and sweeping as to render the rule unrecognizable from its original form. No ~~–reasonable member of the directly affected public”~~ could have anticipated them. Changes that are not sufficiently related to the original regulation require new notice and comment. Gov’t Code § 11346.8(c). Thus, the rule should be republished in accordance with the requirements of Government Code section 11346.5.

***The Revised Statement of Reasons Was Issued Separately From the Changes to the Proposed Regulations.***

Minimum procedures required by the APA include providing to the public a copy of the express terms of a regulation *with* (*i.e.*, at the same time) an initial statement of reasons for proposing the regulation. Cal. Gov. Code § 11346.2. Agencies must give the public at least 45 days to comment on the proposed regulations and initial statement of reasons. Cal. Gov. Code § 11346.4. In this case, however, DTSC issued a revised Initial Statement of Reasons for public comment to address ~~—“substantive drafting issues”~~ without releasing the draft regulatory text language that the revised Initial Statement of Reasons purported to justify. As DTSC stated at the time it issued its revised Initial Statement of Reasons, ~~—“DTSC is NOT proposing changes to the regulations text as part of this notice and related public comment period.”~~ *30 Day Public Notice and Comment Period, Notice of Public Availability of Post-Hearing Changes, Safer Consumer Product Alternatives*, Department Reference Number: R-2011-02, Office of Administrative Law Notice File Number: Z-2012-0717-04. As described above, the original regulatory text was then scrapped. As a result, the public could not and cannot correlate the revised regulations with the revised Initial Statement of Reasons.

As CSPA submitted in its January 22, 2013 comments to the revised Statement of Reasons, by releasing segments of this complex and ambitious regulatory proposal for public review in a piecemeal fashion, DTSC is effectively depriving CSPA and the public of an opportunity to understand and provide meaningful input on the regulations, depriving them of meaningful notice and a meaningful opportunity to comment.

***Rulemaking Fails to Adequately Assess Economic Impacts.***

An agency adopting a regulation must assess and consider the potential for adverse economic impact directly on California business. Cal. Gov. Code § 11346.3. A regulation may be declared invalid if the agency makes an initial determination that an action does not have a significant, statewide adverse economic impact directly affecting business, but that determination is in conflict with substantial evidence in the record. Cal. Gov. Code §§ 11346.5(a)(8), 11350(b)(2). A regulation also may be declared invalid for lack of substantial evidence to support an agency’s determination that the regulation is reasonably necessary to effectuate the purpose of a statute. Cal. Gov. Code § 11350(b)(1).

In assessing the potential for adverse economic impact, an agency is required to base its action ~~on~~ adequate information concerning the need for, and consequences of,” the proposed action, and must ~~consider~~ the proposal's impact on business, with consideration of industries affected.” Cal. Gov. Code § 11346.3(a)(1) & (2).

An agency must also assess whether and to what extent its action will affect the creation or elimination of jobs and businesses in the state, and the expansion of businesses currently doing business within the state. Cal. Gov. Code § 11346.3(b)(1)(A)–(C). In declaring that it has initially determined a regulation ~~will~~ not have a significant, statewide adverse economic impact directly affecting business,” an agency ~~shall~~ provide in the record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination.” Cal. Gov. Code § 11346.5(a)(8).

An agency must do something more than simply consider a proposal's economic impact, and speculative belief is not sufficient to support an initial determination. The APA calls for an analysis based on facts. The agency's obligation in its initial determination is to make a showing that there was some factual basis for it. If an initial determination is in conflict with substantial evidence in the record, this is grounds for finding a regulation to be invalid. *California Assn. of Medical Products Suppliers v. Maxwell–Jolly* (2011) 199 Cal.App.4th 286, 303-304.

Despite the scope of the new regulatory requirements, DTSC provided only cursory conclusions, not facts, and without foundation or analysis, regarding the potential economic impacts of the proposed rule. DTSC states only that (*see, e.g., 45-day Public Notice and Comment Period, Safer Consumer Product Alternatives*, Department Reference Number: R-2011-02, Office of Administrative Law Notice File Number: Z-2012-0717-04):

- DTSC has made a determination that the regulation may have a significant statewide economic impact directly affecting businesses, but that it is not expected to affect the ability of California businesses to compete with businesses in other states.
- It is not possible to estimate how many businesses will be subject to regulatory responses.
- DTSC has determined that this regulation will have an economic impact on businesses. However, DTSC is unable to quantify the economic impact on businesses.
- DTSC has made the determination that the regulation may have a possible short term minimal impact on the reduction of jobs, with a much larger potential for creation of new jobs as new materials and processes are developed. DTSC cannot estimate the number of jobs created or eliminated by the regulations.
- The rulemaking may have a significant statewide economic impact directly affecting some businesses. However, the benefits of this rulemaking outweigh any

adverse economic impacts. Not only does the rulemaking aim to protect public health and the environment from harmful toxic substances, it also presents the potential for the creation of new businesses and jobs and for the market expansion of safer and greener products.

- DTSC has determined that these regulations will have an effect on small businesses. However, DTSC is unable to quantify the economic impact on small businesses for the reasons discussed above.

These findings are speculation. They are also aspirational and internally inconsistent. Such conclusory language, without supporting facts, renders the impacted community and the California public incapable of knowing, and thus evaluating and commenting on, the true economic impacts of DTSC's proposal, and therefore violates the APA.

As a result of at least the deficiencies noted above, DTSC has not provided meaningful public notice or opportunity to comment on the revised Statement of Reasons or the revised regulation.

By restricting and parceling the public's opportunity for comment, DTSC has frustrated the development of the record required for effective judicial review. *See California Assn. of Nursing Homes v. Williams, supra*, at 810-812. These inadequacies demonstrate that the dual requirements of the administrative process – meaningful public participation and effective judicial review – will not be achieved by the rulemaking in its current form. Moreover, DTSC should be concerned that the administrative process undertaken by the agency to implement the statute will frustrate the purposes and intent of the California Legislature. Thus, DTSC should withdraw the regulation, perform an adequate assessment of its economic impact, and republish the draft regulation for a full comment period with a concurrent statement of reasons for the new rule.

#### **Purpose and Applicability (Article 1, § 69501)**

CSPA is concerned that changes to proposed Section 69501, deleting a clause that was intended to clarify that the exclusion under Section 25251 of the Act for a “consumer product” includes certain chemical products used in the *manufacture* of such “consumer products,” will lead to confusion regarding the scope of the Act. For the reasons below, CSPA believes that the clause should be restored.

The newly proposed Section 69501(c), entitled “Harmonization,” improves the proposed regulation. It will emphasize that the proposed regulation does not displace the requirements imposed by other federal and State regulatory programs. CSPA believes this provision should be adopted, and that an additional clause should be added to this provision to emphasize, consistent with Health & Safety Code section 25257.1, that the regulation may not be interpreted or implemented in a way that duplicates requirements imposed by other State or federal agencies.

#### **Section 69501(b)(2).Applicability and Non-Duplication**

As first proposed in the draft regulations, Section 69501(b)(2) provided as follows:

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.

**Proposed Section 69501(b)(2).**

According to the Revised Initial Statement of Reasons (~~“ISOR”~~), Section 69501, ~~“in its entirety,”~~ was to ~~“describe the scope and purpose”~~ and the ~~“applicability”~~ of Chapter 55 of the regulation ~~“by specifying which products are and are not subject to its requirements.”~~ Revised ISOR at 11. Even more specifically, the purpose of Section 69501(b)(2), as drafted above, was to:

exempt[] from the regulations any product that is statutorily exempted from the definition of ~~“consumer product”~~ and any product that is placed into the stream of commerce in this State solely for the manufacture of one or more statutorily exempt products. The statutory definition of ~~“consumer product”~~ and the exemptions from this definition are set out in Health and Safety Code section 25251. *Exemptions to the requirements in this Chapter are necessary in order for the scope of the regulations to be consistent with the authorizing legislation.”*

**Revised ISOR at 11 (emphasis added).**

The italicized sentence above reflects DTSC’s goal to ensure that ~~“any product that is placed into the stream of commerce in [California] solely for the manufacture of . . . statutorily exempt products . . . ,”~~ is exempt from regulation, consistent with the Legislature’s intent in excluding certain categories of products from regulation. Indeed, the next paragraph of the Revised ISOR explicitly says this, explaining that ~~“[i]n accordance with Health and Safety Code section 25251,~~ a consumer product does not include:

- (1) a dangerous drug or device as defined in Section 4022 of the Business and Professions Code;
- (2) dental restorative materials, as defined in Section 4023 of the Business and Professions Code;
- (3) a device as defined in Section 4023 of the Business and Professions Code;
- (4) a food as defined in Section 109935 of the Health and Safety Code;
- (5) the packaging associated with any of the items specified in paragraph (1), (2), or (3);  
or
- (6) a pesticide as defined in section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Section 136 and following).

**Revised ISOR at 12 (definitional footnotes omitted).**

CSPA is concerned that this intent be reflected fully and accurately with respect to any product that is a pesticide, as well as consumer products that contain a pesticide, because many CSPA members manufacture and distribute products that are pesticides or contain pesticides. It is clear from the definitions of the term ~~“consumer product”~~ in the Act and the definition of the term ~~“pesticide”~~ in both the Food and Agricultural Code and the Federal Insecticide, Fungicide and

Rodenticide Act, all referred to above, that the Legislature intended that any product introduced into commerce in California solely for the purpose of manufacturing a pesticide be embraced within the definition of “~~pesticide~~,” and that such a product not be distinguished from a product that is or contains a pesticide.

Examining these definitional terms, Health and Safety Code section 25251(e) defines “~~consumer product~~” to mean “~~a~~ product or any part of the product that is used, brought, or leased for use by any person for any purposes,” and goes on to say that **a “consumer product” does not include a “pesticide** as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 United States Code Sections 136 and following).”.

Food and Agricultural Code, in turn, defines “~~pesticide~~” to mean

~~[a]~~ny substance, or mixture of substances which is intended to be used for defoliating plants, regulating plant growth, or for preventing, destroying, repelling, or mitigating any pest . . . .”

Food & Agric. § 12753. In almost identical terms, the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) defines “~~pesticide~~” as “~~any~~ substance or mixture of substance intended for preventing, destroying, repelling, or mitigating any pest. . . .” 7 U.S.C. § 136(u).

The express incorporation of the term “~~pesticide~~” in describing products that are excluded from the definition of “~~consumer product~~,” as the term “~~pesticide~~” is defined in the Food and Agricultural Code and in FIFRA, means that the definitions of the term “~~pesticide~~” under the those statutes are controlling. Either definition, on its face, would include a chemical compound that is placed into the stream of commerce for the purpose of manufacturing a pesticide within the definition of pesticide. In the end, any chemical compound that is placed into commerce for the sole purpose of manufacturing a pesticide is “~~intended to be used for . . . preventing, destroying, repelling, or mitigating [a pest],”~~ whether it is placed in commerce in its final formulated form, or some different form, as an ingredient to be used in a combination of substances in a final formulation – and excluded from regulation under the Act.

The revised regulation would strike the second clause of proposed Section 69501(b)(2), as follows:

~~–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.”~~

As stated above, CSPA is concerned that striking this clause will create confusion as to the intended scope of the regulation. Specifically, CSPA is concerned that the deletion of this clause from the sentence quoted above will cause the public, including the regulated community, to conclude that a product placed into the stream of commerce in California for the purpose of **manufacturing** a pesticide in the State, *e.g.*, a chemical that is used solely in the manufacture of a pesticide or is used as an ingredient in a pesticide, is not included within the definition of

pesticide” and thus is not excluded from the definition of consumer product” under the regulation, and therefore comes within the scope and application of the regulation.

For the reasons below, such a conclusion would be incorrect. First, the definition of the term pesticide” under both the Food and Agricultural Code and FIFRA include a chemical that is used in the manufacture of a formulated pesticide. This is plain from the definitions themselves, as explained above. Put somewhat differently, there is no reason to exclude from either of those statutory definitions of pesticide” a chemical that is placed into the stream of commerce solely for the manufacture of a [pesticide],” on the ground that such chemical has not yet been incorporated into an end-product. In the end, the purpose for which the chemical is placed into commerce in the state is determinative and in either case, *i.e.*, whether the product placed into commerce is the formulated product or the ingredient, the purpose is for preventing, destroying, repelling, or mitigating [a pest].” Thus, any chemical that is placed into commerce in California solely for the manufacture of a pesticide” is placed into commerce for the purpose of preventing, destroying, repelling, or mitigating [a pest]” within the meanings of both the Food and Agricultural Code and FIFRA.

Second, other definitional provisions of FIFRA and the Food & Agricultural Code, along with the definitions of pesticide” discussed above, provide further context for those statutory definitions and in so doing clarify that chemicals placed in the stream of commerce in California solely for the manufacture of pesticides are treated as part and parcel of the pesticides in which they are used, and that the only difference between the terms is linguistic. At 7 U.S.C. section 136(a), FIFRA defines the term active ingredient” to mean an ingredient which will prevent, destroy, repel, or mitigate any pest;” in the case of a plant growth regulator, an ingredient which . . . will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of . . . plants or the product itself,” and in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant.” At 7 U.S.C section 136(m), FIFRA defines the term inert ingredient” as a ingredient which is not active.” In both cases, it is clear that the term ingredient” has no meaning in the absence of its context, *i.e.*, its use as part of a pesticide.” Indeed, FIFRA defines the term ingredient statement” as a statement that contains the name and percentage of each active ingredient, and the total percentage of all inert ingredients, *in the pesticide.*” 7 U.S.C. § 136(n)(1) (emphasis added).

At 7 U.S.C. section 136a(a), FIFRA prohibits any person in any State from distributing or selling any pesticide that is not registered” by U.S. EPA. In California, the Food and Agricultural Code similarly makes it unlawful to manufacture, deliver or sell any substance or mixture of substances” or the essential ingredients necessary to constitute a pesticide, which is not registered” by the Department of Pesticide Regulation (DPR”). Food & Agric. Code § 12993. In order to obtain a registration from U.S. EPA, an applicant must submit (among other things) the complete formula for the pesticide,” including all of the active and inert ingredients, and scientific data to demonstrate (among other things) that the product will perform its intended effect without unreasonable adverse effects on the environment,” which includes water, air, land, and all plants and man and other animals living therein.” 7 U.S.C. §§ 136a(c)(1)(D), 136a(c)(5)(C), 136a(j).

These data requirements are published in guidelines and regulations specified by U.S. EPA, *see* 7 U.S.C § 136a(c)(2), and embrace all of the criteria above for protection of plant life, animal life and humans, and the environment as a whole. Specifically, US EPA demands Product Chemistry Data that requires applicants to identify all chemicals that make up the chemical composition of the product (*see* 40 C.F.R. § 158.320) and to produce the product (40 C.F.R. § 158.325); to evaluate the safety to humans in the production process (40 C.F.R. § 158.330) and the process for formulating end products (40 C.F.R. § 158.335); to identify any chemical impurities (40 C.F.R. § 158.340); Ecological Effects Data to evaluate the effects of the product on non-target plants and organisms, both terrestrial and aquatic (40 C.F.R. § 158.630, 631); Human Exposure Data to measure and evaluate exposure to workers who apply the products and work in areas where the products are applied (40 C.F.R. § 158.1000); Spray Drift Data, to measure and evaluate exposure to other persons from emissions into the atmosphere upon application (40 C.F.R. § 258.1100); and Environmental Fate Data to evaluate the residual effects of the product, its constituents and any by-products in the environment (40 C.F.R. § 158.1300).

In California, DPR requires the applicant to submit all of the same scientific data (and sometimes more) to evaluate independently the same factors. *See* Food & Agric. Code § 12824 (authorizing DPR to establish data requirements), and 3 Cal. Code Regs. § 6159 (finding data required by the U.S. EPA regulations at 40 C.F.R. pursuant to FIFRA sufficient, with certain exceptions, to meet the data requirements of Food and Agricultural Code section 12824).

After a registration is issued, a pesticide may not be produced or formulated except at a ~~registered~~ establishment.” *See* 7 U.S.C § 136e. All registered establishments are subject to regular inspection by U.S. EPA and, in California, by DPR. *See* 7 U.S.C § 136g (granting U.S. EPA and State agencies authority to inspect). No producer may change **any** of the ingredients in a pesticide product without approval by U.S. EPA and in California, by DPR. *See* 7 U.S.C. § 136j(a)(1)(C) (prohibiting distribution or sale of any pesticide ~~the~~ composition of which differs from its composition as approved in connection with registration”); Food & Agric. Code §§ 12881-884 (defining ~~misbranding~~”), 12991 (defining ~~adulterated~~”), 12992 (prohibiting sale of any pesticide that is ~~misbranded~~” or ~~adulterated~~”).

The regulatory end-point of this all-encompassing scientific evaluation is to determine the conditions under which the product may be manufactured, distributed, used and disposed of in a manner that does not produce ~~unreasonable~~ adverse effects on the environment.” As noted above, this is a broad standard that allows U.S. EPA and DPR to address any factor that would have any effect on human health or the environment. Thus, the reach of these programs is broad enough to address all of the potential environmental impacts listed at Health & Safety Code Section 25252.5, including expressly ~~emissions of air pollutants,~~ ~~contamination of surface water, groundwater or soil,~~” and ~~worker safety and impacts to public health.~~”

In sum, the U.S. EPA and DPR regulatory programs for pesticides reach **all** of the substances used in the manufacture of pesticides as well as the formulated pesticide end-products themselves, and impose on those substances regulatory requirements that address all of the

factors within the scope of the Act and DTSC's proposed regulations. Thus, it is consistent with the purpose of the statute to treat them as ~~pesticides~~" for purposes of Section 25251.

### **Section 69501(c) Harmonization.**

DTSC has included in Revised proposed Section 69501 a new subsection (c), which provides as follows:

~~Harmonization.~~ Nothing in these regulations authorizes the Department to supersede the requirements of another California State or federal regulatory program."

CSPA believes this provision *should* be included in the final regulations. As discussed above, the many provisions of the Food & Agricultural Code that regulate the manufacture, delivery, sale and use of pesticides in California, as well as FIFRA, whose requirements regarding the manufacture, distribution, sale and use of pesticide in *all states*, including California, are comprehensive in scope. These many requirements address all of the goals and requirements of the Act.

In this regard, Health and Safety Code section 25257.1 provides as follows:

~~(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."

(Emphasis added).

Thus, the proposed new subsection is incomplete in its scope. In order to be consistent with Health and Safety Code section 25257.1, the proposed regulation should be expanded to read as follows:

Harmonization. Nothing in these regulations authorizes the Department to supersede the requirements of another California State or federal regulatory program, or to duplicate or adopt conflicting regulations for products in categories already regulated by other agencies under federal or State law.

On a related point, we believe another proposed subsection, which appears at Section 69503.2(b)(2), conflicts with the provision above, and with Section 25257.1 of the Health and Safety Code. Proposed Section 69503(b)(2) identifies ~~Other Regulatory Programs~~" as one of several factors that DTSC should consider in determining whether to ~~list~~" certain chemical-product combinations as ~~Priority Products~~" for potential regulation. In this context, the proposed subsection 69503.2(b)(2) recites as follows:

Other Regulatory Programs. The Department shall next consider the scope of other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemicals in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse impact and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a

Priority Product. If a product is regulated by another entity with respect to the same potential adverse impacts and potential adverse waste and end-of-life effect, the Department may list such a product chemical combination as a Priority Product only if it determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing.

CSPA believes this proposed regulation is at odds with Health and Safety Code section 25257.1, and should be deleted. As discussed above, Section 25257.1 forbids the Department from adopting by regulation requirements that would result in ~~—superseding~~” regulatory authority of other agencies (state or federal) and from adopting regulations that would ~~—duplicate~~” or ~~—conflict~~” with regulations imposed by other agencies for products otherwise regulated.

Proposed Section 69503(b)(2) ignores this prohibition, and invites DTSC instead to *impose* superseding, duplicate or conflicting requirements on the sole judgment and determination of the DTSC that ~~—listing~~ [the product-chemical] would meaningfully enhance protection of public health and/or the environment.”

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

CSPA is concerned that implementation of proposed Section 69501.4 would require ~~—manufacturers,~~ ~~—importers,~~ ~~—assemblers~~” and ~~—retailers~~” to provide product and chemical information even for consumer products specifically excluded from the Act. CSPA believes that this is an overbreadth that renders proposed Section 69501(a)(2) unlawful under the California Administrative Procedures Act (~~—APA~~”), Government Code sections 11340 *et seq.*, and recommends that DTSC eliminate it.

In its October 11, 2012 comments on the July 2012 version of the SCP Regulations, CSPA identified to DTSC its concerns regarding the overbreadth of the then-current version of Section 69501.4. CSPA’s concerns about overbreadth are now even more urgent with DTSC’s proposed revision, which expands the subject matter of the information submission obligation to *any* product or chemical, ~~—not~~ just those products or chemicals subject to the requirements of this chapter.” Section 69501.4(a)(2).

The Act specifically excludes certain categories of ~~—consumer products,~~” including pesticides, from its reach. Health & Safety Code §25251(e)(1)-(6). Proposed Section 69501.4(a)(2) purports to encompass information requests even for such statutorily excluded products. In promulgating Section 69501.4(a)(2) DTSC appears to be acting outside its authority under the law by expanding the scope of products and chemicals that may be subject to regulation through the information requests described in proposed Section 69501(a). *See* Gov’t Code §§11342.1. The proposed regulation also appears inconsistent and in conflict with the Act and other laws, including federal and California pesticide regulation laws governing the operations and products of many CSPA members, and does not seem reasonably necessary to effectuate the purpose of the Act. *See* Gov’t Code §11342.2. Thus, proposed Section 69501(a)(2) appears to be an invalid regulation under the APA. CSPA details the basis of its concerns below.

***Proposed Section 69501.4(a)(2) Is Invalid Under Government Code Section 11341.***

A state agency is prohibited from exercising its rulemaking power in excess of the scope of authority conferred on the agency by the Legislature. Gov't Code §11342.1; *Agnew v. State Bd. of Equalization* (1999) 21 Cal.4th 310, 321; *see also Ontario Community Foundations, Inc. v. State Bd. of Equalization* (1984) 35 Cal.3d 811, 816 (“there is no agency discretion to promulgate a regulation which is inconsistent with the governing statute.”). Here, CSPA cannot discern any authority under the Act for DTSC to impose any requirements relating to those “consumer products” that are specifically excluded from the law. Thus, proposed Section 69501.4(a)(2) appears to be an invalid regulation under Government Code section 11342.1. DTSC’s lack of authority is particularly egregious when measured against the proposed requirement for entities to invest the resources necessary to develop *new* information (defined as including data, documentation and reports) for products beyond the reach of the authorizing statute, and all within a schedule unilaterally specified by DTSC. Section 69504.4(a)(1)(D); Section 69501.1(40). This is no minor burden, and certainly no burden that could have been anticipated by the regulated community from reading the Act or from reading the July 2012 version of the proposed SCP Regulations.

DTSC provides no rationale for this expansion, which contradicts DTSC’s own acknowledgement of the limits of its statutory authority. In discussing the components of the July 2012 version of Section 69501 (“Purpose and Applicability”), DTSC admitted that certain “[e]xemptions to the requirements of this Chapter are necessary in order for the scope of the regulations to be consistent with the authorizing legislation.” Revised Statement of Reasons at 11. For that reason, that version of Section 69501 exempted not only statutorily excluded products from the new regulatory program (as it must), but also, for example, products used solely to manufacture excluded products. Yet, now DTSC appears to assume that it is authorized to require information about any products or chemicals, including those that are explicitly excluded from the law. CSPA requests that DTSC clarify the basis for its authority to promulgate proposed Section 69501.4(a)(2).

***Proposed Section 69501.4(a)(2) Is Inconsistent and In Conflict With The Act and Other Laws.***

“[N]o regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute.” Gov’t Code §11342.2. “A regulation is invalid (as in conflict with a statute) if it would alter or amend the [governing] statutes or enlarge or restrict the agency’s statutory power.” *California Beer and Wine Wholesalers Association, Inc. v. Dep’t of Alcoholic Beverage Control* (1988) 201 Cal.App.3d 100, 106-07 (quoting *Webb v. Swoap* (1974) 40 Cal.App.3d 191, 196). “Even if an agency action is consistent with its authorizing statutes, the action may still be deemed void if it conflicts with another statute.” *County of San Diego v. Bowen* (2008) 166 Cal.App.4th 501, 508 (citing *Agricultural Labor Relations Bd. v. Superior Court* (1976) 16 Cal.3d 392 (“Administrative regulations that violate acts of the Legislature are void.”)).

As already discussed, DTSC here purports to regulate what the Act has excluded, and thereby could be deemed to be altering the statute and expanding its own power in violation of Government Code section 11342.2. The proposed regulation also appears inconsistent and in

conflict with Health & Safety Code section 25257.1, which prohibits DTSC from limiting, superseding or duplicating the regulatory authority of other agencies. CSPA describes the inconsistency and conflict further below.

Many of CSPA's members manufacture and sell pesticide products. Proposed Section 69501.4(a)(2) presents a grave threat to the data requirements and protection of confidential information under the federal and California pesticide regulation programs. Ultimately, DTSC's proposed regulation may interfere substantially with the orderly administration of these programs, and may result in DTSC's altering of Health & Safety Code section 25257.1 and in its enlarging of its own statutory power to extend to these other programs in violation of Government code section 11342.2. Below, CSPA describes a few key components of the federal and state pesticide programs to illustrate its concerns.

The California Food and Agricultural Code, Division 7, Chapter 2 (~~Pesticides~~) and implementing regulations promulgated at Title 3 of the California Code of Regulations, Division 6 (~~Pesticides and Pest Control Operations~~), administered and enforced by the DPR, establish a comprehensive program under which DPR regulates the manufacture, distribution, sale and use of pesticides in California. The dual objectives of the California pesticide regulation program are to —to provide [for the] proper, safe, and efficient use of pesticides essential for production of food and fiber and for protection of the public health and safety,” and ~~to~~ protect the environment from environmentally harmful pesticides by prohibiting, regulating, or ensuring proper stewardship of those pesticides.” Food & Agric. Code § 11501.

It is unlawful to offer a pesticide for sale in California unless it is the subject of a ~~certificate of registration.~~” Food & Agric. Code § 12811. As a fundamental prerequisite to registration in California, a pesticide product must be registered by the U.S. EPA pursuant to FIFRA, which prohibits the sale and use in the United States of any pesticide that is not registered under FIFRA. 2 U.S.C. § 136(a); *see also* 3 Cal. Code Regs. § 6170 (requiring submission of federally approved label as evidence of federal registration as part of application for registration in California). If a pesticide is the subject of a federal registration, then it is eligible for registration in California, provided that the applicant for registration meets any additional requirements that DPR may impose.

In order to apply for a registration in California, an applicant must submit scientific testing data demonstrating that the candidate for registration meets specified criteria. *See* 3 Cal. Code Regs. §§ 6170 (imposing application requirements) and 6158; Food & Agric. Code §§ 12815, 12824, 12825.<sup>2</sup> Such data include all of the data submitted to the U.S. EPA in support of federal

---

<sup>2</sup> These data requirements are not static. Pesticide registrants are obligated to perform and submit additional studies in certain circumstances, including certain circumstances pertaining to a formal regulatory process known as ~~reevaluation.~~” Through reevaluation, DPR may require registrants to conduct additional studies or provide other additional information to address regulatory concerns, or to impose regulatory constraints, if DPR concludes that the regulatory criteria for such action exist. Section 6221 of the DPR Regulations, Reevaluation Criteria, provides that DPR ~~shall~~ also reevaluate a pesticide when certain factors have been found . . . .” These factors include ~~(a)~~ Public

registration under FIFRA, and additional data required pursuant to regulation by DPR. 3 Cal. Code Regs. § 6159. Under FIFRA, these data include the studies necessary to evaluate the potential of the product to cause: toxic effects to humans resulting from acute, subchronic, and chronic exposure, including effects such as reproductive toxicity, neurotoxicity and cancer, see 40 C.F.R. Part 158 (~~“Data Requirements for Pesticides”~~), Subpart F (~~“Toxicology”~~); effects upon animals and other wildlife, Subpart G (~~“Ecological Effects”~~); exposure to applicators and others within range of application sites, Subpart K (~~“Human Exposure”~~); the product to drift through the air from the application site, Subpart L (~~“Spray Drift”~~); the product to degrade into other chemicals, or for those chemicals to migrate in soil or groundwater, Subpart N (~~“Environmental Fate”~~). The studies necessary to support registration applications must comply with specific requirements established by U.S. EPA and DPR. Regulated entities invest millions of dollars to generate these data and studies in order to support their federal and California pesticide registration applications.

The disclosure to the public of the data and studies required to be submitted to U.S. EPA and DPR, as well as other information, is highly restricted. Both federal and California law prohibit the disclosure of any information revealing manufacturing or quality control processes; revealing the details of any methods for testing, detecting, or measuring the quality of any deliberately added inert ingredient of a pesticide; or revealing the identity or percentage quantity of any deliberately added inert ingredient of a pesticide. 7 U.S.C. §136h(d)(1); Gov’t Code §6254.2(f). Information regarding the production, distribution, sale, or inventories of a pesticide also is protected from disclosure to the public. 7 U.S.C. §136h(d)(2); Gov’t Code §6254.2(f). And, both federal and California law prohibit the disclosure of health and safety studies to any ~~employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure.”~~ 7 U.S.C. §136h(g); Gov’t Code §6254.2(g).

From these components of the comprehensive federal and California regulation of pesticides, two observations may be made. First, entities regulated under these federal and California programs operate under extensive and strict requirements for generation of data relating to all aspects of a pesticide product’s life cycle. Second, the protection from disclosure afforded to pesticide-related information is extensive under these programs – and has been fully vetted by both Congress and the California Legislature – but these protections are missing entirely from the Revised SCP Regulation.

Section 69501.4(a)(2) will interfere with these highly regulated programs. By allocating to itself the authority to require the submission of existing studies and the generation of new studies, DTSC ultimately may usurp the authority of U.S. EPA and DPR under their respective programs. In addition, ~~“importers,” “assemblers” and “retailers,”~~ as defined in the Revised SCP Regulation,

---

or worker health hazard. (b) Environmental contamination . . . (d) Fish or wildlife hazard . . . (g) hazardous packaging . . . [or] (j) Other information suggesting a significant adverse risk.” 3 Cal. Code Regs. § 6221.

are ill-suited to comply with data generation requests about pesticide products. Demanding that they do so will undermine the integrity of the data requirements of the federal and California pesticide programs, and also will cause unnecessary, and likely costly, business disruptions in the supply chain. The requirement to submit studies and to undertake even more studies, all without any provision for protection from disclosure as is afforded by already existing federal and California programs, threatens the investment-backed expectations developed by regulated entities which have relied on these statutory protections. This is precisely the type of interference that Health & Safety Code section 25257.1 prohibits, and, further, is precisely the type of conflict that causes proposed Section 69501.4(a)(2) to fail under Government Code section 11342.2.

***Proposed Section 69501.4(a)(2) Is Not Reasonably Necessary To Effectuate the Act's Purpose.***

Finally, proposed Section 69501.4(a)(2) fails to meet the APA's requirement that a regulation be reasonably necessary to effectuate the purpose of the Act. Gov't Code §11342.2. The Legislature's purpose is determined from the language of the statute itself. *Hunt v. Superior Court* (1999) 21 Cal.4<sup>th</sup> 984, 1000. Here, the Legislature has required DTSC to adopt regulations identifying and prioritizing chemicals of concerns in consumer products – *except* for six categories of consumer products including pesticides; establishing a process to evaluate such chemicals in consumer products – *except* for six categories of consumer products including pesticides – and their potential alternatives; and specifying the range of regulatory response to be imposed following the alternatives analysis. Requiring specified entities to submit to the proposed information requirements, for products excluded from the law, cannot be deemed reasonably necessary to effectuate the Act's purpose.

For all of the reasons set forth above, CSPA recommends that DTSC eliminate proposed Section 69501.4(a)(2).

**Alternatives Analysis process (Article 5, §69505).**

CSPA remains concerned the timeframes allowed to complete and submit alternatives analysis (AAs) are too short, especially if consortia are formed. As noted in previously submitted comments, the timelines proposed in this section are aggressive and do not comport with industry's experience involving the development of alternative formulations nor other regulatory agencies (i.e. U.S. EPA's Design for the Environment program).

There are also a number of concerns about the cost of the AAs and uncertainty in the marketplace. The tiered AA described in the regulation could easily incur significant costs unjustifiable in the marketplace, regardless of the inherent safety of the product or viability of successful AA outcome. In addition, there are no explicit protections or means of data compensation provided to a manufacturer for development of an AA. These provisions combined would significantly inhibit the ability of a company to choose the AA pathway and lead to a quasi-product ban which is clearly different than the stated intent of the regulation

The proposed rule now requires all relevant information pertaining to the AA report to be made available on the department's web site and all responses to be summarized in either the final AA

or the abridged AA report. This places a significant burden on the regulated entity, to wit: AA development now resembles a CEQA-like process, including a public review requirement. While some entities *may* have experience with the CEQA process, it is more likely that most manufacturers will *not* have significant experience a CEQA-like process which will complicate the implementation process. Compounding the situation is that it will likely create a disparity in impacts upon small, medium and large companies.

Under this requirement, it is unclear to what degree the manufacturer must circulate the draft AA and comments received. The most conservative reading suggests that this requirement applies at each stage of the process, i.e. Preliminary AA report; draft abridged AA Report; and the alternate process AA work plan. If this is the correct interpretation, the time requirement increases substantially as does the draw on resources to manage the public review process.

Related to this exercise, there is no guidance regarding how public comments should be evaluated. Should the opinion of a public commenter held to the same standard as a scientifically peer-reviewed journal article? How much data, if any, is sufficient to support a commenter's position? It is unclear how a public commenter can adequately consider a redacted AA, especially when comments are directed at provisions within the redacted portion of the AA. In this case, the manufacturer would be forced to divulge proprietary information, confidential business information or trade secrets by responding to or acknowledging the question.

**Public Comment on each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan submitted to the Department.**

Public comment on AA reports is inappropriate for a number of reasons. It has been posited by DTSC that the reason for public comment is to provide “a quality assurance mechanism”. Quality assurance should be provided by an employee of the Regulated Entity with the requisite skills and expertise to conduct an informed review of the materials. As in other environmental regulations the regulatory agency is the “quality assurance” reviewer rather than the public or a third party. Public comment does not equate to quality assurance as the general public on a whole lacks this knowledge. Public comments on the decision making process will only serve to delay and potentially misguide the alternative analysis process. The public has no expectation that it will be directly involved in the internal decision making process of a Responsible Entity's selection of an alternative for a Priority Product. The Responsible Entity is just that - *responsible for the work product*. The decisions and selections made are those of the Responsible Entity and unique to that entity. The decision making process should be based on a Responsible Entity's own internally identified criteria and not be affected or constrained by a public that does not fully understand its business concerns, legal liabilities and technology constraints. It is more appropriate for the public to provide their feedback for a Responsible Entity's choice in the marketplace through their buying preferences. In addition, it is unclear what level of response to comments will be needed and what liabilities may arise due to the decisions made and the response to such comments.

In addition, the requirement that AA reports be made available for public comment creates serious and unnecessary anticompetition concerns. Specifically, because the AA reports are

required to contain economic, technical and functional data, including a detailed review of the economic and technical feasibility and the functional acceptability of various considered alternatives, any public comment requirement essentially mandates the opening-up of competitively sensitive information to the horizontal competitors of the Regulated Entity. Such sharing of competitively sensitive information creates potential exposure under federal antitrust laws, and that exposure cannot be eliminated or minimized on the grounds that the information sharing is mandated by state law. In fact, the federal antitrust law on this topic is quite clear that potentially anticompetitive behavior cannot be shielded by state law from antitrust scrutiny unless the anticompetitive behavior is “clearly articulated and affirmatively expressed” by the state law. At the very least, the anticompetitive behavior must be a “foreseeable result” of what the state has authorized. In this case, the underlying legislation cannot meet any of these tests.

Indeed, the underlying legislation is focused on traditional environmental health and safety purposes; there is no clearly expressed intent to displace commercial competition, and such displacement is not a foreseeable result of the environmental health and safety goals expressed in the underlying legislation. The Supreme Court has just recently reaffirmed all these federal antitrust law principles in the case of *Federal Trade Commission v. Phoebe Putney Health System, Inc.* (slip op. February 19, 2013) (holding that Georgia law creating local hospital authority did not express a state policy to displace competition through permitting potentially anticompetitive hospital mergers). Because the Regulated Entity would remain exposed to potential federal antitrust liability for knowingly sharing commercially sensitive information with its competitors, the proposed regulation could only be permissible if such information sharing, which is generally contrary to federal competition law policy, were mandated by state law or at least a foreseeable result of state law. In this case, the underlying state law does not have a sufficiently expressed state policy in favor of information sharing by competitors, and such information sharing is not what one would reasonably foresee from a traditional environmental health and safety statute.

**Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (§ 69505.3)..**

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

**Alternatives Analysis: Second Stage (§ 69505.6).**

(a)(2)(A) *Multimedia life cycle impact analysis and the applicability of such an analysis to the alternative replacement chemical or other chemicals in the alternatives that differ from the chemicals in the Priority Product.* Therefore, the analysis is not just on the alternative selected, but all identified alternatives considered. CSPA recommends that if a chemical is not on the

Candidate Chemical list, those chemicals should not be subject to such an evaluation. To avoid the AA process being an unintended endless and ineffective task, DTSC must make a distinction between hazard, risk and what is safe. Any chemicals in the alternatives that are not on the Candidate List should be exempt from consideration and analysis. This would streamline the DTSC review process to only those chemicals that the Department has identified as posing a potential “risk” to the user of the final product. In addition, this change would assist the Responsible Entity’s ability to maintain intellectual property rights for the alternatives that are identified and should therefore be protected under the Proposed Regulation as contemplated by the underlying statute. Protection of intellectual property is an important aspect of being able to obtain a market advantage for the resources that are put into the AA and research and development.

In addition to the above concerns, the shifting of the responsibility from the California Environmental Policy Council (CEPC) to Responsible Entities is not authorized by the underlying statute. Health and Safety Code Section 25252.5. DTSC is obligated to conduct a multimedia life cycle evaluation when adopting the regulations. As such, as DTSC goes through the process of identifying chemical/product combinations, they are obliged by the statute to conduct a multimedia life cycle evaluation of these designations as they are part of the process of adopting implementing regulation. DTSC should not abdicate these responsibilities in an effort to reduce the efforts of the State necessary to comply with the underlying statute. Instead of this section, the multimedia life cycle impact analysis should be included as one of the responsibilities of DTSC to request of the CEPC to perform the analysis in Section 69302.2.

**Economic Impacts ((a)(2)(C)1).**

This section instructs Responsible Entities to evaluate ~~a.~~ Public health and environmental costs; and b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.”

To properly monetize these costs would be difficult at best for the most sophisticated Responsible Entity and next to impossible for all others.

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

**Economic Impacts (Section 69505.6(a)(2)(C)(1)(b)).**

The calculation of costs (public goods) now includes ~~non-profit~~ organizations that manage waste, oversee environmental cleanup, et seq.” in addition to government agencies. The inclusion of this language has the power to greatly expand the universe of entities that would need to be considered in the calculation of public good costs and argues for deletion of the reference to

“non-profit” organizations. Absent that, at a minimum, the “non-profit” should be contractually or otherwise obligated to a public agency (local/state/federal) to manage for environmental outcomes or otherwise obligated to a public agency to manage to measurable outcomes; e.g. the Nature Conservancy’s contracts to manage public lands for the Bureau of Land Management, local conservancies and the like.

#### **Alternatives Analysis Reports (§ 69505.7).**

A change of some concern relates to the increased visibility given AA reports; namely, a separate, publically available AA must be submitted with the information of concern “masked”. However, if this version is rejected by the Department, a non-redacted version will have been submitted/made publically available which is contrary to the regulated community’s best interest as it relates to confidential business information, including the affirmative obligation to actively manage the availability of the information in order to assert trade secret status.

#### **Practical Quantitation Level (PQL) of contaminants and removal for intentionally added ingredients (definitions, § 69505.3).**

The intent of the threshold is to specify a level above which action should be required and conversely, below which no action is required. Trying to account for trace levels of chemicals, which are acknowledged by DTSC as not being a priority because they are below the practical quantitation level (PQL) set by DTSC<sup>3</sup>, serves no purpose and will create an excessive burden for responsible companies.

Companies that are not managing the chemicals in their product will simply not submit notifications. If they do not know the chemical content of their products they will certainly not know the trace amount of chemicals which are presumably not intentionally added. Again, with this provision, DTSC is redirecting the energies and monies of industry from the important goals of the Statute to administrative paperwork tasks.

It is important to consider that the PQL is not based upon risk determination but rather on the limits of analytical chemistry. The fact that analytical chemistry advances and continues to be able to detect and quantify chemicals at lower and lower levels says nothing about the risk posed by that chemical in a product. It would be much more constructive to utilize developments in toxicology and environmental science to derive a risk-based threshold. In addition, differing matrices can have vastly different PQL values, which would likely lead to the counterproductive utilization of the “least protective” matrix in the supply chain. Also, contaminants are often unavoidable and can be extremely expensive to remove to the PQL level and likely with no inherent benefit to public health or the environment.

---

<sup>3</sup> As noted in Revised Initial Statement of Reasons, page 112. “The distinction between those Priority Products that are subject to the alternatives analysis and those that are exempt will be primarily based on the minimum detectable concentration for the Chemical of Concern, and the difficulty of avoiding the presence of contaminants that are the source of the Chemical of Concern in the product.”

If the PQL is being viewed as the risk level under which it is acceptable for no AA to be performed, then the same contaminant present in different products at the same amount will be viewed as higher vs. lower risk, even though the amount is the same. If the PQL is not being viewed as a risk level, then it should not be used to decide whether or not an AA should be performed.

Per § 69505.3, DTSC expects that the manufacturer will identify the PQL when it submits its alternatives analysis threshold notification. That is duplicative and wasteful, i.e., a large number of companies and labs would be repeating the same work for similar products. In addition, it almost amounts to allowing a manufacturer to set their own *de minimis*, as certainly lower limits might be possible if only more analytical work and money is spent on establishing a lower PQL. Well characterized chemicals generally have lower PQLs than less well characterized chemicals. This point only reinforces the inappropriateness of using a number from analytical chemistry to drive a regulation that is supposed to deal with hazardous impacts of products.

In addition, usage of the practical quantitation level is inappropriate in most cases: it is also inconsistent with other regulatory approaches and imparts a significant and unwarranted analytical burden. For example, two other jurisdictions with broad chemicals management regulations, namely Washington and Maine, have implemented a PQL approach in a directly opposite fashion from how DTSC is electing to approach it. The draft regulation recognizes the need to avoid regulatory duplication and conflict. A corollary should be to find common ground with other states' "green chemistry" programs. Washington and Maine set the PQL as a limit for *intentionally* added chemicals, while a specific limit (*de minimis*) is set for contaminants. While the PQL approach is still not based in a risk determination, if DTSC persists in using this concept, it should **at a minimum** harmonize with other states and use the PQL only as a limit for intentionally added chemicals; set 0.1% or 0.01% as the limit for contaminants. The fact that analytical chemistry continues to advance the ability to detect compounds at lower and lower levels is no rational basis to require an AA.

**Alternatives Analysis Threshold** – “*Alternatives Analysis Threshold*” means the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant. The PQL is a procedure to determine the quality / validity of a laboratory measurement, it is not appropriate to use as an indicator of safety, it is after all merely an analytical detection limit NOT a measure of or even an indication of exposure. Apart from being an exceptionally low value which effectively nullifies the concept of a *de minimis*, the use of the PQL as a threshold value has no more or no less legitimacy than other policy decisions such as 0.01% or 0.1% by weight. It is in fact a policy decision of the most extreme case. Further, as noted below the use of the PQL creates a lack of both clarity and certainty for the regulated community.

There are several reasons why the PQL is an inappropriate value to be used to establish the Alternatives Analysis Threshold. The PQL is a relative value that is dependent upon the analytical method and the material being tested. The DTSC should recognize the PQL for any given chemical of concern can vary based on the matrix in which the chemical is contained. This

matrix can impact the degree to which the chemical can be detected as well as the appropriateness of any given analytical methodology to detect the chemical. Additionally, the PQL can and does carry a variety of definitions in practical application. As examples, the term “PQL” is defined in several ways by various governmental agencies:

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

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

Potentially the single most important provision of the proposed regulation, it is imperative to the workability of the program that this provision be further revised in line with recommendations previously provided by CSPA and its members. The updated proposal fully eliminates the concept of *de minimis* as a consideration, making the regulation completely unworkable for the regulated community. 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.

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

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

In yet another attempt to find middle ground on the issue with the Department, CSPA suggests DTSC retain the PQL consideration for contaminants and unintentionally added substance and at the same time allow manufacturers to prepare a safety case demonstrating the safety of a product/CoC combination. CSPA urges DTSC to revise the proposed rule to enable manufacturers to demonstrate the safety of specific product/chemical combinations, as necessary. Neither should the regulation, nor DTSC, presume that the mere presence of an identified Candidate Chemical or CoC is reason to suggest potential harm. If manufacturers can demonstrate the safety of their product, the Responsible Entity should not be required to complete the AA process.

Outright elimination or removal of CoCs in products is the proposed favored approach. The PQL concept as drafted will force manufacturers to analyze each intentionally added CoC in the Priority Product, irrespective of the risk posed by the chemical(s) in the product. This does not meet the practical or meaningful standard the Director has set for the regulation.

Another example of this is the proposed “Removal/Replacement Notifications in Lieu of Alternatives Analysis.” While CSPA agrees that the action of manufacturers choosing to move out of a CoC to a replacement chemical, not on the Candidate List, does not fall within the scope of the regulation, this “off-ramp” favors unsubstantiated chemical de-selection.

CSPA is concerned that DTSC is relying too heavily on chemical elimination rather than safe use and incremental improvement. This approach is contrary to the statutory requirement under AB 1879 (Feuer, 2008) that DTSC’s regulation must “...determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern...” DTSC should recognize the importance and benefit of incremental improvements as this program commences. Based on a manufacturer’s demonstration of safe use for particular chemicals in a particular product, limiting exposure or reducing the level of hazard posed should be sufficient for compliance.

We urge the Department to revise their approach on this provision as the single most important provision to ensuring a workable program.

### **Process for Identifying and Prioritizing Product-Chemical Combinations (Article 3 § 69503).**

CSPA is concerned that undue emphasis is placed on ‘potential’ rather than ‘actual’ exposures

CSPA is concerned that the safer alternative language now predisposes DTSC to list if there is a ~~readily available safer alternative~~

CSPA is concerned that the regulation exceeds its authority by regulating a product that is manufactured, stored, transported through California EVEN when destined for use OUTSIDE of California.

CSPA is concerned about regulatory overlap in which the presence of the product/releases now includes homes, schools, workplace and other locations; again, it raises the question of how this aligns with authorities of other regulatory agencies, i.e. CalOSHA/OSHA.

CSPA is concerned that the Department grants itself the authority to assess the adequacy of other state and federal programs as well as international agreements to provide adequate protections with respect to specified adverse effects. To the extent that in earlier provisions of the proposal deference was paid to other state/federal/international programs, this provision would seem to pierce that primacy and/or ~~fire wall~~. This places the regulated community in a position of ~~double jeopardy~~ and obligated to meet what may be mutually exclusive criteria.

### **Product-Chemical Identification and Prioritization (§ 69503.2)**

CSPA supports the use of the conjunctive ~~and~~ for identification and listing as a Priority Product.

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

- (1) There must be **potential public** and/or aquatic, avian, or terrestrial animal or plant organism **exposure** to the Candidate Chemical(s) in the product; **AND***
- (2) There must be the potential for one or more exposures to contribute to or cause **significant or widespread** adverse impacts.*

### **(2) Other Regulatory Programs.**

This subsection provides DTSC with authority to regulate a product already regulated as a Priority Product simply by claiming enhanced protection under the Proposed Regulation. This reservation of discretion to DTSC is not authorized by the underlying statute and goes beyond the delegated statutory authority specifically limited under Health and Safety Code Section 25257.1(a) -(c).

### **(3) Safer Alternatives.**

DTSC may use its judgment as to whether a safer alternative may exist as part of its criteria when prioritizing product-chemical combinations. Despite the long list of public health, safety and environmental concerns identified in the regulation as prioritization factors, this discretion afforded to DTSC allows for prioritization based on convenience. Protection of the public should be based upon risk, the presence of actual hazard, and concerns for routes of significant exposure for the hazard. Convenience is an inappropriate prioritization factor.

**Candidate Lists (Article 2, § 69502).**

CSPA is concerned there is no indication that thresholds or risk determination will be included in the candidate list preparation. Many of the underlying lists incorporate threshold values based upon rigorous scientific determinations of risk, while the process describes indicates that the mere presence on a list warrants inclusion. This situation is further compounded by the changes in the latest version of the regulation that only contaminants may be exempted from consideration, provided they are below the PQL.

CSPA is concerned about the inclusion of respiratory sensitizers E.U. Category 1, Annex VI. The other lists under consideration have undergone rigorous scientific justification and substantiation via the public comment by their inclusion in the Initial Statement of Reasons. Each other list has been evaluated publically on the basis of the criteria elicited in the ISOR Table 2.1 (Hazard Trait, Regulatory Basis, Enforcement Consequences, Policy or Risk Management Decisions, Harmonize, Strong Evidence, Updated), as well as a thorough explanation for the basis of the list within the ISOR. For these reasons, CSPA objects to the inclusion and requests the removal of this list.

CSPA is concerned about the inclusion of pollutants from 303(d) of the federal Clean Water Act which includes chemicals/constituents already “managed” by water quality agencies. As noted previously, both the California State Water Resources Control Board, under the authority granted to it through the Porter-Cologne Act, and U.S. EPA, under the Clean Water Act, have jurisdiction as well as demonstrated performance to manage the waters of the state and the United States. Utilization of the 303(d) listing process, on its face, does not appear to be additive to identifying chemicals used in consumer products which pose risk to the public and/or natural environment. In addition, the other lists under consideration have undergone rigorous scientific justification and substantiation via the public comment by their inclusion in the Initial Statement of Reasons. Each other list has been evaluated publically on the basis of the criteria elicited in the ISOR Table 2.1 (Hazard Trait, Regulatory Basis, Enforcement Consequences, Policy or Risk Management Decisions, Harmonize, Strong Evidence, Updated), as well as a thorough explanation for the basis of the list within the ISOR. For these reasons, CSPA objects to the inclusion and requests the removal of this list.

**Trade Secret/CBI issues (Article 9, § 69509).**

CSPA is extremely concerned the proposed regulation is not legally defensible, exceeds statutory authority and is inconsistent with California Civil Code. The case for ensuring adequate protection of intellectual property right and trade secret and other confidential business information (CBI) is straightforward, practical, and steeped in the history of American business ingenuity and success. The first patent was awarded in 1790 for a process to make potash; one of the earliest cases to recognize trade secrets was decided in 1837 in a case involving protecting the making of chocolate. American companies have relied on this protection of their most valuable intangible asset from disclosure to competitors to support innovation and growth. For these reasons, trade secrets and other CBI must be carefully safeguarded from competitors to ensure a financial return on the significant costs of research and development (R&D) and to preserve brand integrity and distinction.

Trade secrets and other CBI that are protected under state laws (most of which are based on the Uniform Trade Secrets Act), the Federal Freedom of Information Act, and/or the Federal Economic Espionage Act of 1996 should **always** be considered confidential under the Safer Consumer Products regulation.

As a means to being appropriately protective this Article should address ~~“Confidential Business Information,”~~ which includes not only trade secrets, but also commercial or financial information that is privileged or confidential. Moreover, it must set forth a protocol that contains information security systems, employee protocols and training to assure that the Department has the ability to protect trade secret information that is supplied in connection with the regulation. To our knowledge, the Department does not have such a protocol in place, and without it, there is no means to actually ensuring that trade secret information is actually protected, even if it is the Department’s intent to do so.

**Assertion of a Trade Secret Protection (§ 69509(e)).**

CSPA is concerned about documentation supporting a claim of trade secret protection which contains information that is itself subject to a claim of trade secret protection. This section of the regulation should focus on the interrelationship of the new Safer Consumer Chemicals law with the preexisting California laws on trade secrets. California Civil Code § 3426.1 provides

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

(1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and

(2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one should show that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by the Department under California Health and Safety Code § 25257(d) should logically begin by looking at those two questions.

Another issue that arises relative to trade secrets is whether the information is readily ascertainable by proper means (e.g., reverse engineering). If information can be readily determined through legitimate analysis or examination and study of a product, that information probably is not a trade secret.

Thus it would be reasonable to approach the question of supporting a claim of trade secrecy by asking the submitter to provide information relevant to items (1) and (2) above and relevant to the difficulty of discovering the information through analyzing the product. Much of the current draft regulation § 69509 is not needed in order to show that submitted information meets the

definition of a trade secret under California law, and those items should not be required of the person (company) claiming trade secret rights.

Further, given that, under § 69509(f) of the draft regulations, trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient, there is no reason why the lengthy and intrusive list of questions in the draft regulation is necessary. Answering all of those questions for each trade secret claimed will be a burden requiring needless expenditure of resources by trade secret owners, adding cost to consumer products.

It is worth pointing out that the California Statute which these draft regulations purport to implement says in Health and Safety § 25253(c):

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

The current draft regulations fail to fulfill the aspiration set forth in this Statute. In their treatment of trade secrets, they do not ensure a process that is easy to use, nor are they simplified tools that manufacturers, distributors, and retailers can use.

CSPA requests protection of confidential business information which may not be considered ~~trade secret.~~"

As a threshold matter, the DTSC requirement that one can only claim as trade secret a replacement chemical that is the subject of a patent application improperly conflates two distinct forms of intellectual property protection, in a manner which seriously erodes existing statutory and common law property rights currently guaranteed to owners of trade secrets under both federal and state law. Under both the model federal statutory law, the Uniform Trade Secrets Act, and both state common law and statutory law, an entity may claim as a trade secret any non-publicly-disclosed information, from which the entity derives or may derive an economic advantage, for as long as reasonable measures are taken by the entity to maintain the information as a secret. Under current law, the property right in a trade secret is maintained as long as the information is kept secret, i.e. not publicly disclosed without an express written obligation of confidentiality. There is no requirement under any current statutory or common law that ever requires the holder of a trade secret to seek patent protection in order to be able to maintain its property interest in the trade secret, nor to disclose trade secrets unless there is a written obligation of confidentiality binding the receiver of the trade secret information.

In fact, it is a bedrock principle of intellectual property law that an entity making a discovery or invention may freely choose whether to seek the potentially unlimited temporal protection should

the entity maintain a trade secret, or alternatively, to file a patent application and thereby waive trade secret protection upon publication of the patent application disclosing the trade secret, in exchange for the mere possibility of obtaining a 20 year limited exclusive right upon issuance of a patent covering the invention. Many companies rely on a combination of trade secret and patent protection in order to protect their discoveries and inventions. In some cases, where the trade secret is not readily discernible from the product, electing trade secret protection is the preferred intellectual property protection scheme, and a patent will never be filed. In fact, some entities may elect never to file a patent application, relying instead on trade secret protection to protect their discovery or invention (e.g. Colonel Sander's "secret" chicken recipe, or Coca-Cola Company's "secret" formula for Coke).

The DTSC draft proposal thus errs in making three critical assumptions:

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

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

Third, the DTSC proposal errs in assuming that it has a proper legal basis to require entities to either waive their property rights with respect to their existing trade secrets, or to force those entities to take on the considerable expense of preparing, filing, prosecuting and maintaining patent protection over all of their inventions and discoveries, in order to continue to avail itself of its statutory and common law rights governing trade secret protection, even if only for the limited 18 month time interval for the patent to publish. The waiver requirement would likely be successfully challenged in court as an unconstitutional "taking" of property; the "patent-filing" requirement would likely be successfully challenged in court as an unconstitutional "forced expenditure" inconsistent with the Constitutional intent underlying Patent Act, 35 U.S.C. Section 101 et seq.. In other words, it would be unconstitutional to apply the Patent Act in a manner which required inventors to seek patent protection for all of their discoveries, or alternatively, to require public disclosure of these discoveries, thereby causing loss of their existing property interest in maintaining the discovery or invention as a trade secret.

Requiring disclosure of trade secret product formulations in a manner that does not impose an affirmative obligation on the receiving party not to disclose the received trade secret to any third party, automatically triggers the loss of trade secret protection, because such disclosure is viewed as a public disclosure.

The only way that entities could disclose trade secret product formulation information without losing their economically valuable trade secret protection and the economic advantage derived from the trade secret, is if the disclosure is made under a written obligation of confidentiality and non-disclosure of the trade secret by the receiving party. Absent such a requirement, DTSC's proposed disclosure requirements would likely have the unintended consequence of placing American, and more particularly California companies, in the untenable position of having to disclose their most economically valuable trade secret product formulations in a manner which ultimately would place those trade secrets in the hands of foreign competitors.

For all of the foregoing reasons, we do not believe that the latest DTSC draft properly addresses the substantial unintended economic effects of requiring mandatory disclosure of trade secrets.

These concerns are heightened due to the changes made to the definition of Responsible Entity and addition of Assembler in the Proposed Regulations. These changes create a situation that may cause inadvertent disclosure of trade secrets or other proprietary information to DTSC in the numerous documents that are being requested of Responsible Entities. CSPA suggests that DTSC consider including the ability for the owner of a trade secret to provide the confidential information directly to DTSC so long as that information is not materially significant to the alternative selected by the Responsible Entity. This process would be similar to that adopted by the U.S. Environmental Protection Agency under the Toxic Substance and Control Act (TSCA) for Chemical Data Reporting (CDR) purposes for joint submission to protect confidential information. 40 CFR 711.15(b)(3)(i)(A)-(C).

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

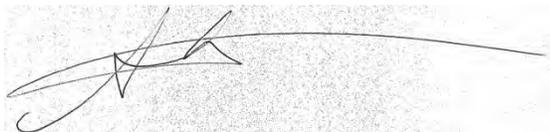
The lack of strong protections for trade secrets in the proposed regulations counteract the efforts of the President's Administration as outlined in the recently released strategy which highlights

the real threat of corporate espionage and how failure to protect intellectual property creates an enormous disadvantages to U.S. companies. The disadvantage comes from not being able to protect innovation, ingenuity and creativity in the global marketplace. DTSC's revised Proposed SCP Regulation would ignore the strong messages in the Administration's Strategy and provide an open door to all competitors to access sensitive information

CSPA appreciates the opportunity to comment on the revised Safer Consumer Product Regulation and remains supportive of the principles of Green Chemistry and programs that are consistent with those principles.

We appreciate the significant stakeholder outreach and communication; however, we urge DTSC to address the significant concerns that this regulatory process is not science-based, economically and technically feasible, and workable for both DTSC and the regulated community.

Respectfully submitted,



Steven Bennett, Ph.D.  
Director, Scientific Affairs



Kristin Power  
Director, State Affairs – West Region

cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency  
Miriam Barcellona-Ingenito, Deputy Secretary for Environmental Policy,  
California Environmental Protection Agency  
Michael E. Rossi, Senior Advisor for Jobs and Business Development,  
Office of the Governor  
CSPA State Government Affairs Advisory Committee  
CSPA Scientific Affairs Committee Green Chemistry Task Force  
Laurie Nelson, Randlett/Nelson/Madden