	15-DAY NOTICE (APRIL 2013 REVISED PROPOSED REGULATIONS TEXT) LIST OF PUBLIC COMMENTERS		
#	NAME OF ENTITY	DATE REC'D	LATE
1	Airlines for America and Boeing	4/25/2013	
2	Alliance of Automobile Manufacturers	4/25/2013	
3	American Apparel & Footwear Association	4/25/2013	
4	American Chemistry Council	4/25/2013	
5	American Cleaning Institute	4/25/2013	
6	American Coatings Association	4/25/2013	
7	American Forest & Paper Association	4/25/2013	
8	Association of Global Automakers	4/25/2013	
9	Association of Home Appliance Manufacturers	4/25/2013	
10	Automotive Aftermarket Industry Association	4/25/2013	
11	BizNGO	4/25/2013	
12	Boots Retail USA	4/25/2013	
13	California Product Stewardship Council	4/22/2013	
14	CHANGE (Californians for a Healthy & Green Economy)	4/25/2013	
15	Chemical Industry Council of California	4/21/2013	
16	Community Computer Connection	4/24/2013	
17	Complex Durable Goods Coalition	4/25/2013	
18	Computers for Classrooms (Furr, Pat)	4/24/2013	
19	Computers for Classrooms (Serrano, Ozzie)	4/24/2013	
20	Consumer Specialty Products Association	4/25/2013	
21	Direct Selling Association	4/25/2013	
22	Electronics Industry	4/25/2013	
23	European Commission	4/19/2013	
24	Food Packaging Coalition	4/25/2013	
25	Green Chemistry Alliance	4/25/2013	
26	Grocery Manufacturers Association	4/25/2013	
27	Hewlett-Packard Company	4/25/2013	
28	International Fragrance Association North America	4/25/2013	
29	IPC (Association Connecting Electronics Industries)	4/24/2013	
30	Japan Electronics & Information Technology Industries Association	4/23/2013	
31	Koch Industries	4/25/2013	
32	Minnesota Computers for Schools	4/24/2013	
33	Nancy Jo	4/24/2013	
34	Outdoor Power Equipment Institute	4/24/2013	
35	PC Rebuilders & Recyclers	4/23/2013	
36	Personal Care Products Council	4/25/2013	
37	Plumbing Manufacturers International	4/25/2013	
38	Procter & Gamble Company	4/25/2013	

	15-DAY NOTICE (APRIL 2013 REVISED PROPOSED REGULATIONS TEXT) LIST OF PUBLIC COMMENTERS		
#	NAME OF ENTITY	DATE REC'D	LATE
39	Quint, Julia	4/25/2013	**LATE**
40	Renew Computers Inc.	4/24/2013	
41	Rubber Manufacturers Association	4/25/2013	
42	San Francisco Estuary Institute	4/25/2013	
43	Sierra Club California	4/25/2013	
44	TechSoup Global (Brown, Stephen)	4/24/2013	
45	TechSoup Global (Lynch, Jim)	4/25/2013	
46	Toy Industry Association	4/25/2013	
47	Unilever	4/25/2013	**LATE**
48	Worksafe	4/25/2013	

April 25, 2013

Submitted Via Email:
Ms. Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

RE: Comments on the April 10, 2013 Revisions to the Proposed Safer Consumer Products Regulations; Department Reference Number: R-2011-02; OAL Notice File Number: Z-2012-0717-04

To Whom It May Concern:

Airlines for America ("A4A") and The Boeing Company ("Boeing") appreciate the opportunity to comment on the April 10, 2013 revisions to the proposed Safer Consumer Product ("SCP") regulations.[1] A4A is the principal trade and service organization of the U.S. airline industry.[2] 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.

With regard to the April 10 revisions, A4A, its members, and Boeing are primarily concerned by the addition of maintenance, repair and refurbishment to the definition of "assemble."[3] This change is inconsistent with previous versions of the proposed SCP

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[1] These comments refer to the Text of Proposed Regulations – Additional Post-Hearing Changes, dated April 13, 2013, available at: http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/2-SCP-REVISED-Proposed-Regulations_APA-MARKUP-April-2013.pdf.

[2] 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.

[3] To provide context for these comments on the April 10, 2013 SCP revisions, A4A and its members incorporate by reference their previous (October 11, 2012, February 28, 2013 and March 28, 2013) comments offered to the Department of Toxic Substances Control ("DTSC" or "the Department") on the proposed SCP regulations and associated rulemaking documents. These previous comments are included in Attachment 1.

regulations, and if adopted it would lead to an illogical result (namely, designation of a person who maintains, repairs, or refurbishes a product as a "responsible entity" under the SCP regulations). Moreover, regulation of the aviation industry in relation to these activities, or supplies and parts needed to perform these activities, is preempted under federal law.

1. Regulation of Those Performing Maintenance, Repair, or Refurbishment Activity is Inconsistent with DTSC's Previous SCP Proposals and Statements of Reasons

Previous versions of the proposed SCP regulations did not include repair, maintenance or refurbishment as activities that would qualify a person as a responsible entity.[4] In fact, in its Initial Statement of Reasons ("ISOR") for the proposed SCP regulations, the Department emphasized the need to exclude repair and maintenance of existing products, particularly durable goods, without the involvement of the SCP regulatory program.[5] Similarly, in the Revised Initial Statement of Reasons ("RISOR"), the Department specifically stated that "replacing worn, or depleted parts, repairing defective or nonworking components, or restoring or rebuilding a product" would not cause a person to be classified as a manufacturer [or other responsible entity].[6] These statements were consistent with DTSC's goal to give the proposed regulations a "forward looking" focus.[7]

When the Department released the January 2013 proposed SCP regulations, references to repair, refurbishment, and installation of standardized components were completely stricken from the manufacturer definition (where they had previously appeared as *exclusions* from the definition, subject to certain limitations).[8] The January 2013 proposal also added and defined a new category of responsible entities and associated definitions, "assembler" and "assemble," respectively that made no reference to repair, maintenance or refurbishment.[9] Accordingly, repair, refurbishment, and installation of standardized components were squarely outside the scope of activities that would qualify a person as a responsible entity under the SCP regulations.

In the latest proposed revisions, dated April 10, 2013, the definition of "assemble" was revised without explanation to specifically *include* repair, refurbishment, maintenance, or non-material alterations to a consumer product. As a result, a person performing these activities in relation to an existing product would be captured under the SCP regulatory framework as a

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[4] *See* previous SCP proposals released by the Department, available at: http://www.dtsc.ca.gov/SCPRegulations.cfm and http://www.dtsc.ca.gov/SCPRegulationsArchive.cfm.

[5] *See* ISOR, dated July 2012 at p. 28, lines 42-45.

[6] *See* RISOR, dated December 20, 2012 at p. 31, lines 7-11.

[7] *See* ISOR at p. 29, lines 8-9 and RISOR at p. 31, lines 11-13.

[8] A4A and Boeing provided comments on the July 2012 proposed SCP regulations, including the definition of "manufacture," to explain why the limitations placed on the exclusion of repair, refurbishment and installation of standardized components in the July 2012 proposed regulations should be removed. A4A, its members, and Boeing hereby reassert the arguments made related to this issue in their October 11, 2012 comments. *See* Attachment 1, October 11, 2012 comments of A4A and Boeing at pp. 12-13.

[9] "Assemble" was defined as "to fit, join, put, or otherwise bring together components to create a consumer product." "Assembler" was defined as "any person who assembles a product containing a component that is a product subject to the requirements of this chapter." *See* Proposed SCP Regulations, dated January 29, 2013 at § 69501.1(a)(15) and (16).

responsible entity. This revision is a major departure from the previous SCP regulations[10] and runs counter to the explanations and objectives outlined by the Department in the Initial and Revised Statements of Reasons. Accordingly, A4A, its members, and Boeing respectfully request that the Department revert to the definitions for "manufacturer," "manufacture," "assembler," and "assemble" that were provided in the January 2013 proposed SCP regulations.[11]

2. Designation of Persons who Perform Maintenance, Repair, and/or Refurbishment as Responsible Entities Does Not Make Sense

It does not make sense to regulate performance of repairs, maintenance, refurbishment and non-material alterations on existing products and equipment under the SCP regulations because these activities focus on prolonging the useful life of existing products rather than on production or development of new products. To designate entities engaged in these activities as responsible entities under the SCP regulatory framework would result in regulating these entities with respect to design and purchasing decisions over which they have no control.[12] Since the only specified option for complying with the SCP regulations for these entities would be to stop purchasing parts for repair and maintenance that have been identified as priority products, the proposed April 10 revision to the "assembler" definition would effectively deprive these entities of their livelihoods, deprive product and equipment owners of the ability to repair and maintain their property, and would require Californians to retire or sell existing complex durable goods to purchase new products for which repair and maintenance supplies are available.

In the context of aviation, if those performing repair and maintenance in California were not able to continue purchasing needed parts and supplies, aircraft operators would be unable to comply with the FAA requirement to have repair stations along the routes of service. As written, the "assembler" definition provided in the April 10, 2013 revisions would have the

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[10] The changes in the April 10, 2013 revisions, including changes to the "assemble" definition are not "sufficiently related changes," as defined in California Government Code Section 11346.8 and Title 1 of the California Code of Regulations, section 42 (the latter of which provides: "[c]hanges to the original text of a regulation shall be deemed to be "sufficiently related," as that term is used in Government Code Section 11346.8, if a reasonable member of the directly affected public could have determined from the notice that these changes to the regulation could have resulted"). Accordingly, these changes require a public comment period longer than fifteen days under California Government Code requirements. It is particularly important to provide opportunity for comment on this change because (1) the change does not appear to have been made in response to any comment on previous versions of the regulations, (2) no explanation for the change has been provided in DTSC written materials, and (3) in informal conversations, DTSC staff have not identified the source of this change or provided an explanation for it.

[11] The proposed SCP regulations dated January 29, 2013 defined "manufacture" as "to make or produce. 'Manufacture' does not include acts that meet the definition of 'assemble.'" "Manufacturer" is defined in the January 29, 2013 proposal to mean "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." *See* FN 9, above, for the January 2013 definitions of "assemble" and "assembler."

[12] As explained in previous comments, aircraft operators do not have control over the replacement parts or supplies must be used to maintain or repair aircraft in accordance with manufacturer and FAA specifications. Operation of aircraft that are not maintained in accordance with these specific procedures is prohibited by law. *See* Attachment 1, October 11, 2012 comments of A4A and Boeing at pp. 8-9 and 12-13; and, February 28, 2013 comments of A4A and Boeing at p. 9.

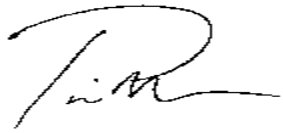
effect of forcing aircraft operators to obtain an injunction based on federal preemption, blocking enforcement of the SCP regulations as applied to repair and maintenance activities.[13] Even prior to the preemption issue coming to a head in relation to repair and maintenance supplies, the April 10 assembler definition would have the effect of driving aircraft maintenance jobs out of California based on the potential disruptive effect of the SCP regulations on these operations.

3. DTSC is Preempted from Regulating Aviation Maintenance, Repair, and Refurbishment, Including Parts and Supplies Needed to Perform these Activities

As explained in detail in the comments submitted by A4A and Boeing on October 11, 2012 and February 28, 2013, DTSC is preempted from regulating aviation. 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.[14] A4A, its members, and Boeing respectfully request that the Department refer to these previous comments, which have been incorporated in these comments by reference.

Thank you for your consideration of our comments on the April 13, 2013 revisions to the proposed Safer Consumer Products regulations.

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

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[13] *See* Attachment 1, October 11, 2012 comments of A4A and Boeing at pp. 8-9 (beginning on p. 8, section B).

[14] 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).

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BOEING

Attachment 1
(10-11-2012 Comments)

October 11, 2012

Submitted Via Email:
Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
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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.[1] 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 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.

[1] 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.

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.[2]

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.[3] 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.[4]
- "[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]."[5]
- "[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."[6]
- 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).[7]
- Within the State of California, Boeing is the largest manufacturer with about 21,000 employees.

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[2] 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).

[3] 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.

[4] *Id.* at p. 8.

[5] *Id.* at p. 40.

[6] *Id*.

[7] 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).

- 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.[8]

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[9] 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.[10] 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[11] and its stated intent to avoid "duplicat[ion of] or conflict with existing federal law"[12]: (1) acknowledge in the final regulations, or in the rulemaking record, that the State is precluded from regulating

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[8] Based on 2011 annual data.

[9] 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.

[10] *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)).

[11] 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.")

[12] Initial Statement of Reasons ("ISOR") for the California Green Chemistry Proposed Safer Consumer Product Alternative Regulations (R-2010-05) at p. 10.

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,"[13] 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.[14]

The FAA Act provides that "[t]he United States Government has exclusive sovereignty of airspace of the United States."[15] The principal objectives of the FAA Act are to promote safety and efficiency and the development of air commerce.[16] To achieve the statutory purposes of the FAA Act, Congress provided extensive and plenary authority to the FAA to implement these

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[13] ISOR at p. 10.

[14] 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.

[15] 49 U.S.C. § 40103(a).

[16] 49 U.S.C. § 40101 *et seq*.

objectives.[17] The FAA has exercised this authority by promulgating regulations that broadly regulate aircraft and passenger safety.[18] 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."[19]

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.[20] 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."[21] 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.[22]

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.[23]

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[17] *See, e.g.,* 49 U.S.C. §§ 40103, 44502, and 44721.

[18] *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).

[19] *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007) (emphasis added).

[20] *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973).

[21] *Id.*

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

[23] *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

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.[24] Requirements in FAA regulations can also specify or limit the use of certain chemicals.[25] 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.[26]

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).

[24] *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.)

[25] *E.g.*, 76 Fed. Reg. 77367-69 (requiring use of "alodined rub strips").

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

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."[27] 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.[28] 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.[29] 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.[30]

In *Rowe v. N.H. Motor Transportation Association,* the Supreme Court recently reaffirmed *Morales* and its broad interpretation of ADA preemption.[31] 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."[32]

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.[33]

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[27] 49 U.S.C. § 41713(b)(1).

[28] *Morales v. Trans World Airlines, Inc.,* 504 U.S. 374, 384 (1992).

[29] *Id.* at 388-90.

[30] *Id.* at 386.

[31] *Rowe v. N.H. Motor Transp. Ass'n*, 128 S. Ct. 989 (U.S. 2008).

[32] *Id.* at 995 (internal quotation marks omitted).

[33] 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

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[34] 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.[35] 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.[36] 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.[37] Airworthiness Directives, including referenced manufacturer Service Bulletins or Instructions for Continued Airworthiness ("ICAs"), are explicit regarding the actions to be performed and materials to be used.[38] ADs address the full range of aircraft parts and

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more broadly based on the inference that Congress intended to occupy the entire field at the exclusion of state regulation in the same area.

[34] In the present context, air transportation is a service, not a product.

[35] 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).

[36] *See id.* at section 4002(a)(9).

[37] *See* FAA database of Current Airworthiness Directives by Make, *available at* http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgAD.nsf/Frameset?OpenPage.

[38] *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.

components, from aircraft engines and skins to aircraft furnishings, insulation, and coffee makers.[39]

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.[40] 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.[41]

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.[42] 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.[43]

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:

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

§ 69501.1(a)(22)<u>(D) "Consumer product" or "Product" does not mean a "federally certified product."</u>

And,

§ 69501.1(a)<u>(XX) "Federally certified product" means:</u>

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[39] *See* FAA database of Current Airworthiness Directives.

[40] *Morales v. Trans World Airlines, Inc.,* 504 U.S. 374, 384 (1992).

[41] *Rowe at* 364; *Morales* at 390.

[42] *See e.g.,* 14 CFR §121.105.

[43] 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.

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.[44]

d. Include language in the FSOR acknowledging that the ADA expressly preempts state laws that relate to airline rates, routes, or services.[45]

(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:

§ 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

[44] *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).

[45] *See* 49 U.S.C. § 41713(b)(1).

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.[46]

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

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[46] 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.

§ 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)[47]-(41) to clarify that aircraft operators would not be considered "manufacturers" of aircraft based on their 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).[48]

[47] 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.)

[48] 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.

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.[49]

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."

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. <u>"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.</u>

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

[49] ISOR at 28-29.

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), 69595.4(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:

(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.[50] If this is the case, we ask that 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.[51] The APA specifies that:

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[50] *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 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").

[51] 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,

> [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.*[52]

We respectfully request DTSC's acknowledgement that it will comply with APA requirements (including, but not limited to analysis of economic impacts)[53] 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 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

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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."

[52] California Government Code §11346.3(a)(1)-(2) (emphasis added).

[53] 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).

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,

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Sr. Managing Director
Environmental Affairs
Airlines for America

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

Airlines for America™
We Connect the World

BOEING

Attachment 1
(02-28-2013 Comments)

February 28, 2013

Submitted Via Email:
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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") [1] and The Boeing Company[2] 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

[1] 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.

[2] 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);[3] introduction of "Assemblers" as an additional category of responsible entities;[4] a significant adjustment to how Alternatives Analysis Thresholds are defined;[5] and wholesale removal of certified assessors from the alternatives analysis process.[6]

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.[7] This represents an unsignaled 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.[8] This change is inconsistent with fundamental Administrative Procedure Act ("APA") and administrative due process requirements.[9] 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.

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[3] *See* proposed §§ 69501.1(a)(43)-(44).

[4] *See* proposed §§ 69501.1(a)(15)-(16).

[5] *See* proposed § 69501.1(a)(12).

[6] *See e.g.,* stricken language in proposed §69505.1(e).

[7] *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.

[8] 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.

[9] 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[10] 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.[11] 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.[12]

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[10] 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.

[11] *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)).

[12] *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."[13] 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.[14] 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[15] is necessary to comply with section 25257.1(b).[16]

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.[17] 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:

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[13] *See* California Health & Safety Code § 25257.1(b) (emphasis added).

[14] "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 (9th 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).

[15] Again, see our 2012 SCP Comments.

[16] 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).

[17] *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).[18]

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

[18] 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).

[19] 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,[20] technical feasibility, and economic feasibility within the Priority Product identification and prioritization process. The

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

[20] 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.[21] We suggest the following language be added to address this issue:

[21] 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…" (emaphasis 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"),[22] as well as confirmation that the new "Assemble"/"Assembler" definitions do not bring repair and maintenance back into scope.[23]

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:

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[22] 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.

[23] 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.[24] Finally, Proposition 65 is its own law, with its own enforcement mechanism for exposures from products in California.

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

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.

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[24] 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.

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Attachment 1
(02-28-2013 Comments)

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

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Attachment 1
(03-28-2013 Comments)

March 28, 2013

Submitted Via Email:
Ms. Jackie Buttle, Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

RE: Comments on the Scientific External Peer Reviewer Reports for the Safer Consumer Products Regulations; Department Reference Number: R-2011-02; OAL Notice File Number: Z-2012-0717-04

To Whom It May Concern:

Airlines for America ("A4A") and its members appreciate the opportunity to comment on the External Scientific Peer Review ("ESPR") Reports on the revised proposed Safer Consumer Product ("SCP") regulations.[1] A4A is the principal trade and service organization of the U.S. airline industry.[2] Its member airlines and their affiliates transport more than 90 percent of all U.S. airline passenger and cargo traffic.

A4A and its members respectfully request that the Department of Toxic Substances Control ("DTSC") exclude certain portions of the ESPR comments that do not relate to scientific basis of the proposed regulations, including the portions of the D. Hattis report related to the proposed definition of "importer."[3] DTSC is not required to consider these comments, nor should they be part of the rulemaking record, because they are not scientific portions of the proposed rule and are therefore outside the scope of review authorized in California Health and Safety Code section 57004.[4] If DTSC does not remove the non-scientific portions of the D. Hattis report from consideration, A4A and its members request that DTSC nonetheless retain the second sentence of the "importer" definition in the proposed regulations because the concern raised in the D. Hattis report is addressed by other sections of the proposed regulations.

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[1] "Revised Proposed SCP Regulations" or "proposed regulations" means the proposed SCP regulations dated January 29, 2013.

[2] 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.

[3] *See* ESPR Report of Dale Hattis, Ph.D., at p. 8 (Feb. 18, 2013).

[4] California Health & Safety Code section 57004(d)(2) states that the Department may revise the scientific portions of the proposed rule in response to an ESPR report finding that the Department has failed to demonstrate that the scientific portions of the proposed rule are based upon sound scientific knowledge, methods, and practices.

1. **DTSC Should Not Consider ESPR Comments Related to the Non-Scientific Portions of the Proposed Rules**

Prior to adoption of a California environmental protection rule, the agency, board, or department must obtain reports from external scientific peer reviewers that evaluate whether the scientific portions of a proposed rule are based upon sound scientific knowledge, methods, and practices.[5] "Scientific portion" means "those foundations of a rule that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions establishing a regulatory level, standard, or other requirement for the protection of public health or the environment."[6] DTSC gave the reviewers instructions to answer four specific questions that the Department identified as constituting the scientific basis of the proposed regulations.[7] The comments offered on pages 7-9 of the D. Hattis report, including the comments regarding the definition of "importer," are outside the scope of DTSC's four questions and are clearly not related to the scientific portion of the proposed regulations.[8] Accordingly, these comments should not be considered as part of the rulemaking record.[9]

2. **DTSC Should Retain the Second Sentence of the Proposed "Importer" Definition**

DTSC's revised proposed SCP Regulations define "import" to mean "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…."[10] "Importer" is defined to mean "a person who imports a consumer product into the United States 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."[11]

A4A and its members urge DTSC to retain the second sentence of the proposed importer definition because removal of this language could have unintended and unjust consequences. For example, as explained in our October 11, 2012 comments, the Federal Aviation Administration ("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. If the second sentence of the importer definition were removed and if aviation were regulated under the

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[5] *See* California Health & Safety Code § 57004(d).

[6] *See id.* at §57004(a)(2).

[7] *See* Notice to Proceed with Scientific Peer Review for Safer Consumer Products Regulations, from Jeff Wong, Ph.D. to Scientific Peer Reviewers, dated January 30, 201[3].

[8] Following the response to the four review issues identified by DTSC as the scientific basis of the proposed regulatory action, the D. Hattis report adds a section entitled, "Other Issues Posed by the Current Draft." *See* ESPR Report of Dale Hattis at pp. 7-9. This section includes unsolicited feedback on the definitions of the terms, "importer", "economically feasible," and "economic impacts," none of which relate to the scientific basis of the proposed rule.

[9] An external peer reviewer could certainly comment on non-scientific portions of the proposed regulations; however, to be included in the rulemaking record, such comments should have been submitted to DTSC during one of the public comment periods on the proposed regulations.

[10] Revised Proposed SCP Regulations at § 69501.1(a)(38).

[11] *Id.* at § 69501.1(a)(39).

proposed regulations, an airline would be considered an importer (and thus a responsible party) for products that it is federally mandated to keep in stock for use by its employees or contractors in servicing aircraft in order to maintain the required FAA airworthiness certification.

A. Concern Raised in ESRP Report is Addressed in Other Sections of the Revised Proposed Regulations

The concern raised in the D. Hattis report regarding the second sentence of the importer definition is also unfounded. Professor Hattis speculates that, for example, a particleboard maker could import an adhesive known to contain and emit formaldehyde. If the particleboard maker used the adhesive in its workplace to manufacture particleboard but did not sell or distribute the adhesive itself, Professor Hattis states that emissions from the particleboard would go unregulated.[12] This is simply not the case. If there were issues with formaldehyde emissions from the particleboard, there is nothing that would prevent DTSC from regulating the particleboard maker as an assembler or a manufacturer.[13]

The term "assemble," as defined in the proposed regulations means "to fit, join, put, or otherwise bring together components *to create* a consumer product."[14] The term "assembler," in turn, captures "any person who assembles a product containing a component that is a product subject to the requirements of this chapter."[15] In the scenario offered by Professor Hattis, the adhesive is the substance of concern and would be treated as "a component that is a product subject to the requirements of this chapter" and the "person/firm" would be regulated as an assembler because it is *creating* the particleboard, which is the consumer product. Thus, the regulations would apply to protect consumers in this scenario independent of the scope of the importer definition.

Alternatively, in scenarios that raise concerns similar to the particleboard example above but where the person cannot be considered an assembler, the revised draft regulations would still capture the activity of manufacturing. Specifically, the term "manufacturer" is defined as "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."[16] In this alternative, even if the particular entity were not properly defined as an assembler, the activity posing the real health risk (the manufacture and sale of formaldehyde-laden particleboard) would still be subject to the regulations, thus ensuring protection of the public.

B. Retention of Second Sentence of Importer Definition Preserves Treatment of Maintenance Activities

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[12] *See* ESPR Report of Dale Hattis at p. 8.

[13] In addition, emissions from composites such as particleboard are already regulated by the California Air Resources Board ("CARB") through Airborne Toxic Control Measure ("ATCM") regulations that restrict formaldehyde emissions from composite wood products. *See* 17 California Code of Regulations §§ 93120 to 93120.12.

[14] Revised Proposed SCP Regulations at § 69501.1(a)(15)(emphasis added).

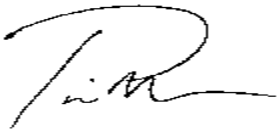
[15] *Id.* at § 69501.1(a)(16).

[16] *Id.* at § 69501.1(a)(44).

Finally, we note that the purpose behind the adding sentence two to the definition of "importer" was to ensure that maintenance activities, which are conducted within the workplace and do not create a product that can be distributed or sold to the public, should be treated separately from assembling or fabricating a consumer product. Absent the modification of the definition of "importer" the regulation risks being over-inclusive without achieving any additional public health benefit.

Thank you for your consideration of our comments on the ESPR reports.

Sincerely yours,



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

AUTO ALLIANCE
DRIVING INNOVATION®

April 25, 2013

VIA EMAIL
gcregs@dtsc.ca.gov

VIA MAIL
Ms. Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-2806

Re: Comments on Revisions to Text of Safer Consumer Product Regulations Released on April 10, 2013 (R-2011-02/OAL File No:Z-2012-0717-04)

Dear Ms. Buttle:

On behalf of the Alliance of Automobile Manufacturers ("Alliance"), we submit the following comments in response to the latest revisions to the text of the Safer Consumer Product regulations released on April 10, 2013 (the "Revised Regulations"). 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, the effort put forth to date, and embraces the goals and vision for safer consumer products embodied in California's Green Chemistry Statute (the "Statute").

However, after reviewing the Revised Regulations we are dismayed that, after nearly five years in the making, they still leave open so many unanswered questions and provide little guidance on what will be deemed acceptable compliance. We acknowledge that in the few areas addressed in the Revised Regulations, there are some improvements and attempts to address serious and practical implementation problems such as recognition of the difference between contaminants and intentionally-added chemicals; recognition that there may need to be different minimum thresholds to perform an Alternatives Analysis ("AA") for each [each what?], depending on the chemical-product combination selected; recognition that the threshold may need to be higher than the practical quantitation limit ("PQL"); recognition that the Department of Toxic Substances Control ("Department" or "DTSC") must exercise its expert judgment in filtering and scoping the range of public comments received and determining which are relevant to the inquiry for inclusion in the AA Report

Addendum. But these few improvements do not make up for the overall lack of certainty or the massive practical problems that appear to be the end result of this rulemaking. The past five years have resembled a long disjointed bargaining process, rather than a scientific regulatory design to stimulate and reward innovation in greener materials and products. Were this a scientific process, the Department would exclude contaminants and establish a clear *de minimis* threshold of 0.1%. Doing so would allow global industries to better focus their resources on finding replacements for the toxic ingredients that are found in greater than *de minimus* levels, and to plan and design their products accordingly.

The revision to the definition of "manufacturer" is a step in the right direction as it is important to clarify that the manufacturer is the entity which "specifies the use of chemicals" in a product. However, we urge further clarification and refinement as follows:

"specifies the use of chemicals ~~to be included~~ in the Priority P~~p~~roduct"

Additionally, we are puzzled by the changes to the definition of "assembler." Why would the DTSC want to pull in additional entities into the chain of liability such as refurbishers and small auto repair businesses, which have no knowledge of chemical use or an ability to perform an alternatives analysis? It seems the only effect will be to reduce the number of refurbishers in the State who cannot afford the new liability requirements, driving more products to early disposal.

Further, we remain gravely concerned with the fundamental failure to produce a set of regulations that were promised would be "practical, meaningful and legally defensible." We are equally disappointed with the disjointed, segmented rulemaking process that DTSC has followed and its failure to follow the rules governing state agency actions and our collective notions of procedural fairness.

In our first set of comments to the initial proposed regulations released on July 27, 2012, we provided detailed comments and a full redline text to assist the Department in crafting workable regulations that would be practical, meaningful and legally defensible. Knowing that the Department had many stakeholder concerns to balance and may not be able to adopt our entire redline text, we worked hard to narrow our suggested improvements to the top five changes that would both assist the Department and give us greater certainty that these regulations could be accomplished by most product manufacturers.[1] And yet, we find that even these few modest changes have not been included in the Revised Regulations.

To quickly recap, our top five issue area suggestions, offered to ensure that the Department's regulations achieved the following five objectives, are as follows:

1) Set an achievable project scope.

2) Set an achievable chemical scope.

3) Establish practical regulatory responses.

4) Eliminate duplicative regulation

5) Set an achievable reporting scope.

[1] The Alliance incorporates by reference all comments submitted on previous drafts.

A copy of the suggested language revisions in these top five issue areas is included again in this letter in the hopes that the Department might reconsider the inclusion of these modest clarifications. Such changes would go a long way to assuring that the Revised Regulations were meaningful, practical and legally defensible.[2]

The Revised Regulations will ask each manufacturer to conduct a vast analysis of its entire supply chain and - to the extent substitutions of chemicals are warranted by that analysis - to make changes in its supply chain. This will be a very expensive undertaking. As just one example, we provide the Department a copy of a report commissioned by the Consumer Electronics Association that examined the costs to 205 companies (58% OEMs (original equipment manufacturers), 16% component manufacturers, 13% contract manufacturers) to make the chemical ingredient substitutions required by the European Union's Restriction of Hazardous Substances (RoHS) requirements for six chemicals. It found the average cost per company to achieve compliance was $2.64 million for initial compliance and $482,000 for ongoing compliance. With the number of global electronics companies numbering over 90,000 (50,000 OEMs, 36,000 component suppliers, 3,000 contract manufacturers), and assuming that the average cost was only $50,000 per company (far lower than the survey results from the 200), the estimated costs to the electronics industry to achieve EU RoHS compliance was $38.3 billion. See Attachment B.[3]

DTSC has an obligation to consider less costly means to achieve the statute's objectives, such as those which set an achievable scope for the regulations, as provided in Attachment A. Again, we urge the Department to look closely at our top five issue areas and reconsider our suggested language changes very seriously.

Throughout the regulatory development process, the Alliance has consistently advocated for revisions that will render the Proposed Regulations more effective, while providing the public health and environmental benefits envisioned by the Statute.

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 or (202) 326-5551.

Sincerely,

Filipa Rio
Director, Environmental Affairs

Attachments

Attachment A – Top Five Issues

Attachment B – Chemical Substitution Cost Study (RoHS)

[2] Attachment A – Top Five Issues.

[3] Attachment B – Chemical Substitution Cost Study (RoHS), *Economic Impact of the European Union RoHS* Directive on the Electronics Industry*, Technology Forecasters, Inc. for Consumer Electronics Association (January 21, 2008).

Top 5 Issues	Suggested Language Revisions to July 27, 2012 Draft
One	**Set achievable project scope**
	69503.4 .1 (a)(2)(B)(4) ~~Subparagraph 2. does not apply to either of the following types of products:~~ For purposes of subparagraph 2, "component" means a uniquely identifiable material within a single uniquely identifiable part or piece, not comprised of subparts, of a highly durable product. § 69503.4(a)(2) For each listed highly durable product, the Department shall specify no more than ~~ten (10)~~ five (5) components ~~and/or homogenous materials~~ per product every three (3) years. § 69501.1 (34) "Historic product" means a product manufactured prior to the effective date of the regulatory response selected by the Department for the Priority Product, including all service, repair and replacement parts associated with the historic product even if manufactured after a regulatory response. ~~69501.1 (22)(B)(1) "Consumer Product" or "Product" does not mean historic product.~~ § 69506 (d) In no case shall the Department apply a regulatory response to a historic product. In the case of service, repair and replacement parts for historic products, the Department may only impose regulatory responses related to handling and warning requirements.
Two	**Set achievable chemical scope**
	§ 69501.1 *Add definition* *(48)* Practical Quantitation Limit (PQL)" means the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the chemicals of concern in the listed priority product results in an exemption for that product from the alternatives assessment process. § 69503.5. (c) The Department shall specify an alternatives analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product. In establishing an alternatives analysis threshold, the Department shall exempt for a highly durable product: (1) A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product; and (2) A contaminant in recycled materials that are common and are frequently used to manufacture the product. ; and, except as provided in paragraph (3), take into consideration, based on available reliable information, the factors specified in paragraph (1), if relevant, and paragraph (2): (1) The ease or difficulty of removing from the product, or otherwise avoiding the presence in the product of, the Chemical of Concern, if the source(s) of the Chemical of Concern

	is/are one or more of the following: ~~(A) A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product;~~ (A) Air or water frequently used as a processing agent or an ingredient to manufacture the product; ~~(c) A contaminant in recycled materials that are common and are frequently used to manufacture the product;~~ and/or (B) A processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended. § 69505.3(b)(3) (B) Compare each of the alternative chemicals being considered with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated under subparagraph (A); (C) Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines poses equal or greater adverse public health and/or environmental impacts than the Chemical(s) of Concern; § 69505.3 *Add* (D)-Eliminate from further consideration in the AA any economically infeasible alternative chemical(s) which is projected to be economically infeasible at time of implementation and use.
Three	**Revise regulatory responses to be practical**
	§ 69506. Regulatory Response Selection Principles. (a) The Department shall identify and require implementation of regulatory responses designed to protect public health and the environment from the harm caused by the Chemical of Concern in the Priority Product or the substitute product design required by the Department following completion of the alternatives analysis, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible. (b) In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, "inherent protection" refers to avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a Priority P~~p~~roduct or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern in the Priority P~~p~~roduct . (c) In selecting regulatory responses, the Department may consider any or all of the following factors: (1) The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the Chemical of Concern in the Priority Pr~~pr~~oduct or selected substitute product; §69506.2 (b) Within one year of the completion of the Alternatives Assessment, t~~T~~he

	Department may ~~at any time~~ require a responsible entity to obtain or develop, within a time frame specified by the Department, information to fill one or more of the information gaps identified in the Final AA Report, under section 69505.5(i)(2), if the Department determines this information is needed to re-evaluate, under section 69506.10(b), the initial regulatory response(s) imposed for a selected alternative or a Priority Product that remains in commerce. § 69506.4(a)(1) Except as provided in paragraph (2), this section may apply~~ies~~ to a Priority Product, or a selected alternative to a ~~product~~s, Priority Product~~s~~, containing a Chemical of Concern above the alternatives analysis threshold ~~for which an alternative is not selected, and Priority Products~~. § 69506.5 Use Restrictions on Chemical(s) of Concern and Consumer Products. The Department may impose restrictions on the use of one or more Chemicals of Concern in a selected alternative, or in a Priority Product for which an alternative is not selected, or restrictions on the use of the product itself, to reduce the ability of the product to contribute to or cause adverse public health and/or environmental impacts. Use restrictions may include one or more of the following: (a) Restrictions on the amount or concentration of the Chemical(s) of Concern permitted in a product; ~~(b) Restrictions on the settings in which a product may be sold or used;~~ (b~~c~~) Restrictions regarding the form in which a product is sold; and/or ~~(d) Restrictions on who may purchase and/or use a product;~~ ~~(e) Requirements for training of product purchasers and/or users; and/or~~ (c~~f~~) Any other use restriction that reduces the amount of any Chemical(s) of Concern in the product, or reduces the ability of the product to contribute to or cause an exposure to the Chemical(s) of Concern in the product. § 69506.7 (b) Engineering or administrative controls may be imposed by the Department to either integrally contain the Chemical(s) of Concern within the structure of the product or limit exposure to the Chemical(s) of Concern, if one or more of the following applies: (1) Reliable information indicates the presence of the Chemical(s) of Concern ~~or, its/their degradate, metabolite, or reaction products,~~ i in a particular subpopulation that has one or more routes of exposure to the chemical(s) and where such controls are necessary to limit exposure to the chemical of concern in the consumer product. ~~)~~ §69506.8(a)(2)(A) (7) a. ~~A financial guarantee provided by the responsible entity to insure a sustainable end-of-life management program for the product.~~ ~~b. "Financial guarantee" means any mechanism, including the mechanisms described in article 8 of chapter 14, to ensure that adequate funding is available to pay for future end-of life management costs for products placed into the stream of commerce in California.~~ §69506.8(a)(2)(B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and owners/operators of prospective collection sites. That program must include mechanisms, including market-based mechanisms, to ensure that there will be funding for the costs, if any, of proper collection of the products for the period of the product's useful life after the manufacturer ceases to exist. ~~The collection program must include one or both of the following: 1. Collection mechanisms; and/or 2. Compensation to retailers and other~~

	~~persons who agree to administer or participate in the collection program~~. ~~.~~ §69506.10 (b) ~~The Department may periodically re-evaluate any regulatory response imposed under this section to determine if changes are needed based upon changed circumstances or information identified since a regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report under section 69505.5(i)(2). The Department may accordingly require a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department, in a specified time period~~ ~~.~~
Four	**Eliminate duplicative regulation**
	§69501(b)(4) 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.
Five	**Set achievable reporting scope**
	1 - ***Delete AA threshold exemption notifications, chemical of concern removal notifications , and regulatory response exemption requests*** **2 -** ***Have AA Reports with reasonable parameters*** § 69505.3 Move to § 69505.1 (a) All references in this ~~section~~ article to "Chemical (s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being included on the Priority Products list. § 69505.4 (b)(4) Any ~~absent or~~ conflicting data regarding a relevant factor~~, and either or both of the following, as appropriate~~: ~~(A) Available data that is most protective of public health and the environment, unless there are sound methodological reasons for rejecting such data; and/or~~ ~~(B) A value for the metric, using a method for dealing with data uncertainty due to absent or missing data that has been adopted by an authoritative organization, as defined in section 69401.2(b), or generally accepted in peer reviewed literature~~ ~~;~~ § 69505.4 (b)(~~8) Any other known evaluation of the Priority Product or one or more of the alternatives that comes to different conclusions, regarding the relative overall performance or public health and/or environmental impacts, and the reasons for the difference in the conclusions (.~~ § 69505.5 (a)(5) The responsible entity shall identify and explain in the Final AA Report differing conclusions from the Preliminary AA Report ~~all major differences~~ ~~…~~ § 69505.5 (e)(3) Identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for the product being included on the Priority Product list ~~and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the product~~

	3 - *Delete requirements of listing customers who purchased products within the last 12 months* §69505.5 (d)(3) ~~The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months~~ ; § 69505.6. (c)(2) If the Department requires one or more regulatory responses under sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10, the Department shall specify in the notice the proposed due date(s) for implementation of the regulatory response(s). In assigning a due date for completing a regulatory response, the Department shall consider the complexity of implementing the regulatory response. If a product design change is required, the Department shall allow sufficient time for prototype development and testing for highly durable products . **4 - *Extend time period to seek judicial review to enjoin disclosure of trade secret information*** § 69510.1 (b)(2) If the submitter fails to provide the information within the timeframe specified, the Department shall notify the submitter by certified mail that the claim is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department sixty ~~thirty~~ (60~~30~~) days after such notice is mailed. During this 60~~30~~-day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief. (c) If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department sixty ~~thirty~~ (60~~30~~) days after such notice is mailed. During this 60~~30~~-day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief.

TECHNOLOGY FORECASTERS INC.

CEA Consumer Electronics Association

TFI ENVIRONMENT

Economic Impact of the European Union RoHS*Directive on the Electronics Industry

January 21, 2008

***RoHS**: Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

Purpose of this Study

- To calculate the economic cost of compliance with EU RoHS and associated impacts on the global electronics industry
  - Study undertaken by third-party consulting firm experienced in this market
  - Impact measured by using an objective research approach
  - Analyzed both costs and business benefits

Who is Behind this Study

Consulting firm conducting the research

- Technology Forecasters Inc. (TFI) is a consulting and research firm founded in 1987.
- TFI Environment helps high-tech clients comply with all applicable environmental regulations and simultaneously realize significant competitive advantages and cost savings.
- The consultants are primarily based in the United States, with offices in Mexico, China, Japan, the UK, and France

Sponsor of the research

- The Consumer Electronics Association (CEA) is a trade association representing more than 2,200 companies in high-tech industry.
- CEA member companies are engaged in the development, manufacturing and distribution of all consumer electronics, communications and multimedia products and services that are sold through global consumer channels.
- CEA is located in Arlington, VA and is the producer of the International CES in Las Vegas.

Study Methodology

1. TFI designed and conducted a web survey which included questions about EU RoHS compliance costs and procedures, as well as other existing substance restriction laws.
   - Sent the web survey to more than 1,000 companies
   - 271 people started the survey, 205 completed it (76% participation rate)
   - The completed surveys were by…
     - 58% OEM, 16% component manufacturers, and 13% contract manufacturers (also called electronics manufacturing services (EMS)
     - 64% North America, 15% Europe, 12% Asia
2. TFI designed a questionnaire for follow-up telephone interviews; interviewed 23 people
   - Gave respondents opportunity to share detailed views on the compliance process
   - Obtained further details on costs
   - Took time and care to form relationship with respondents for consistent results

Study Methodology (Continued)

3. Analyzed all data (both quantitative from web-survey results/telephone results and qualitative from telephone results)
   - Compared results by the respondents' different geographies, industry sectors, types and sizes of companies, year began RoHS compliance, etc.
4. For the cost calculation specifically
   - Some outlying responses were culled
   - Analyzed responses from companies exempt from EU RoHS ("out of scope") separately from those "in scope" (at top level)
   - Cross-correlated key data to company type or size
   - Extrapolated study's data to calculate total industry cost

In-Scope and Out-of-Scope

- Of the 205 responses, we were able to use 171* for cost-of-compliance calculations:
  - 48 were from companies exempt from EU RoHS ("out of scope")
  - 123 were from companies "in scope"
- Counted companies not stating whether RoHS exemptions apply to them as "in scope."
- "Out-of-scope" respondents are mixed bag
  - Some voluntarily complying--fully or partly
  - Some not complying, but still affected by discontinuation of non-compliant parts
- Cost calculations included both in- and out-of-scope, because each had individual RoHS-generated costs.

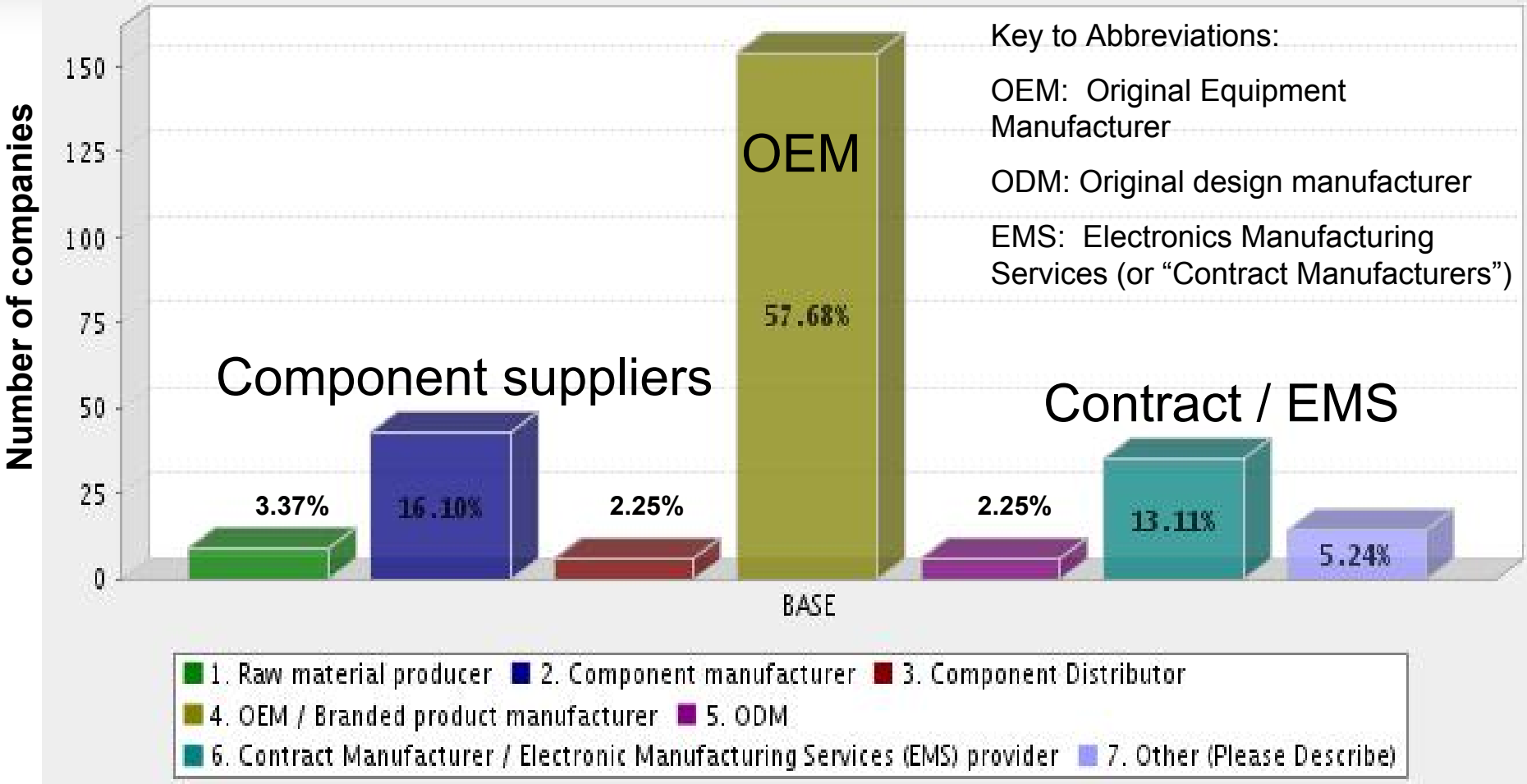
*34 incomplete responses removed

Results

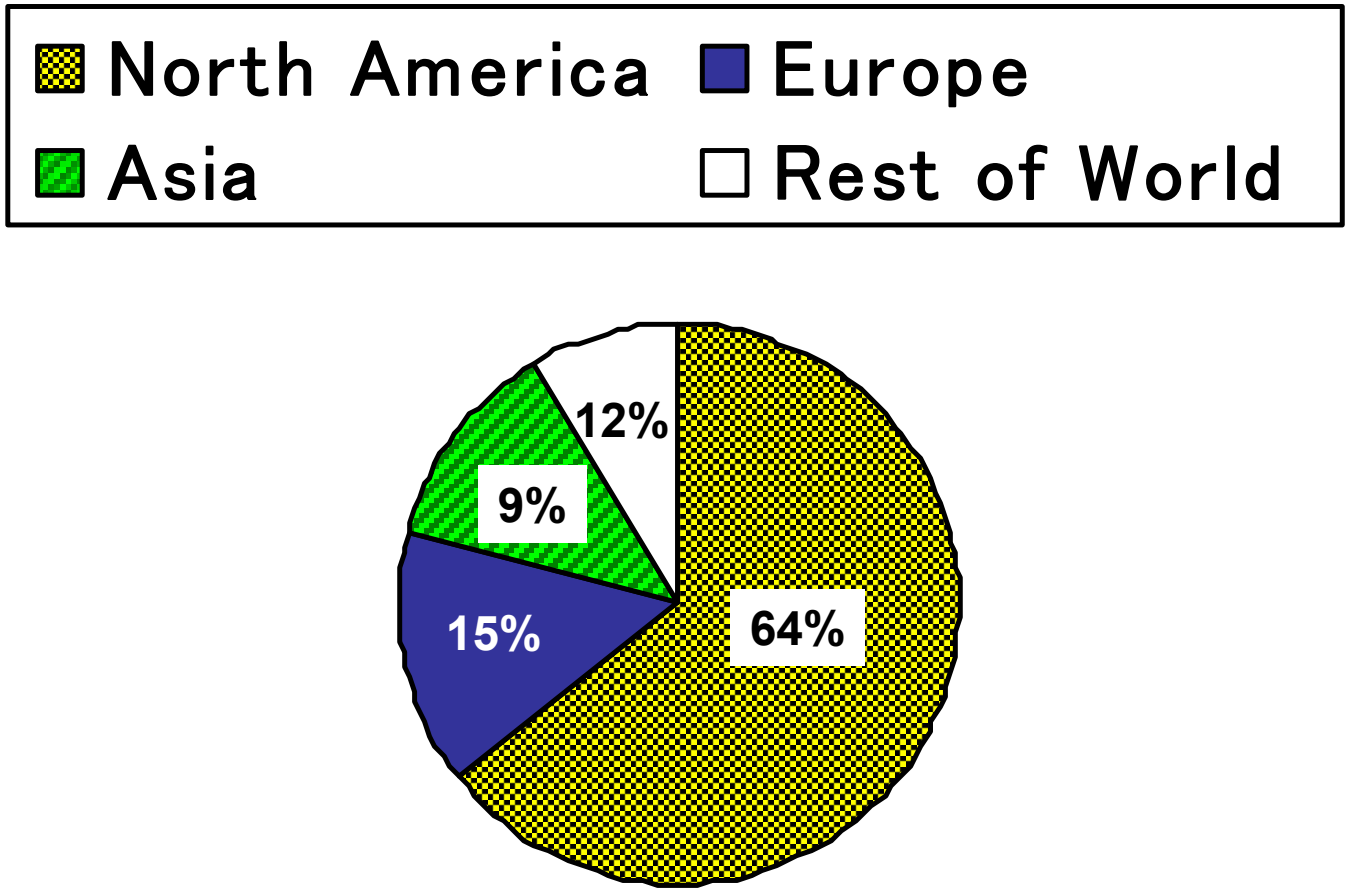
General Feedback on EU RoHS

- Several OEMs and EMSs expressed concern over other companies' (particularly suppliers') preparedness
  - Suppliers weren't ready, didn't understand, or weren't competent at supplying materials data.
  - Several suppliers indicated that proving compliance to customers is challenging.
- Companies criticize the RoHS directive itself
  - *"I think the biggest struggle is trying to understand what the requirements are."* (Large North American EMS)
  - *"The directive itself was vague and unclear."* (Large North American OEM)
- Several said complying with RoHS is "Time-consuming" or "Tedious"

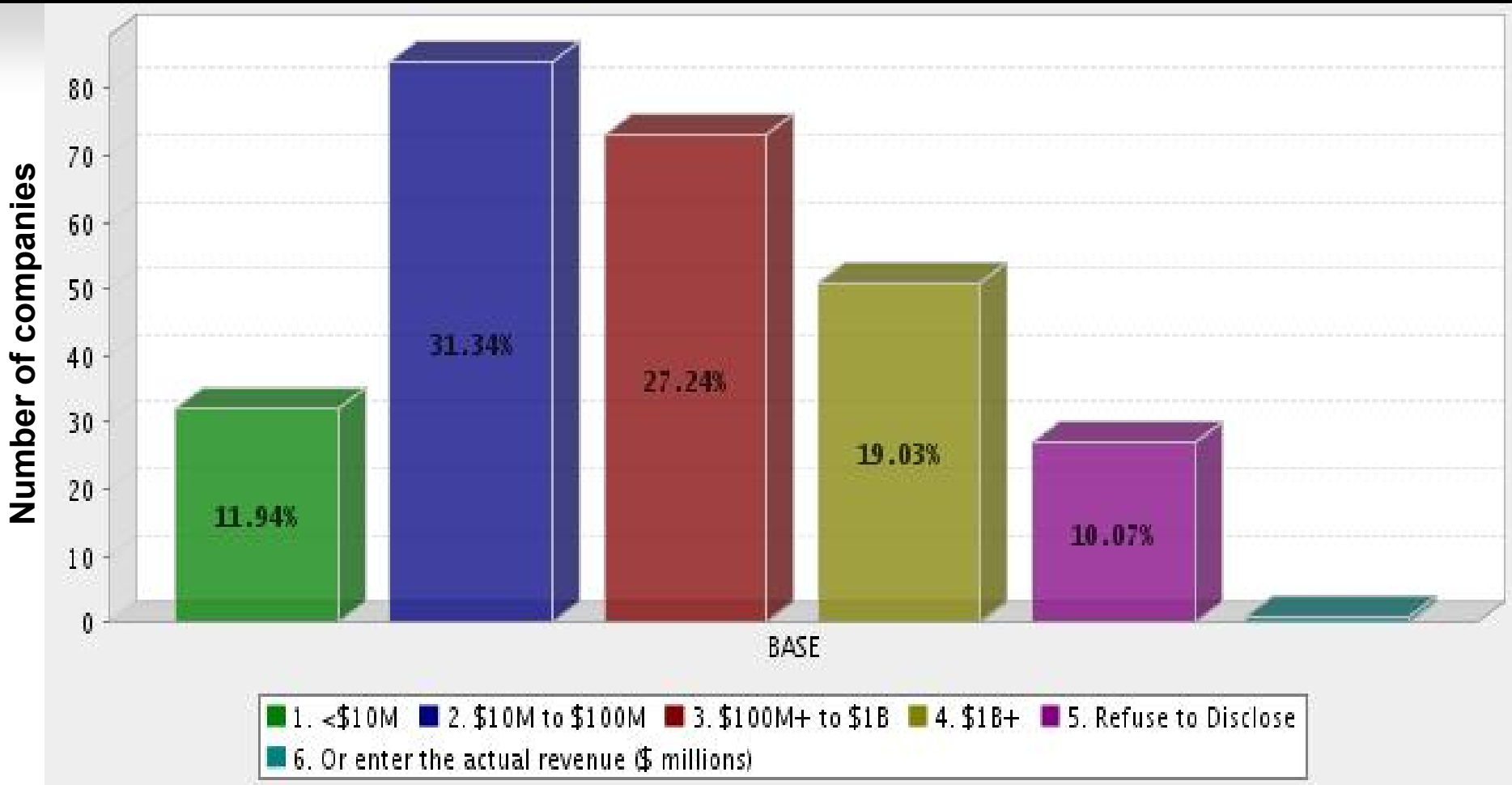
Type of Companies Responding to Study



Geographic Distribution of the Respondents' Headquarters Locations



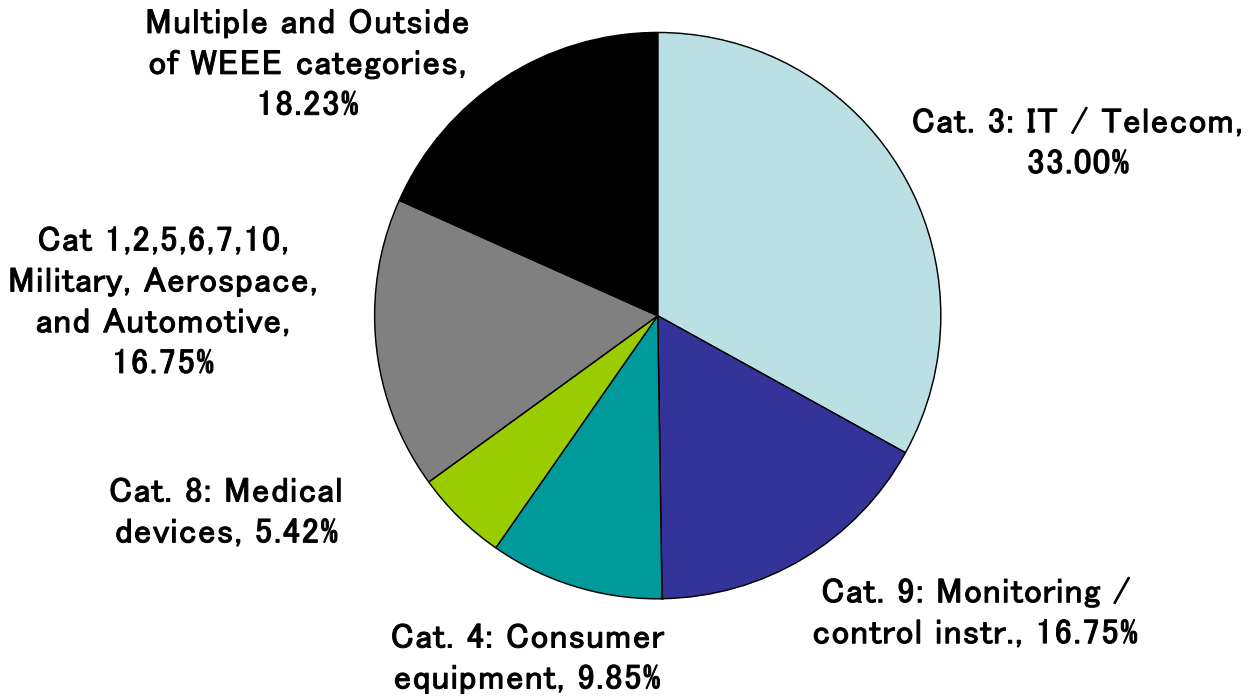
Revenue of Respondents' Companies*



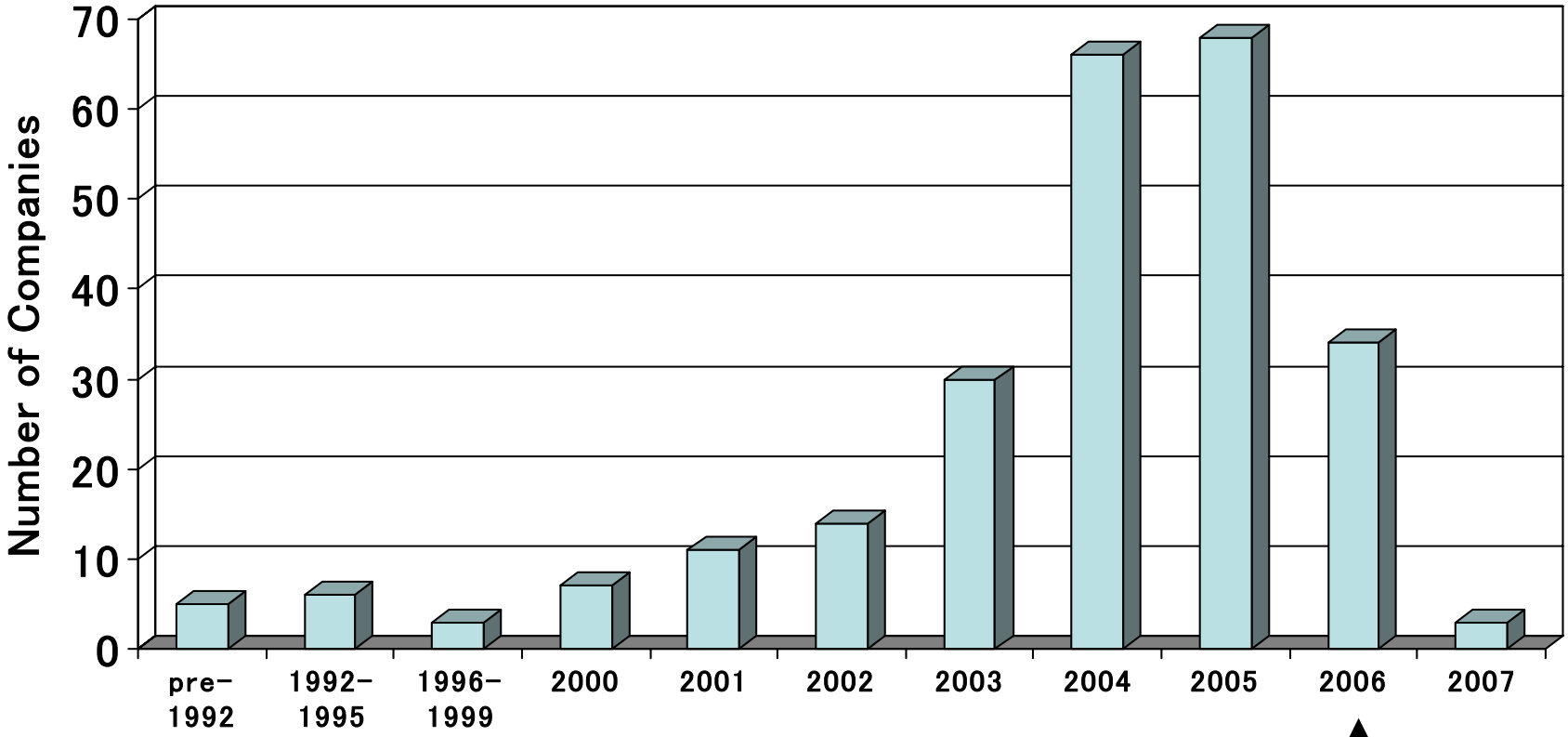
* From most recently completed fiscal year

Primary Industrial Sectors of Respondents

21% were currently out-of-scope ("exempt" from RoHS)

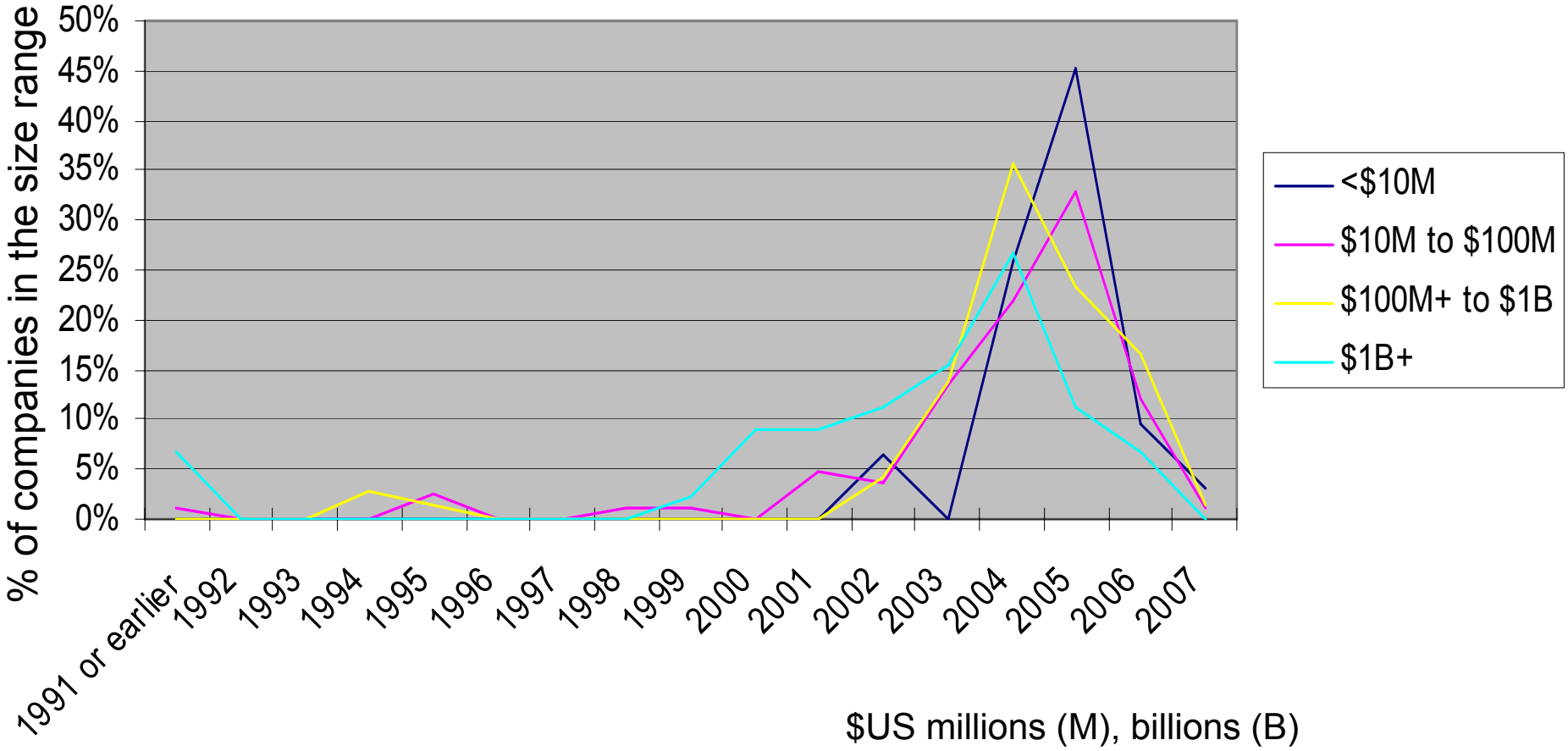


Year the Respondents Began Work on EU RoHS Compliance

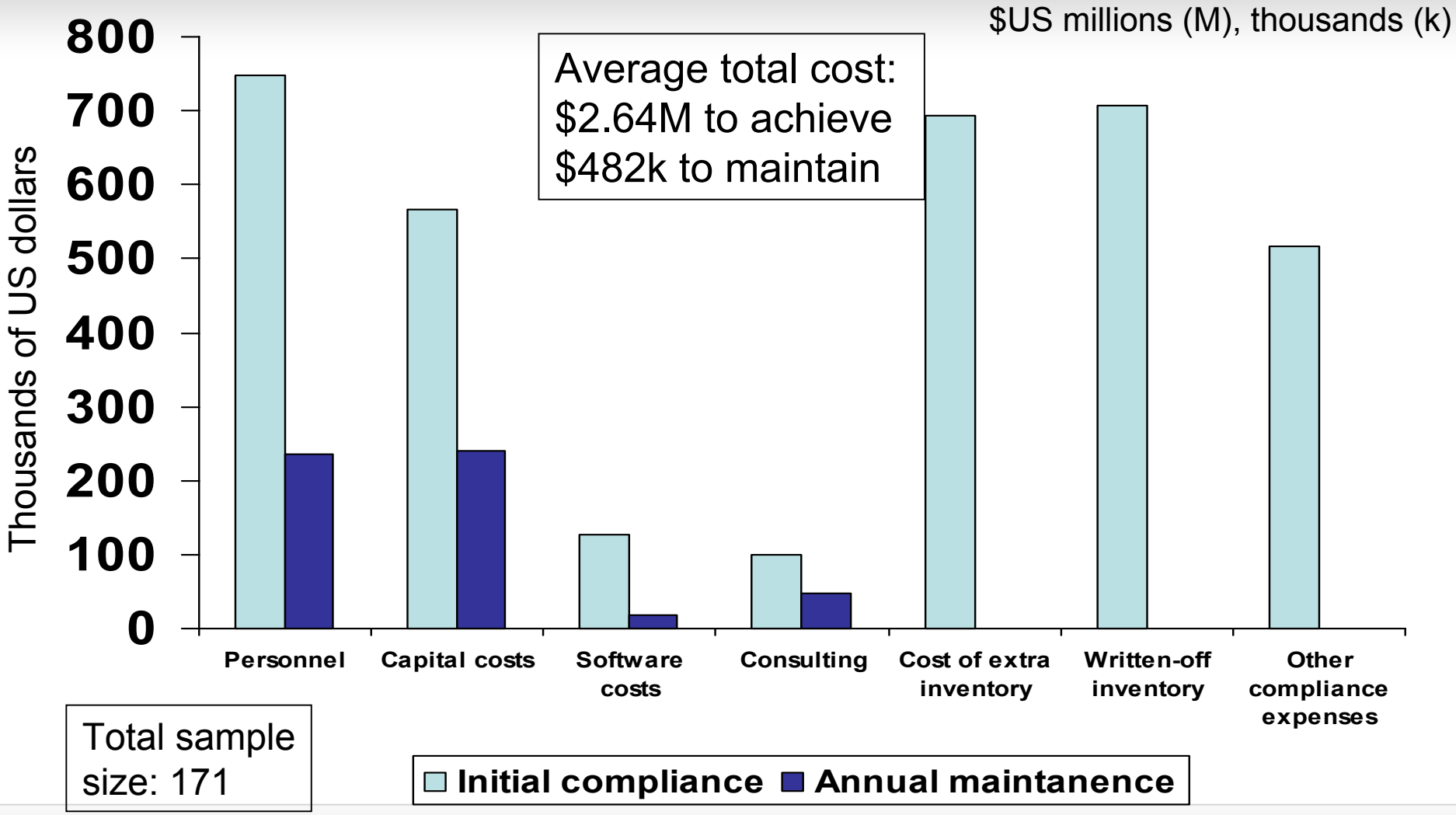


EU RoHS took effect July 1, 2006

Larger Companies Started Work on Compliance Earlier



Average Costs from EU RoHS Compliance

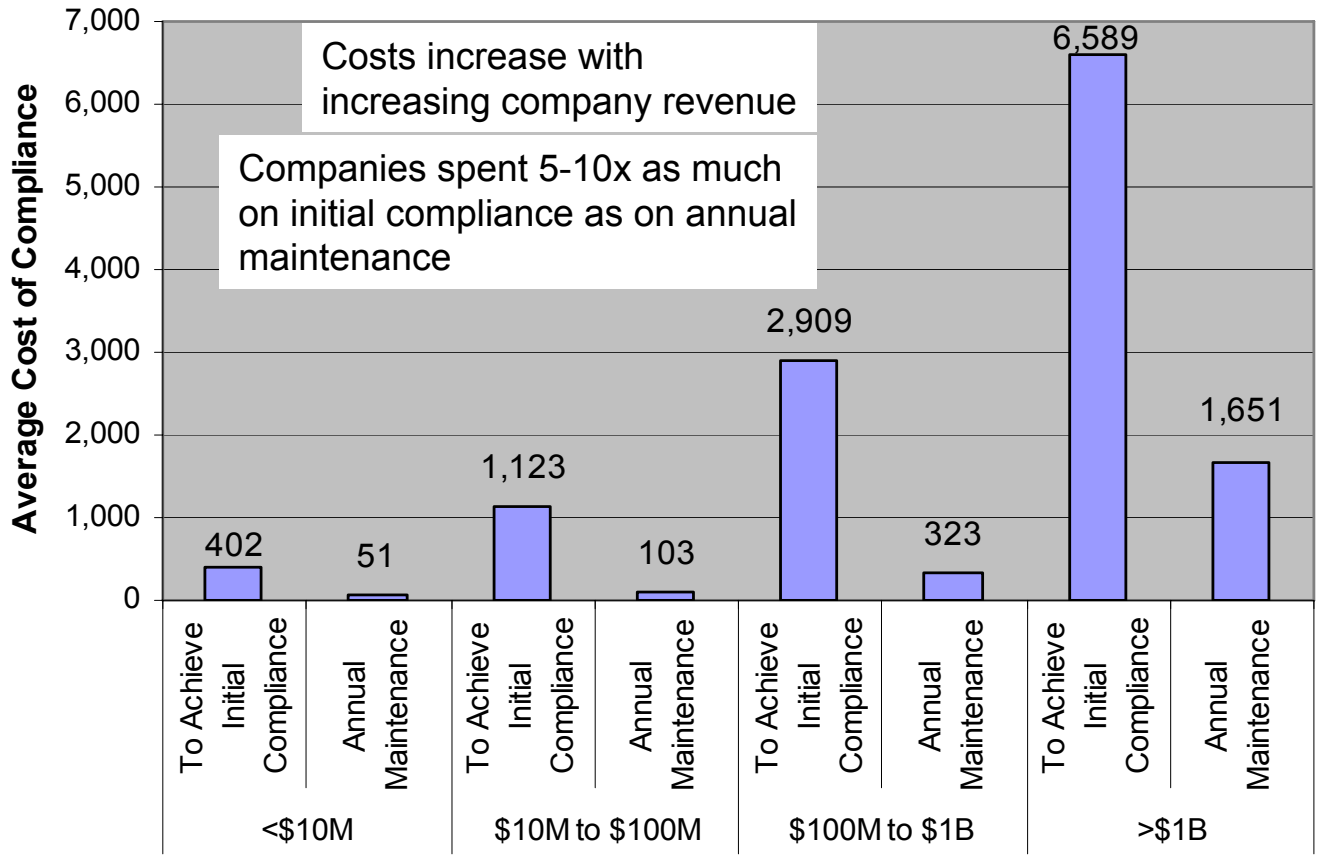


Average Cost vs. Median Cost and Weighted Average Cost

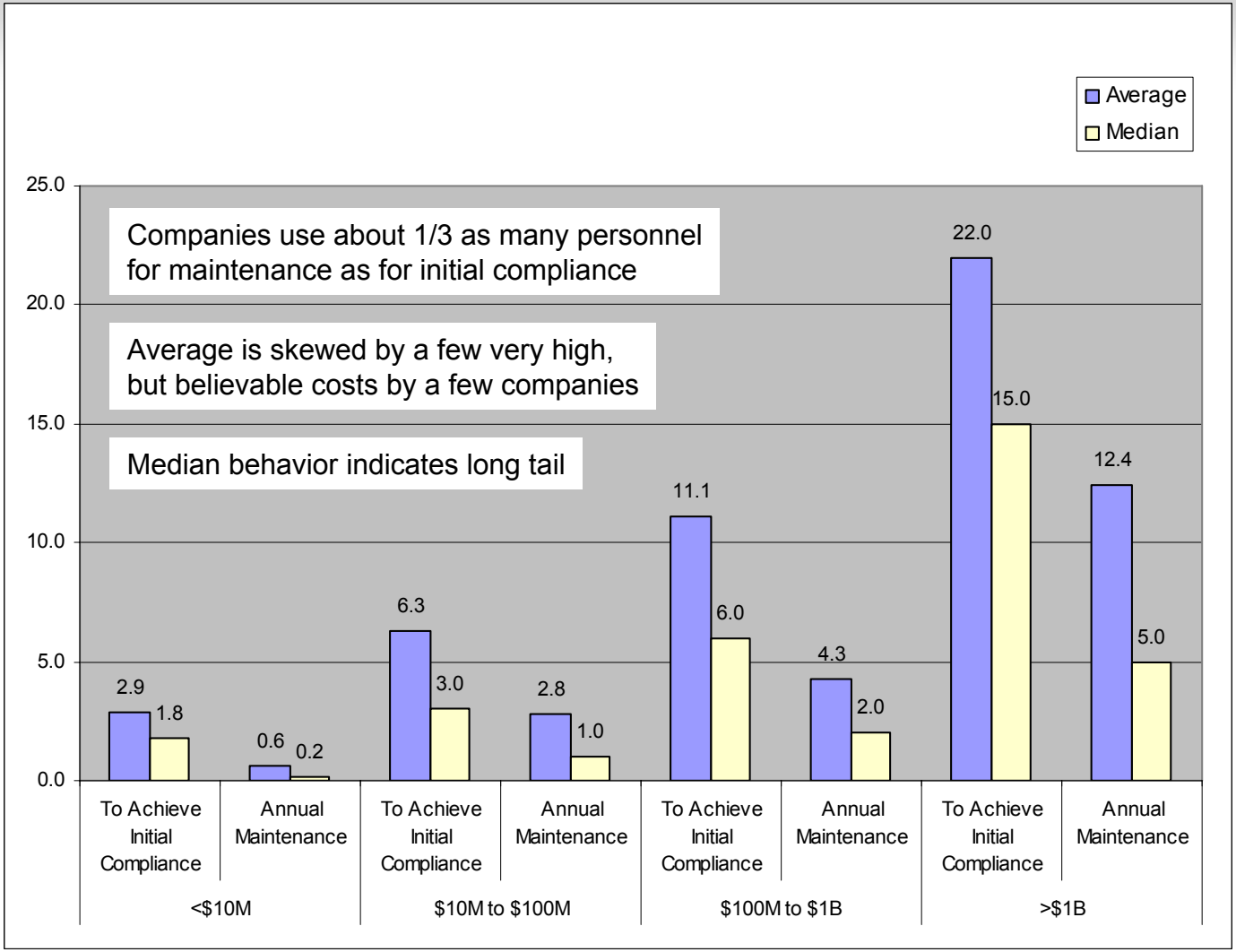
- Total average cost was $2.64 million for initial compliance, $482,000 for annual maintenance (based on our 171-company sample).
- Total median cost was $721,000 for initial compliance, $118,000 for annual maintenance (based on our 171-company sample).
- Total weighted average cost* was $5.94M for initial compliance, $1.44M for annual maintenance (based on our 171-company sample).
- Due to the effect of large companies with larger compliance costs:
  - The median is smaller than the straight average.
  - The weighted average is larger than the straight average.

* Weighted by company revenue. Each revenue category was assigned an avg value (same as Slide 49)

Company Revenue vs. Average Cost for Compliance with EU RoHS (US$ thousands)



Company Revenue vs. Average Number of Full-time-equivalent Employees



Adding/Retraining Personnel

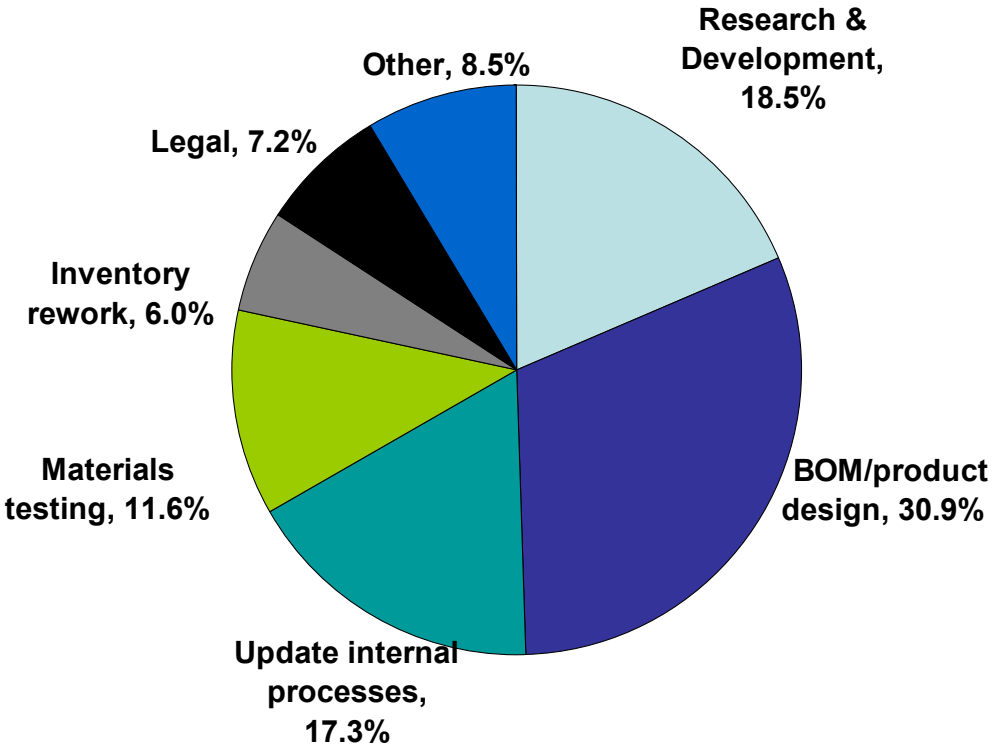
The vast majority of companies hired zero or one employee for RoHS compliance, relying instead on internal resources.

- *"We're still trying to invent the ways to get this done. We're borrowing and reassigning people to get it done because you don't get extra people."* (Large North American OEM)
- *"This does not include the time and effort that was absorbed with the current headcount. Our people were stretched more thinly."* (Medium-sized North American OEM)
- *"We tried to reassign existing people and expand their jobs. People worked overtime."* (Large North American EMS)
- *"People were not added, but stolen from elsewhere and made to work harder… It was a long, hard row for a lot of people."* (Large North American OEM)

Reassigning Existing Personnel

- *"Some retraining and change of work tasks have been taking place. How many additional resources are hard to estimate, since the way of working has been changed to some extent at the same time. "* (Small European Contract Manufacturer)
- *"Everything we touch affects the current process, so we had to get a lot of groups involved. We have a lot of heads working on the problem, so this does not include the cost involved with getting all these people together and the cost of taking them away from their current jobs. "* (Medium-sized North American OEM)
- "In the beginning, before the implementation, there were 2 reassigned people, and now there is 1 person. There was nothing added financially, but they were appointed (reassigned) to this project and tasked with taking care of the initiative." (Large European OEM)

Average Distribution of Compliance Personnel

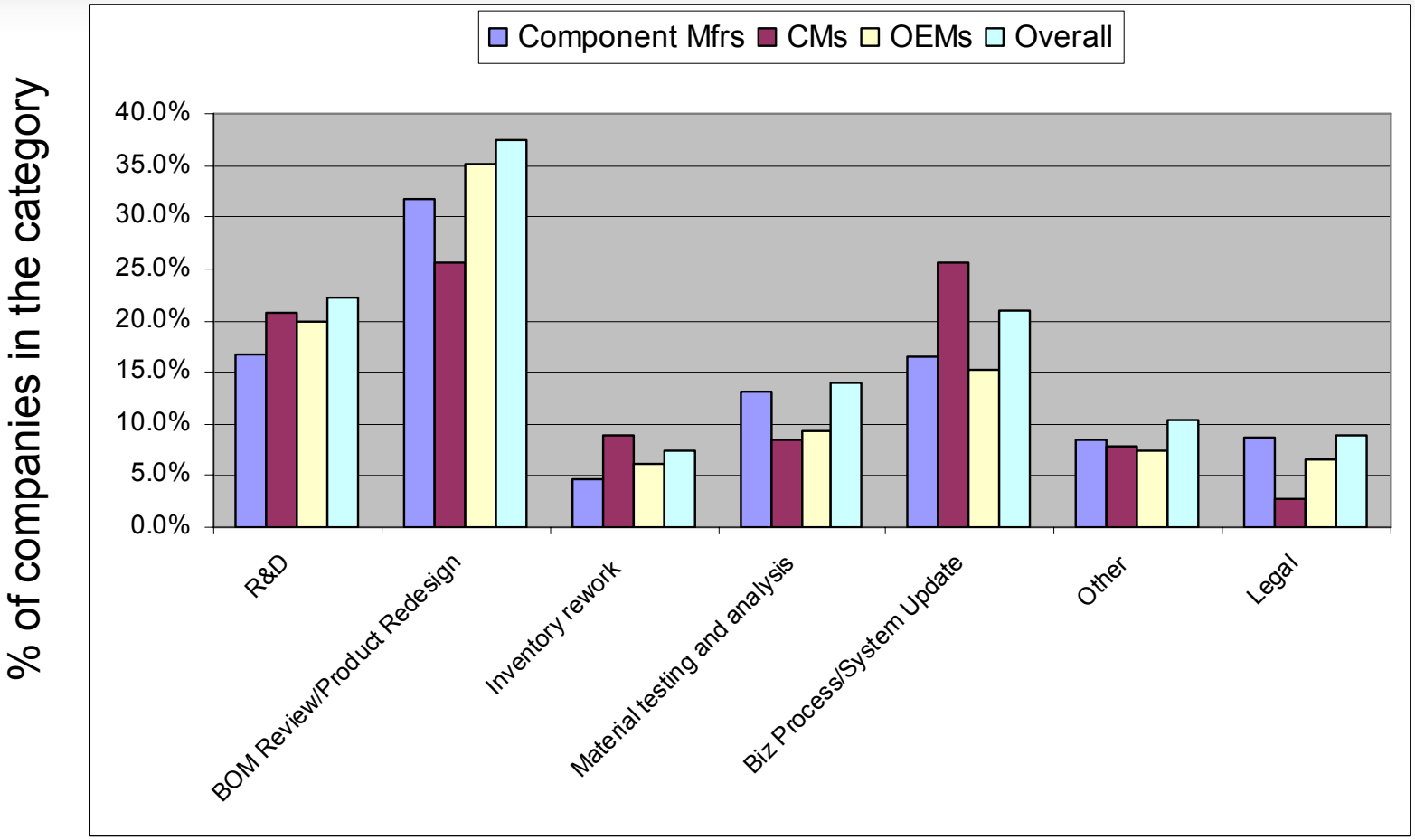


BOM: bill of materials

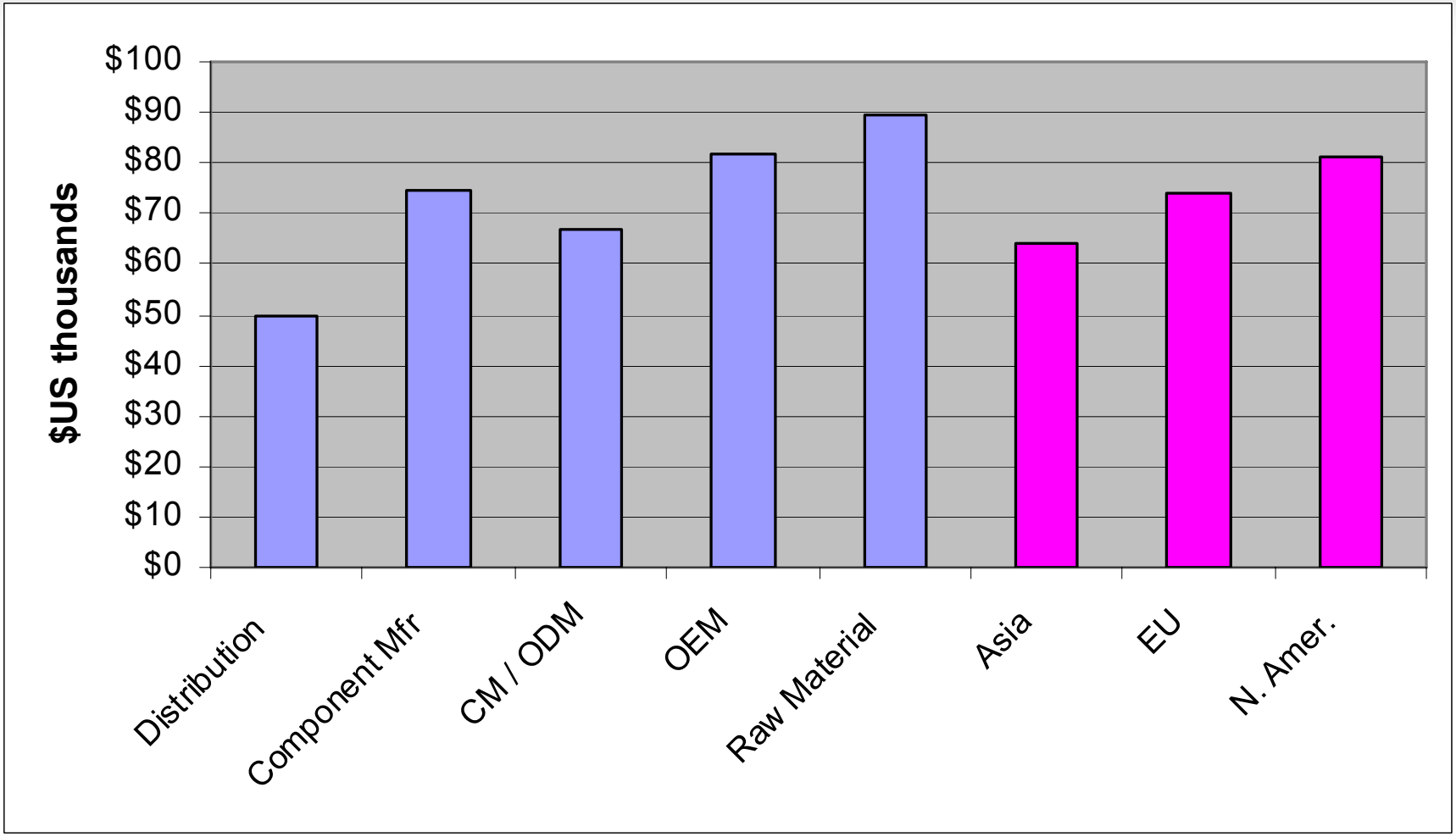
Personnel Analysis by Company Type

- Contract Manufacturers (CM)/EMS had to spend the most effort on business process and system updates
- Component manufacturers and OEMs had to spend the most effort on BOM reviews and product redesign
- Everyone had an equal burden in R&D

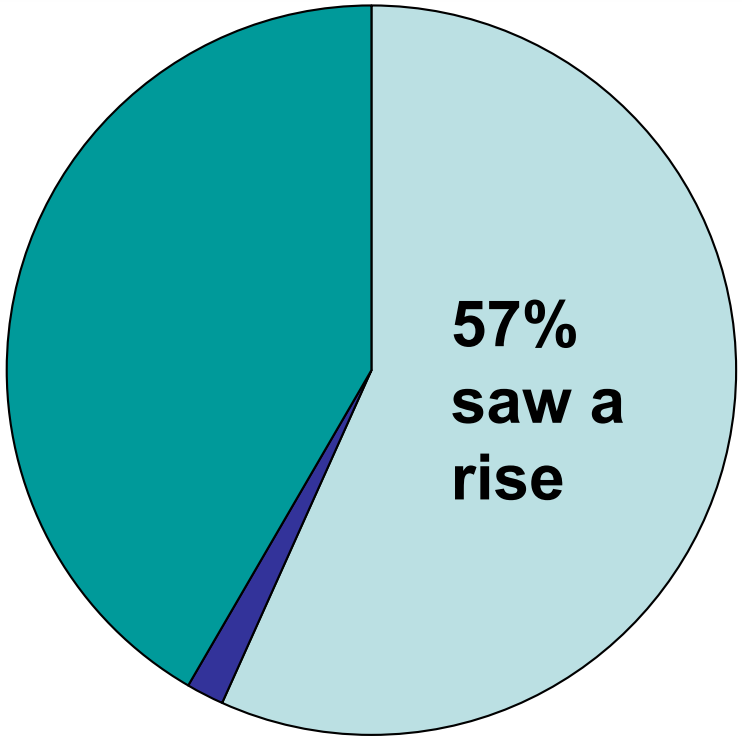
Where did RoHS Personnel Spend their Time?



Average Annual Personnel Cost by Industry Segment & Headquarters Location



Effect of EU RoHS on Inventory*



Increase | Decrease | No change/ Don't know

Avg reported rise over pre-RoHS inventory level: 21%

Avg reported cost of carrying this inventory: $688,000

Avg reported value of scrapped or written-down inventory: $698,000

* Raw materials, work-in-process, finished goods, spares

Interview Results: Inventory

Varied views; some companies were more proactive than others.

- *"It took about 6 months ramp up and then another 6 months to stabilize."* (Large North American OEM)
- *"Everything pretty much stayed the same. We said to our customer: If you want these parts, here is your last ship date … otherwise you will have to wait for the new stuff. Then we restricted them to ordering the new RoHS compliant products."* (Medium-sized North American OEM)
- *"Every time there is an obsolete part, it changes the schematic, the BOM, everything-- it is a nightmare."* (Medium-sized North American OEM)

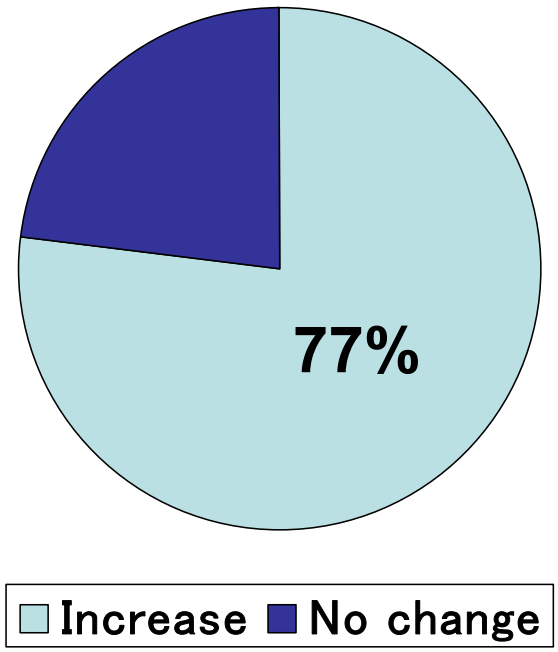
BOM = bill of materials

Interview Results: Inventory

- *"Because we started a whole year in advance, we did not have the peaks and valleys. We shifted the non-RoHS products to non-RoHS locations. Our goal was to be fully compliant by Jan 2006--6 months before the deadline. We pressured our suppliers to be compliant before Jan. 1 so that we did not have to carry a heavy inventory."* (Large European OEM)
- *"We had perfectly good product, but our biggest market was the EU and we could no longer ship lead product there. We basically reserved against it and took it off our books."* (Mid-sized North American OEM)
- *"We were very successful at mitigating our losses with our compliant vs. non-RoHS compliant inventory. This was not a losing proposition." (Large North American Contract Manufacturer)*

BOM = bill of materials

Effect of EU RoHS on Component, Module, and Manufacturing Costs

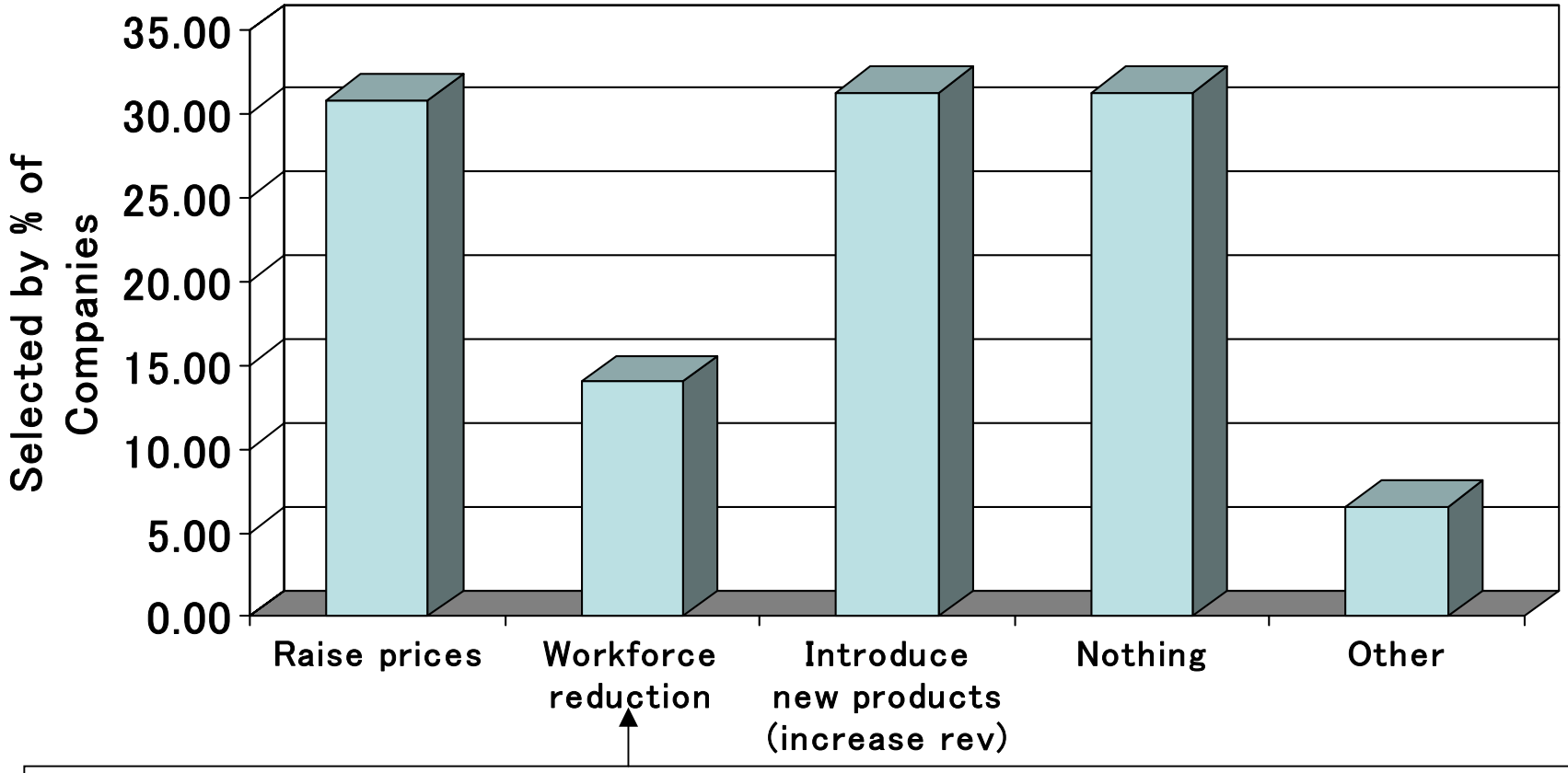


Avg cost increase experienced (OEM) or added (ODM or EMS) = 11.6%

(Three respondents reported a decrease)

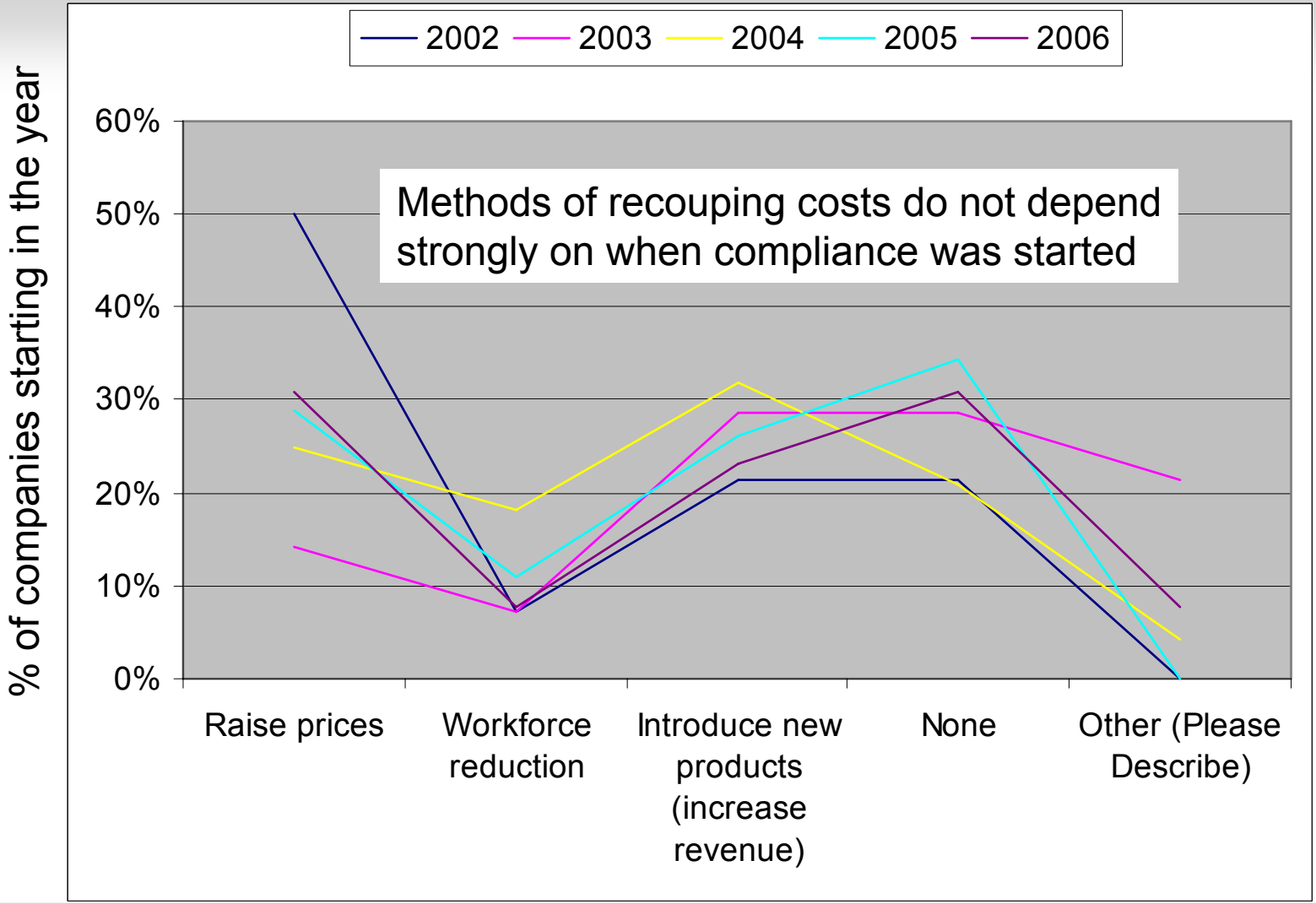
What is Being Done to Recoup Costs?

*** Respondents could select more than one**



Companies were less likely to reduce headcount than to choose other options, including doing nothing.

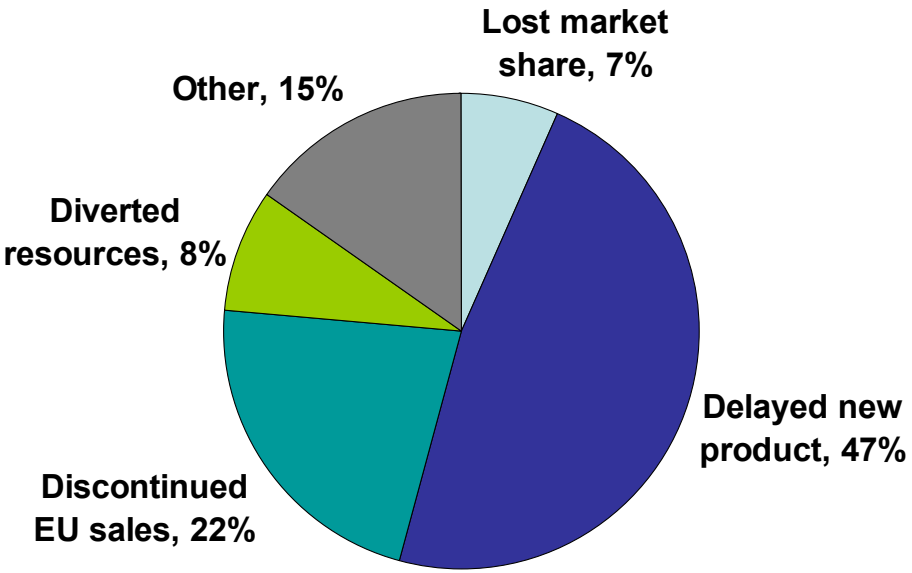
How Costs Have Been Recouped vs. Start Year



Lost Sales Due to EU RoHS

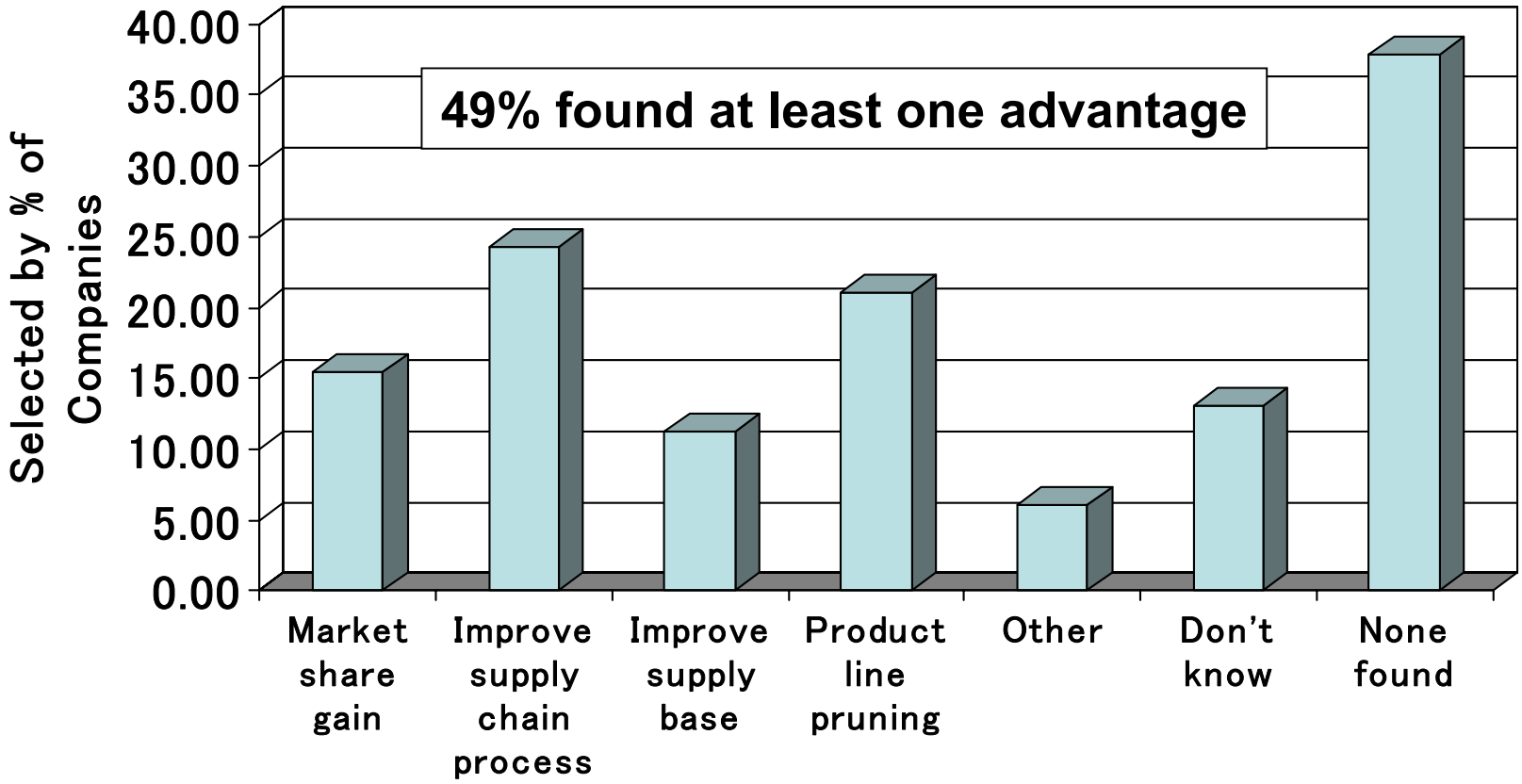
- Lost sales reported by 28.6% of respondents
- Average loss = $1.84 million

Primary cause of lost sales:



Advantages Discovered in Compliance Process

* Respondents could select more than one



Advantages Discovered in Compliance Process

"We redistributed non-compliant products to those locations that did not require RoHS. We also took the time to prune our inventory and some end-of-life inventory earlier, because it was cost effective at the time."
(Mid-sized North American OEM)

Who Got the Advantages?

- Main winners were EMS providers
  - 75% found at least one advantage
  - 60% improved their supply-chain processes
  - 50% saw a market-share gain
  - 50% rationalized their product lines
- Component manufacturers also fared well
  - 70% found at least one advantage
  - 26% saw a market share gain
- Half of OEMs found at least one advantage
  - Of these, about half improved their supply chain processes (27% of total)

Comments on Sales

- *"We haven't missed any sales because we didn't have a lead-free product in time for the RoHS deadline. However, we did miss sales because of our inability to meet a deadline on having the lab reports required from the corporate customer. It's significant, and nothing gets management's attention as missed P.O.s."* (Large North American OEM)
- *"We didn't lose sales at all! If anything, we did well because of RoHS!"* (Large North American EMS)

Changes to Business Processes

- Training & (continuing) Education across the company
  - Some incorporate environmental objectives in to MBOs (MBO=management by objective, or job requirements)
- R&D/Product Development (OEMs) – Revise component selection processes to include assessment of RoHS compliance
  - Use of existing standards, like IPC 1752
  - For existing products, had to review parts in existing BOMs
- Data Management – buy new or configure existing product lifecycle management (PLM) systems to manage and reflect data
  - And update processes to enable use of the data
  - Often new part numbering systems were implemented at both supplier and OEMs
    - Often the cause of customer frustration for both

IT Systems Were Modified or Added

- *No new system purchased, "But we may have to buy something in the future because the regulations are getting too complex for our home-built system (it cannot handle the detail)." (Large North American Contract Manufacturer)*
- *"No new software, but our old software was modified. It took approximately 9 months to modify software to accept new part codes and include supplier data."* (Mid-sized North American OEM)
- *"We purchased [a commercial] System at a cost of $200,000, it cost $10,000 to implement. The cost of annual upgrades is $20,000…." (Mid-sized North American OEM)*

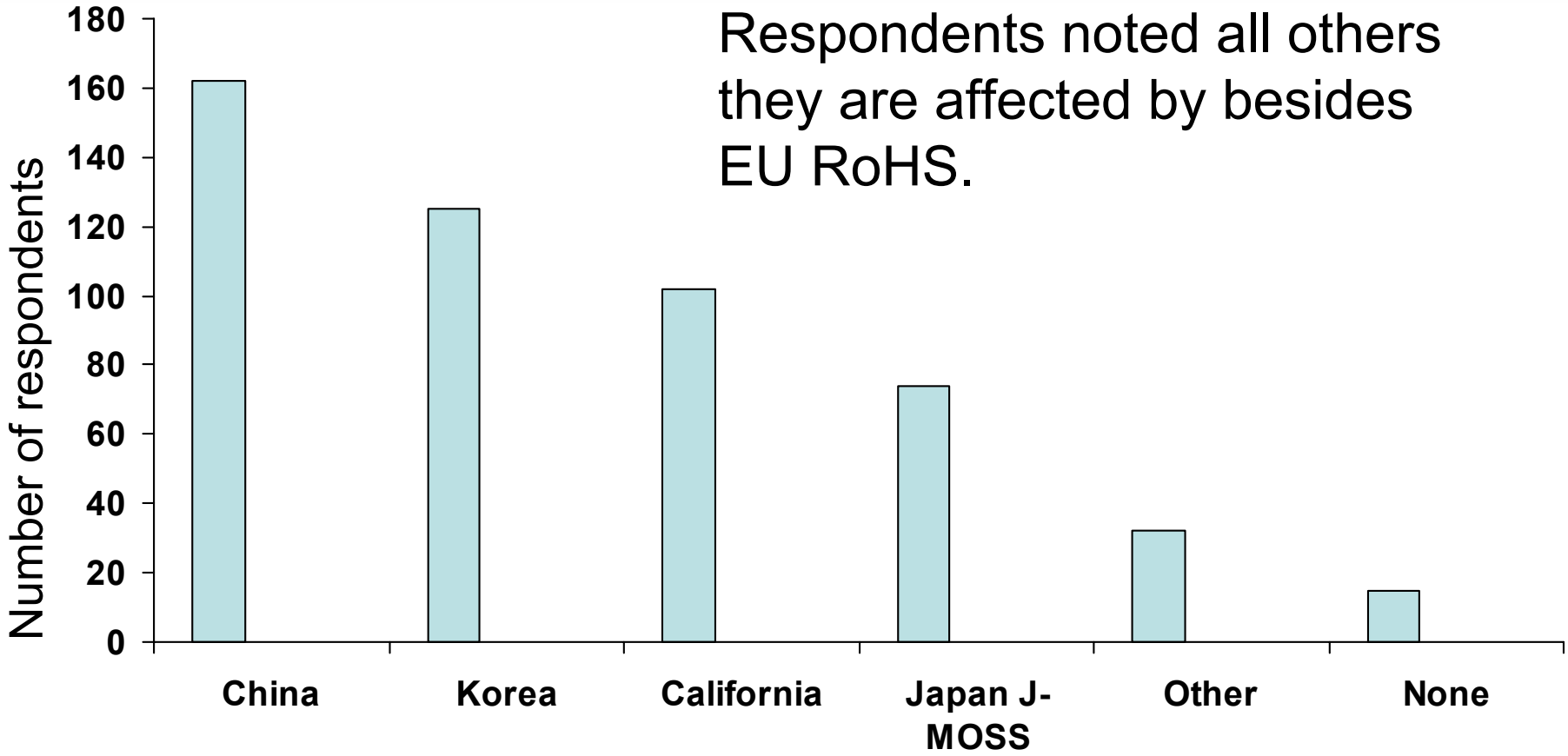
More Changes to Business Processes

- Supplier Management/Procurement
  - Make sure suppliers understand and manage environmental requirements
  - Identify replacements for those that do not
- Manufacturing
  - Changes to inventory management to segregate RoHS from non-RoHS items
  - Review/Change Design for Manufacturing (DfM) rules to reflect impacts (Pb-free solder, for instance)
    - EMSs needed to implement or change test and manufacturing processes and procedures
  - Occasional spot testing (XRF or other analysis methods)

Pb = lead

EMS = electronics mfg. services

Other Substance Restriction Regulations



Respondents noted all others they are affected by besides EU RoHS.

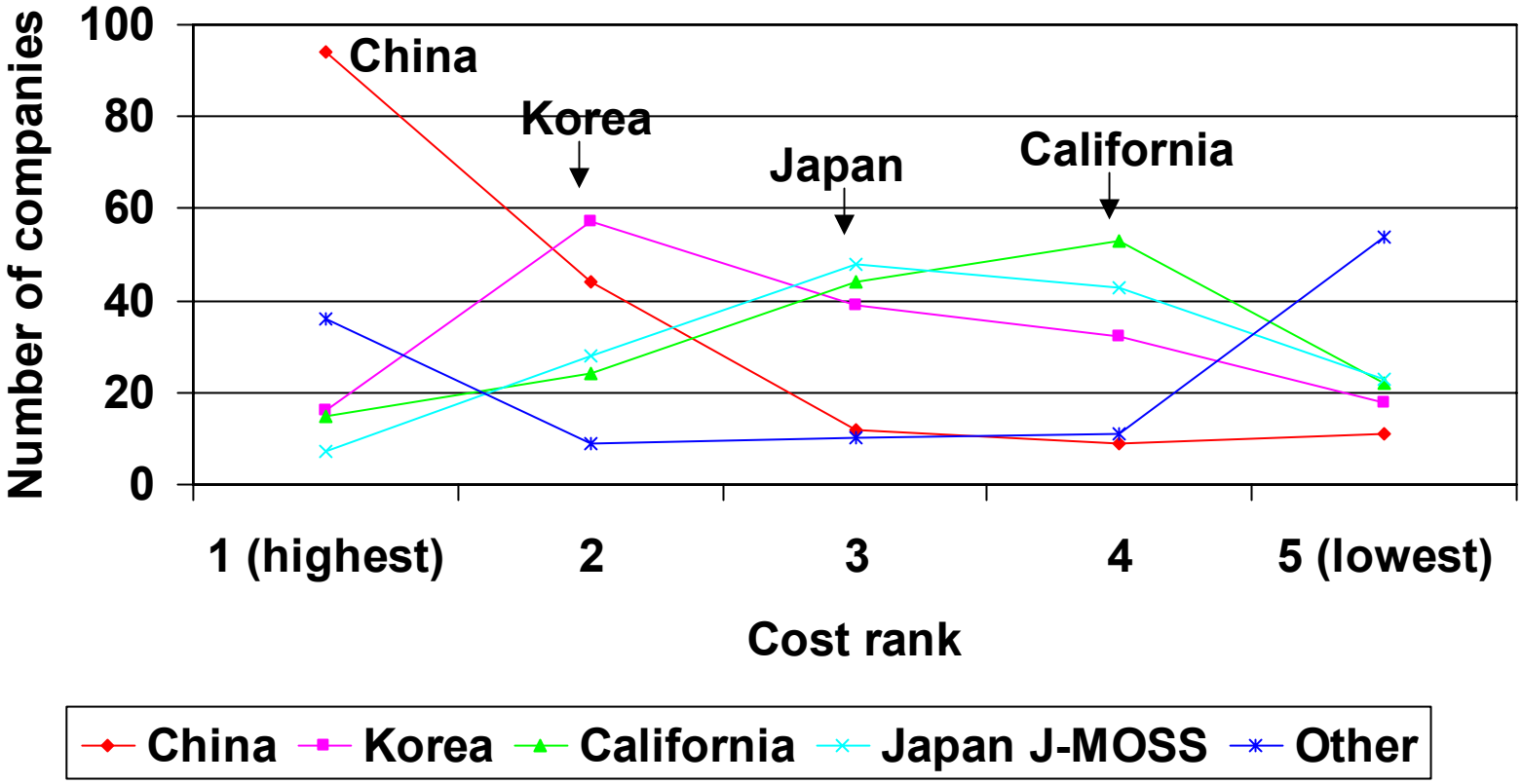
Other Substance Restrictions Regulations

69.4% said handling compliance with multiple RoHS directives brought additional costs.

- *"So far there has not been any significant impact other than China with the labeling exercise. It was been about 2 man-years for China RoHS (sic.) alone."* (Small North American OEM)
- *"China is probably the most difficult, because it is different. Many of the other countries are jumping on board with using the EU guideline."* (Mid-sized North American OEM)
- *"After the internal processes have been altered for the first time, then the same structures can be used for subsequent laws too, so it's not so bad."* (Large North American OEM)
- *"China [is different]; they are imposing a specific marking, so we have to conform in some ways. We have a team in China so it is easy to understand. In the future…we will have to follow packaging regulations; I am also concerned about REACH*."* (Large European OEM)

*Registration Evaluation and Authorization of Chemicals Regulation (EU)

Rank of Other Substance Restriction Directives by Cost Burden



What Would Help?

Multiple respondents suggested standards or centralization to simplify and streamline environmental behavior.

- *"Most of all, we want an international standard, and are working toward that end. We would also love a general resource (from CEA? from government?) to help companies comply. It is so challenging to keep up that we are simply in 'reaction mode.'"* (Mid-sized North American OEM)
- *"Why not create an MBS similar to the automotive industry where there is a centralized database for the electronic industry?"* (Large North American OEM)
- *"The main thing that I would like to communicate is to get some harmonization in this thing, because it is challenging for us, everybody has something different."* (Mid-sized North American OEM)

Taking the Long View

- *"I really appreciate all these directives. I have studied environmental sciences, and I am well aware how responsible we are for our health and for the planet. In following the directives, companies are really obeying the environment, not the EU, or Japan, or Korea, or California. I am proud to be helping the environment through my company."* (Small Asian component supplier)

Regulations vs. company's overall culture and social responsibility goals

- *"As a repercussion of RoHS, we have taken a much greener stance in looking at environmental [proactivity]. We look at environmental things such as packaging, so I think that it has been a positive impact in that regard."* (Mid-sized North American OEM)
- *"To be honest, I would definitely say that [our company's social responsible culture] is because of the regulations out there. We are a company that is trying to become greener."* (Mid-sized North American OEM)
- *"We have our social responsibility goals that we sustain, but legislation has put it over and above 'requirement'. So we went into this because of the requirement of the legislation and this accelerated the requirements."* (Large North American OEM)
- *"I would say it was due to the requirement / regulations."* (Large European OEM)

Estimated Costs for the Entire Industry

How We Applied Study Results to Estimate Total Industry Costs

- Used census and other public data to estimate total number of global electronics companies
  - 50,000 OEMs, 36,000 component suppliers, 3,000 EMS, 1,000 other (Total: 90,000)
- Reorganized these 90,000 companies into revenue categories using 2002 census data:

$1B+	314
$100M to $1B	4,530
$10M to $100M	11,610
$5M to $10M	7,583
$1M to $5M	27,828
<$1M	38,135

Broke smallest category into three parts because average reported cost was higher than revenue of smallest companies.

How We Applied Study Results to Estimate Total Industry Costs (continued)

- Estimated US$50,000 initial compliance, $5,000 annual maintenance for revenue category $1M-$5M (million)
- Dropped companies with <$1M revenue
- Used average costs from our survey for each category to multiply out the total cost:

	Extrapolated cost to achieve ($k)	Extrapolated annual maintenance ($k)
$1B+	2,068,946	518,414
$100M to $1B	13,176,665	1,463,067
$10M to $100M	13,038,030	1,195,830
$5M to $10M	3,048,310	386,726
$1M to $5M	1,391,418	139,142

$k = US$ thousands

Estimated Total Industry Costs

- Cost to electronics industry to achieve EU RoHS compliance: US**$32.7 billion (B)**
- Cost for annual maintenance: US**$3.7B**
- Total cost of compliance to date* = **$38.25B**

*Given that EU RoHS has been in effect for 1.5 years: 1.5 years $3.7B

Estimated Total Industry Costs, by % Revenue

- Total revenue of electronics companies in each revenue category (assuming a smooth distribution weighted toward the lower end):

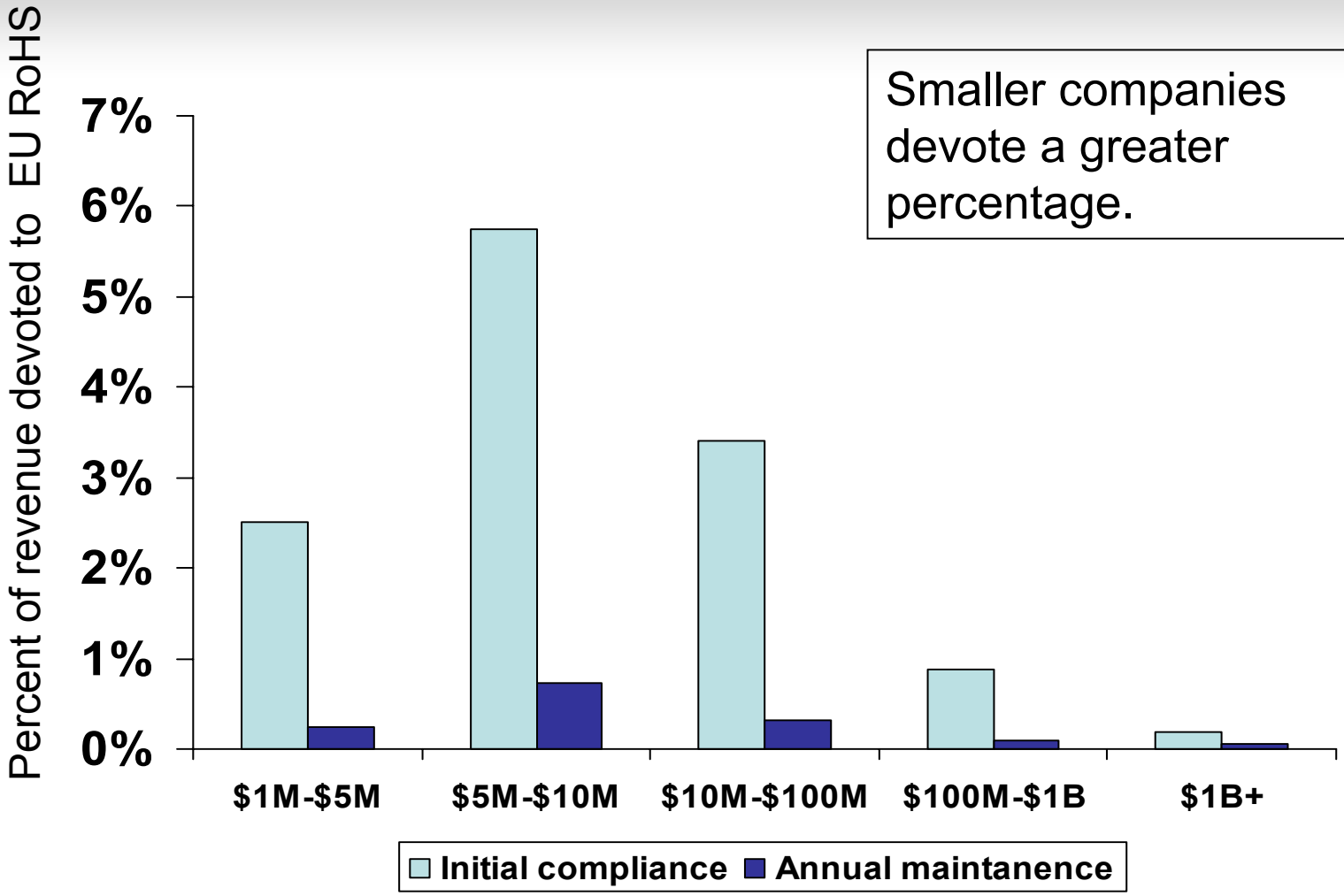
	Avg Revenue ($k)	Total revenue for category
$1B+	$3,400,000	$1,067,600,000
$100M to $1B	$330,000	$1,494,774,600
$10M to $100M	$33,000	$383,130,000
$5M to $10M	$7,000	$53,080,020
$1M to $5M	$2,000	$55,656,720
<$1M	$600	$22,881,096

Calculated from data for $1B+ category, then estimated for others.

Average revenue times number of companies in category

- Total compliance cost for the industry totals **1.1%** (average) of industry revenue
- Annual maintenance for industry **0.12% of revenue**

Estimated Total Industry Costs, by % Revenue



Smaller companies devote a greater percentage.

Opportunity Cost

- Whereas 1.1% of revenue may not seem to be a large figure, let's consider the opportunity cost
  - In other words, how could the funds have been spent to otherwise improve products?
  - On average, research and development (R&D) at electronics companies averages 4%-6% of revenue (much less for contract manufacturers)
- In first-quarter 2004, TFI forecast the cost of RoHS compliance at 1.5% to 2.5% of electronics companies' cost of goods sold (COGS); this is roughly equivalent to the 1.1% of revenue costs indeed incurred.

Summary

EU RoHS Compliance: Summary

- TFI survey elicited data from 200+ companies.
  - Well-balanced in terms of region, company type, and company revenue
  - Most began compliance work during 2003-2006, but a solid minority began earlier
- Average total cost per company from our sample:
  - $US2,640,000 to achieve initial compliance
  - $US482,000 annual maintenance
- Companies required 5-10 full-time-equivalent employees for compliance, almost exclusively drawn from existing internal resources.
  - Personnel represented the largest cost.
- 57% reported a rise in inventory at the initiation of RoHS (July 2006)
- 77% saw increased component or module costs

EU RoHS Compliance: Summary

- 29% reported lost sales due to RoHS (average loss US$1.84 million)
  - 2/3 of these came from delayed new product or discontinued EU sales
- Nearly 50% reported at least one advantage from the EU RoHS compliance process
- Most companies are affected by substance restriction laws in other regions too
  - China's substance restriction law was deemed the most challenging: Tedious labeling requirements and lack of clarity
- Many companies longed for a more standardized set of directives to simplify compliance

EU RoHS Compliance: Summary

- Estimated total cost to industry: approx. US$32 billion for initial compliance (1.1% of industry revenue)
- Annual maintenance requires 0.12% of revenue
  - Generally from improving their supply chain process or pruning their product lines
- Much of the challenge lies in retraining, redesigning processes, etc. – Just what businesses must always do to stay in the game!

Contact Information

for people involved in this study

- Consumer Electronics Association (CEA)
  - Parker Brugge, pbrugge@ce.org
  - Joanne Sonenshine, jsonenshine@ce.org
- Technology Forecasters Inc. (TFI)
  - Pamela Gordon, C.M.C., pgordon@techforecasters.com
  - Mike Kirschner, mike@designchainassociates.com
  - Kim Allen, Ph.D., kimall@mindspring.com
  - Anne Feith, afeith@techforecasters.com
  - Holly A. Evans, Esq. h.evans@cox.net

american apparel & footwear association

we wear[SM] our mission

April 25, 2013

Ms. Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Public Notice and Comment Period - Revisions to Proposed Safer Consumer Product Regulations; Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04 (released April 10, 2013)

Dear Ms. Buttle:

On behalf of the American Apparel and 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 revisions to the proposed Safer Consumer Product Regulations released on April 10, 2013 (Proposed Revisions).

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 427 American companies which represent one of the largest consumer segments in the United States. Of these companies, 53 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 provide comments. Upon review of this latest draft of the proposed revisions, we are pleased to see some response by DTSC to the use of practical quantitation limits (PQLs) as the threshold requirement to perform alternatives analysis, but disappointed there have been no changes to prioritize and create realistic timeframes for compliance with these very complex regulations.

Appropriate Threshold for Performing an Alternatives Analysis

We find it a positive development that the proposed revisions recognize and give DTSC the flexibility to select an alternatives analysis threshold above the PQL. We are also encouraged that the proposed revisions now differentiate between intentionally-added ingredients which are part of a product's design and purposefully added to perform some function in the product and those chemicals which are merely contaminants, and allow for different thresholds for each. While we understand DTSC would like maximum flexibility in setting the threshold for each chemical-product combination it selects to undergo an alternatives analysis, we urge DTSC to be practical and focus the resources of manufacturers on chemicals present in larger amounts than the PQL so these expensive analyses are directed to those chemicals appearing in concentrations above 0.1%. This is where Californians will experience the greatest benefit to public health and the environment.

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Definition of Manufacturer
We find the revisions to the definition of "manufacturer" to be a positive refinement. We agree the principal entity responsible for performing the alternatives assessment should be the entity that "specifies the use of a chemical" in a product and not any entity with the capacity to do so.

Alternatives Analysis Public Comment Process
We find the revisions to the public comment process on manufacturer's alternative analysis to be a positive refinement. We agree DTSC should use its expert judgment to winnow down the public comments to those relevant to the search for a safer alternative. The regulatory text would be improved however by specifying what criteria DTSC will use in filtering public comments and when DTSC will require manufacturers to respond to those comments.

Trade Secret Protection
We are concerned with the potential disclosure and release of trade secret and confidential business information in the proposed revisions. The proposed revision improperly limits trade secret protection to only those ingredients and products where patent protection is being sought and only for the time period until the patent is issued or denied. This violates the statute which requires all trade secrets, not just patents, to be protected. Also, the proposed revision requires manufacturers to provide significant substantiation information before DTSC will agree to protect information as confidential. These requirements exceed what is required under trade secret law and create unnecessary burdens on companies. Informing the public of information about the toxicity of chemicals and their potential substitutes should not be expanded to reveal trade secrets to competitors.

Prioritization of Chemicals and Products
We are disappointed the proposed revisions do not attempt to provide prioritization of higher risk chemicals in consumer products, as this leaves companies with no ability to effectively anticipate and plan for innovation to safer materials.

We are heartened to see DTSC will enter a new rulemaking to identify and prioritize chemical-product combinations to select the first set of Priority Products that must meet two key criteria: potential for exposure, and potential for that exposure to have significant or widespread impacts, and that the initial set will contain no more than five (5) chemical-product combinations.

We urge DTSC to employ a rigorous scientific process in its selection. We are concerned the proposed revisions lack quantitative, objective criteria for prioritization. The focus needs to be on real risks to human and environmental health. Without a scientifically-defensible prioritization process, many resources may be wasted and the potential for meaningful improvements in public and environmental health will be lost.

Timeframes to Find Alternatives are Unrealistic
We are disappointed to see there have been no changes to make the time frames more flexible or realistic in the proposed revisions.

In many cases, it will take far longer than one to two years to complete an alternatives analysis, as many companies' experience with U.S. Design for the Environment program can attest. In addition to the need to extend the timeframe to accommodate the complexity of the process, these timeframes need to be extended where consortia are formed among manufacturers of similar product types to conduct a joint alternatives analysis.

Finally, while we acknowledge the DTSC has conducted a very long rulemaking process and made efforts to incorporate stakeholder input into the revised regulations, we are disappointed that so few of the points of contention on which we have previously commented were not addressed in the revised regulations.

It is disconcerting that at this late stage of the process, after so many times of asking for prioritization, clarity, and practical timeframes to ensure manufacturers can comply with the spirit and intent of the law, the proposed revisions still fall far short of a workable set of regulations.

Thank you for your time and consideration in this matter. Please contact Marie D'Avignon at 703-797-9038 or mdavignon@wewear.org if you need any additional information.

Sincerely,

Kevin M. Burke
President & CEO

April 25, 2013

Ms. Krysia Von Burg
Department of Toxic Substances Control
Regulations Section
P.O. Box 806
Sacramento, California 98512-0806
Via E-mail: gcregs@dtsc.ca.gov

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

Dear Ms. Von Burg:

The American Chemistry Council (ACC) submits the attached comments on the Department of Toxic Substances Control's (DTSC) proposed additional post-hearing changes to the Safer Consumer Products Regulation, dated April 10, 2013. As an active member of the Green Chemistry Alliance (GCA), we support GCA's comments on the April 10 proposed regulation.

ACC notes that DTSC has made many changes to the January 29 revision, in conjunction with the April 10 revision. Using our January 29 comments as a framework, the following comments identify changes in the April 10 proposal that ACC supports, as well as areas that require additional consideration before the rule is made final. As DTSC has not responded to our October 11, 2012, comments or our February 28, 2013, comments (both enclosed), we ask that these three sets be considered together for this comment period. Please do not hesitate to contact me if you have any questions.

Sincerely,

Emily V. Tipaldo
Manager
Regulatory and Technical Affairs

CC: The Honorable Matt Rodriquez, Secretary, CalEPA (SectyRodriquez@calepa.ca.gov)

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

ENCLOSURES: ACC Comments on the proposed regulations, Safer Consumer Products Regulation, July 27, 2012 (dated 10/11/12)

ACC Comments on the proposed regulations, post-hearing changes to the Safer Consumer Products Regulation, January 29, 2013 (dated 02/28/13)

ACC COMMENTS ON THE ADDITIONAL POST-HEARING CHANGES TO THE SAFER CONSUMER PRODUCTS REGULATION APRIL 2013

A. The revisions to the definitions of "chemical" and "reliable information" require further clarity.

ACC questions the elaboration of the definition of "molecular identity" in the revised proposed regulation. Would any variation in the properties listed in the definition give rise to a new molecular identity? For example, if mean particle density were to vary among batches of the same substance, would DTSC treat each batch as if it had a new molecular identity? ACC notes that it is well understood that many, if not most, of the characteristics listed in the new definition are strongly influenced by environmental conditions and may change in dynamic ways depending on ambient conditions. As a simple example, many of the listed characteristics will be irrelevant once a substance is dissolved. How will DTSC consider this dynamic in identification of molecular identity? ACC cautions that the inclusion of such factors creates an obligation on DTSC's part to develop guidance that will help responsible entities understand DTSC's thinking about which properties are relevant to which states of matter under what conditions for the purposes of making hazard and exposure determinations. Finally, ACC questions the scientific rationale for the elaboration of factors. It is our understanding that the phrase "physicochemical properties and structure" would cover everything.

Additionally, it is unclear why the definition of "reliable information," which had been marginally improved, has since been edited to eliminate references to independent review and independent confirmation or replication. We are left to conclude that DTSC disagrees with the notion that reproducibility is a cornerstone of the scientific method and will instead base its decisions on studies that though attempted to be, cannot be reproduced. A sound definition of "reliable information" that includes independent review and independent confirmation or replication would enhance the scientific credibility of the complex regulatory proposal. ACC encourages DTSC to reinstate the previous language, adding a provision for weight-of-the-evidence assessment as part of the standard protocol.

B. DTSC should focus its efforts only on chemicals and products subject to the requirements of the regulation.

DTSC should focus its efforts on chemicals in consumer products that have the highest hazard and exposure to Californians. Similarly, the Department should also concentrate its efforts on those chemicals and products that are explicitly subject to the proposed regulation. It is questionable whether DTSC currently has authority under Health and Safety Code Sections 25252-25255, and 25257, to require manufacturers, importers, assemblers, and retailers "of any product" to provide information regardless of whether these chemicals or products are subject to the regulation.[1] DTSC must focus the scope of the regulation on chemicals and products that are subject to the proposed rule.

[1] Proposed revised, post-hearing changes Safer Consumer Products Regulation, §69501.4(a)(2).

C. DTSC should correctly characterize chemical lists and should not rely upon European lists still under development as the basis of candidate chemical listing.

In revisions to the citations for the "Candidate Chemical" list sources in Section 69502.2(a)(1), items (B), (C), (G) and (I) are cited as being classified by or included as Substances of Very High Concern (SVHC) candidates for REACH "by the European Commission." While these processes are conducted under European Union laws, both classification and SVHC approaches are conducted by the European Chemicals Agency (ECHA), which works together with Member States, but has ultimate responsibility for both regulations. The proper citation would be "…by the European Chemicals Agency." In addition, the revision to (C) indicates that there are "Category 1" endocrine disruptors on the SVHC Candidate list. The SVHC process has no "Category" designation, and therefore "Category 1" should be deleted. The official REACH rationale for these SVHC listings is, "[e]quivalent level of concern having probable serious effects to human health or the environment under Article 57(f)."[2] There are presently 16 chemicals and groups that are candidates under this rationale, some but not all of which are based on endocrine disruption issues. Because the ECHA candidate listing and designations are subject to authorization decisions, which could change their designations, DTSC should not rely on these in developing their own Candidate Chemical list.

D. The distinction between intentionally added chemicals and contaminants is appropriate, but will likely be inefficient in practice.

ACC is encouraged that DTSC differentiates between intentionally added chemicals and contaminants, proposing to allow manufacturers to have a dialogue with the Department regarding appropriate "Alternatives Analysis Thresholds" for intentionally added chemicals. However, contaminants continue to be subject to the alternatives assessment (AA) process. As part of the regulatory process, manufacturers would be required to 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."[3]

The 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. To keep from indefinitely chasing molecules of contaminants, ACC suggests that DTSC treat intentionally added chemicals and contaminants in a manner that incentivizes efforts to limit them throughout

[2] Article 57(f) of Regulation (EC) No 1907/2006.
[3] §69501.1(a)(52).

the manufacturing process. DTSC should strike the proposed requirement to measure contaminants down to the PQL. Instead, DTSC could recognize manufacturing due diligence to mitigate contaminants in the final consumer product. 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 demonstrate that they execute a program to minimize contaminants in their products.

E. Public review and comment on Final AA Reports, coupled with DTSC's review is a more practical process.

ACC supports the change made regarding public review and comment of AA reports. It is preferable for the public to provide comments on the Final AA Report, rather than during the middle of the process, and, it is appropriate for DTSC to collect, review, respond to comments at that time, and to propose an "AA Addendum" if necessary. The comment review process should be more consistent when handled by the Department, rather than each manufacturer posting, collecting, reviewing, and responding to public comments directly.

F. The proposed regulation to protect confidential chemical identities is inconsistent with California trade secret law and should be changed.

The proposed revised 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" or "safer" substances. 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.

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.[4]

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 granting the patent holder right to sue 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.

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 via a confidentiality agreement or submission to a government agency pursuant to a statute that

[4] Cal. Civ. Code §3426.1(d).

guarantees confidentiality. Absent such a requirement, DTSC's proposed disclosure requirements would expose valuable trade secrets to foreign and domestic competitors, causing significant economic harm.

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

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."[1] 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.[2] WoE means a

[1] §69501.1(a)(38).

[2] 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."[3] 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.

[3] §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." [4]

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.*[5]

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."[6] 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."[7] 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.

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

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

[6] PEOPLE v. KRUGER, 48 Cal.App.3d Supp. 15 (1975).

[7] §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.[8] 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."[9] 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."[10]

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.

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[8] ACC Comments on the Proposed Safer Consumer Products Regulation, October 11, 2012, p. 20.

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

[10] 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").[11] 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.[12] 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

[11] §69501.1(a)(51)(A).

[12] 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…"[13] 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.

[13] 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.[14]

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.

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[14] 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 to 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.[15] 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.[16] 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."[17]

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[15] §69503.3(a)(1)(B)-(C).

[16] See, e.g., §69502.3(d).

[17] ACC Comments on the Revised Initial Statement of Reasons, Proposed Safer Consumer Products Regulation, January 22, 2013, p. 2.

Comments of the American Chemistry Council on the Proposed Safer Consumer Product Regulation (July 27, 2012 (R-2011-02))

October 11, 1012

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Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to comment on the California Department of Toxic Substances Control's (DTSC) proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code, to promote safer consumer products.

Despite industry's considerable efforts over the last five years to suggest meaningful, practical and legally defensible regulatory alternatives to DTSC, the current proposal demonstrates limited progress in critical areas of the regulation. Although minor changes are reflected, the regulatory Green Chemistry program must have a stronger objective and scientific foundation in order to credibly inform choices made by consumers and other participants in the value chain. In ACC's view, the regulations require considerable additional work before they are made final.

ACC is particularly concerned that the complexity, scope and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to chemicals that pose risks of harm and promoting innovation. At best the proposed regulation will produce a marginal improvement in human health and environmental safety, but at great expense and lost opportunities for businesses nationwide. Although DTSC has estimated that some 1,200 substances will be covered by the regulation, ACC estimates that the regulation would affect at least 4,000, if not more. Among the significant implementation costs is the need for extensive government resources, at a time when the State is already facing critical resource.[1]

ACC is also concerned that the regulation creates the real prospect of consumer confusion and unwarranted alarm as more than a thousand of the most commercially important substances are designated as subjects of the state's "concern," based only on a loose assessment of hazard characteristics gleaned from lists compiled by other (non-State) entities. In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer products. More to the point, consumer apprehension will certainly lead to deselection by the value chain, resulting in product performance which fails to meet consumer expectations and needs. ACC believes that DTSC has not fully assessed the potential for the regulation to result in sports equipment that is less protective, building products that are less weather-resistant or energy efficient, and food packaging that provides shorter shelf life, to name just a few.

Indicative of the ACC's general concern with the proposed regulation is that DTSC's economic analysis fails to provide any meaningful insight into whether the proposal is an efficient and effective means of implementing the relevant Code provisions in the least burdensome manner, as required under California law.

ACC strongly recommends DTSC consider a tailored program that is practical, meets the goals of AB 1879, and is focused on substances in consumer products identified as a potential risk for

[1] The California State Budget 2012-2013 indicates that the State debt is estimated to be $16 billion, coupled with a $3.5 billion tax (revenue) shortfall in the current fiscal year. *See* http://www.ebudget.ca.gov/pdf/Revised/BudgetSummary/FullBudgetSummary.pdf.

human health and the environment based on a scientific assessment of hazard and exposure. We believe that a more direct approach to the implementing regulation would address the practical problems raised by the scope and complexity of the proposed rule. In summary a properly scaled program would:

- Identify a relatively small, initial set of chemical substances that meet specific criteria.
- Identify the consumer product uses of those substances that are not otherwise regulated by federal or state law, or that have exposure and use patterns that may pose risks.
- Prioritize those substances for additional evaluation and review. ACC has developed a chemical prioritization tool that can be adapted to DTSC's use, with appropriate modifications addressing consumer product uses. A copy of the prioritization approach is attached to these comments.
- Identify and prioritize future "batches" of chemical substances using the same approach.
- Request manufacturers and importers of priority products to submit data and information on the chemical substance and its use in the identified consumer product.
- Require alternative assessments only when the chemical of concern in the priority product poses a substantial risk of harm.

Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

The following areas are of particular concern to ACC and its members. Each area is discussed in Section II in the context of the standards for necessity, authority, clarity, consistency and non-duplication established by the California Office of Administrative Law.

- Identification and Prioritization of Chemicals of Concern
- Priority Product Prioritization Process
- Trade Secrets
- Public Participation and Transparency
- Alternatives Analysis Exemption Threshold

ACC's comments include constructive recommendations for improving the proposed regulation, minimizing its potential negative impacts, and realizing the stated objectives of the underlying statute. We look forward to continuing our work with DTSC toward these mutual goals.

I. General Comments

A. Practicality and Efficient Implementation Should Guide the Regulation

The 78 pages constituting the proposed regulation provide a complex approach to a problem that should be amenable to relatively simple solutions. In an apparent attempt to ensure that the regulation is comprehensive, DTSC has cast a wide net that implicates nearly every segment of the national economy. ACC firmly believes that a more tailored approach is warranted given the concerns raised by the proposed regulation.

ACC supports DTSC's primary objective to protect human health and the environment from harmful exposures to chemical substances. Chemistry touches 96% of all manufactured goods, including the consumer products which are the target of the regulation. The non-confidential federal Toxic Substances Control Act (TSCA) Inventory includes some 85,000 substances (some 7,000 of which are in general U.S. commerce in substantial amounts). Nearly every one of those substances is potentially subject to listing as a "chemical of concern" under this proposed regulation, despite the fact that many are used safely every day, in thousands of applications.

1. Products otherwise regulated by federal law should be excluded.

Until DTSC makes an affirmative determination as to the relationship between the proposed regulation and regulations under other federal or state laws, the regulation applies to products regulated under other comprehensive systems, including the Federal Food, Drug and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), and TSCA.[2] Even food contact packaging – otherwise regulated nationally by the Food and Drug Administration – is subject to the proposed regulation.

The proposed regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans and operations to be made publicly available. ACC is particularly concerned that DTSC will not have the staff or financial resources to properly process and manage the volume of information that will be reported under the proposal. Most importantly, DTSC needs to be mindful about how the information related to chemicals used in consumer products is communicated to the public. The proposed regulation will have little value if it simply creates unwarranted consumer anxiety about chemicals (e.g., suggesting a risk of harm where none exists), or imposes regulatory requirements that have marginal impact on health and environmental protection beyond that provided by existing labeling, warning, and use restrictions.

2. DTSC must assure that reliable information is the basis for listing chemicals and products.

The broad scope and complexity of the regulation is exacerbated by an approach that relies on loosely defined "reliable information" as the basis for listing a chemical of concern. It is a general principle of hazard assessment that all available data must be considered and the totality

[2] See attached "List of Federal Statutes Regulating Chemicals".

of relevant and reliable information integrated in order to arrive at a scientifically defensible decision regarding chemical hazard. Since, in many cases, dozens of toxicological studies will be available for review on any given chemical, the only valid scientific approach is to consider the weight-of-the-evidence as part of the standard protocol. A scientifically sound weight of the evidence analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies.

Unfortunately, the proposed regulation does not adopt a weight-of-the-evidence approach. Without that 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.[3] The framework that DTSC and the Office of Environmental Health Hazard Assessment ("OEHHA") should employ must include a transparent, scientifically-based evaluation of the overall weight of evidence to establish a *causal* relationship between an outcome of concern and exposure to a substance. We urge DTSC to include a weight-of-the-evidence approach in the regulation and articulate it will be used in decision-making, particularly with regard to prioritizing chemicals of concern and products.

3. Aggregate and cumulative risk evaluation imposes considerable burden.

DTSC proposes to consider aggregate and cumulative effects as part of the chemical identification and the priority product prioritization process. It is unclear when, how often and through what process DTSC will evaluate aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or both. ACC is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks (the total exposure to a specific chemical from all different sources and routes) requires considerable data and information that manufacturers of individual products typically do not have and may be difficult to readily obtain. Aggregate assessments should only be required on a case-by-case basis for chemicals that meet certain criteria (e.g., cases that present a very narrow margin of safety).

The assessment of cumulative effects or risks (the common toxic effect from concurrent exposure to risks from other chemical and non-chemical sources) poses even greater challenges. Cumulative risk assessment is far from settled science. As with aggregate effects, scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. For example, the most recent cumulative risk assessment recommendations of the U.S. National Research Council expert panel contrast with EPA's current practices and those of the World Health Organization's International Programme on Chemical Safety.[4] In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

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[3] OEHHA Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).

[4] Compare, e.g., Phthalates and Cumulative Risk Assessment: The Task Ahead (2008), Committee on the Health Risks of Phthalates, National Research Council, The National Academies Press, Washington, D.C. with Risk Assessment Of Combined Exposures To Multiple Chemicals: A Who/IPCS Framework (2009). World Health Organization, International Programme on Chemical Safety (IPCS), Harmonization Project DRAFT Document for

It is not clear if DTSC intends to follow the practice of the federal Environmental Protection Agency in assessing the cumulative effects of certain pesticides, which is to conform to the state of the science. The level of knowledge required to conduct a cumulative assessment, even for a group of chemicals that share a common mechanism of toxicity, is orders of magnitude over and above that required to conduct an aggregate assessment, and is not practical for the vast majority of chemical substances, mixtures and uses.

In the 16 years since the federal Food Quality Protection Act (FQPA) was enacted, the science has proven to be so difficult, even for groups of chemicals having a common mechanism of toxicity, that EPA has only been able to conduct cumulative risk assessments for 4 groups of pesticide active ingredients. For all practical purposes, DTSC would require an encyclopedia of all substances arrayed by the adverse effects they are capable of producing and the dose levels associated with such effects, both natural substances and synthetic agents, including consumer products, industrial chemicals and pharmaceuticals and understand the temporal, demographic and geographic exposures to each of these. Beyond that, DTSC would also need to know the background exposure for the chemical being evaluated.

Complicating this analysis is that DTSC would have to go through the same exercise for any additional priority product, add that exposure to the evaluation, resulting in a virtually infinite analysis loop.

Simply, ACC believes there is no practical way to incorporate cumulative assessment as a routine component of the Safer Consumer Product regulation. The burden of analysis on DTSC and the industry would be very high, and will divert scarce resources from managing important risks.

4. DTSC's approach to threshold concentrations is focused on eliminating exposures, rather than minimizing them.

DTSC's proposed regulation and the Initial Statement of Reason (ISOR) indicate that DTSC will defer to the "minimum detectable concentration" level for the "Chemical of Concern" in the product.[5] ACC is concerned that reliance on the limit of detection focuses DTSC's efforts on chemical elimination rather than safe use. This concern is heightened by DTSC's proposed reliance on regulatory responses that provide the greatest level of "inherent protection." .This approach stands in sharp contrast to the statutory requirement that DTSC's regulations must "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, in accordance with the review process specified in Section 25252.5."[6]

Public and Peer Review, available at http://www.who.int/ipcs/methods/harmonization/areas/aggregate/en/index.html.

[5] Initial Statement of Reasons: Safer Consumer Products, R-2011-02, http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf, p. 104, §69503.5, p. 107, §69503.5(c)(2)(A).

[6] California Health and Safety Code Section 25253 (emphasis added).

A minimum detectable concentration cannot function as an exemption threshold, nor can it be used to document incremental improvement in a particular product. The ISOR importantly notes that "at very low concentrations, it is impossible for analytical instruments to distinguish the difference between signals from analytes and signals created by the instrument."[7] In practical terms, the minimum *detectable* concentration is essentially zero. It is unclear how a manufacturer or importer covered by the regulation would use a minimum detectable concentration to demonstrate reductions in chemicals of concern?

5. DTSC should clarify its authority to impose regulatory restrictions on substances and products.

The proposed regulation also raises an interesting question about DTSC's grant of authority to impose regulatory restrictions. DTSC should address this issue before making the regulation final. The underlying statute permits DTSC to adopt regulations to establish criteria for identifying and prioritizing chemicals of concern and to develop criteria to evaluate them and their alternatives in consumer products (Health and Safety Code §§25252-25253(a)(1)). Additionally, the statute authorizes DTSC to "specify the range of regulatory response that the department may take following the completion of the alternatives analysis" (HSC §25253(b)). ACC encourages DTSC to clarify how the apparent authority to impose product information disclosure requirements, end-of-life management schemes, product bans, and a range of other potential regulatory responses will be exercised.

II. DTSC Should Conduct a More Robust Economic Assessment

DTSC estimates that it will be able to implement the entirety of the program within the Administration's proposed 2012 budget, applying 39 full-time employees and a $6 million budget.[8] ACC believes DTSC has significantly underestimated the costs of the program, and strongly recommends that the Agency conduct a more robust economic assessment of the regulation.

The Chemical Risk Review and Reduction program at the federal EPA has been estimated to cost $40-$45 million (not including new chemicals). Even if California managed to operate at half of EPA's budget, it would still need at least three times more than the $6 million budgeted for the regulation. Based on knowledge of EPA's processes and costs and an independent assessment of the potential costs to DTSC, annual implementation costs are estimated to range from about $9 million to $27.2 million in the first six years, depending on the scope of the Safer Consumer Product program.[9]

California's chemical industry is far more complex than what is depicted in DTSC's economic analysis of the proposed regulation. There are approximately 600 chemicals that are produced in

[7] Id.
[8] Attachment 3 to the Economic and Fiscal Impact Statement (Std. Form 399) Safer Consumer Product Regulations.
[9] For further projected costs to both the state of California as well as the regulated communities, please see the attached reports developed by ICF under contract for ACC: "Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Alternatives Regulations under CCR 22," July 26, 2012, and, "Addendum: Industry Costs."

the state of California.[10] The value of the chemical shipments is almost $46 billion and the California chemical industry exports $12.5 billion worth of chemicals throughout the world. The business of chemistry directly employs 74,000 people and indirectly contributes 239,000 jobs in California. For every chemistry industry job in California, 4.2 jobs are created downstream within the state. Together these jobs generate $23 billion in earnings which then also generate state and federal revenues through taxes. State and federal income taxes on these industries' payrolls support government programs for the residents of California.

These indicators provide a starting point for a more robust economic analysis of the regulation that assesses the impact of a regulation on the chemical industry and on California's economy as a whole. Dr. Kahn's analysis for the State[11] is not sufficient. The analysis provides no quantitative estimate of costs or benefits, and takes no account of the chemical industry and the downstream impacts in the State.

Similarly, the proposed regulation neglects to mention small businesses or acknowledge potential compliance challenges that small and medium-sized businesses will face as a result of the proposed regulation. While ACC believes that all responsible parties should be held to the same standards, DTSC should consider compliance challenges, particularly costs, for small and medium-sized businesses. We urge DTSC to assess the potential impacts of the regulation on small and medium-sized enterprises.

III. A Review of the Proposed Regulation Against Standards Established by the Office of Administrative Law Establishes a Number of Shortcomings.

A. Necessity (Government Code §11349(a))

1. DTSC should include a weight-of-the-evidence assessment process.

To build overall confidence in the Green Chemistry Program, DTSC must ensure that the regulation adopts a rigorous, science-based approach, in concert with state, federal and international best practices. The reliance on rigorous science must be evident in the selection of chemicals of concern and priority products, in identifying a threshold for and process of alternatives assessment, and in determining what regulatory responses the Agency will take.

The proposed regulations raise significant concerns that the Department will oversee a program that simply accommodates inadequate, unreliable or low quality science. If this occurs, resources will not be directed to the most compelling chemical hazards, but to controversies generated by unreliable studies and amplified by special interest groups and a media that thrives on novel health scares.

Our concerns start with inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure," which do not require a means to assess

[10] IHS™ Directory of Chemical Producers®, Englewood Colorado.
[11] Attachment 2, "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Matthew E. Kahn, March 2012.

the quality of information, but focus on whether the information is in the public domain. This problem is exacerbated by an absence of emphasis on a weight of evidence evaluation of information, as well as the dependence on the "most protective" study independent of its actual quality and reliability. Leading to an even more unscientific position is the Department's position that when all other factors are equal, decisions will not necessarily be driven by conclusions from the most relevant and highest quality studies, but rather from the "greater amount of information."

In evaluating information to make decisions and substantiate their conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts," DTSC should be guided by the following principles:

- DTSC's decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for the public to have sufficient confidence in DTSC's use for health and environmental regulatory decision making. If the process does not meet these benchmarks, there is no assurance that the program will in fact benefit consumers.
- All evaluations must rely on the best available scientific information regarding possible hazards of substances, and must employ consistent, objective methods and models to derive realistic determinations of risks at environmentally relevant levels of exposure.
- Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.
- All evaluations must be based on a framework that takes into account and integrates all relevant studies while <u>giving the greatest weight to information from the most relevant and highest quality studies</u>.
- Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks. The characterization should provide a full picture of what is known and what has been inferred, and should also present results based on alternative plausible assumptions.
- Assessments must provide full disclosure of key information. When assumptions (or policy preferences) are used in lieu of scientific data, the assumptions (and policy preferences) must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

ACC believes it is necessary for DTSC to incorporate these principles into Article 1 of the regulations to provide the overall theme and foundation for science-based implementation.

In Sections 69502.2(b)(3) 69503.2(a)(2) of the proposed regulation, it is not clear how or whether a weight-of-the-evidence assessment will be applied when a chemical or a product is being evaluated. It is also not clear whether the Department simply intends to assign a higher priority to the chemical substance that simply has a greater amount of information. DTSC must clarify its approach to weight-of-the-evidence assessments.

2. DTSC must assure it has the resources to manage data and information.

DTSC is proposing to provide an unprecedented (and arguably unnecessary) level of information about products, chemicals, and manufacturer's business plans to the public, public interest groups, competitors, and retailers. Overall, ACC is concerned that DTSC will not have the resources to properly manage the volume of information that will be reported under the existing proposal. DTSC should also be mindful of how the various forms of information are communicated to the public. Specifically, ACC recommends that DTSC exercise a concerted and purposeful communication effort not to create unwarranted consumer or public anxiety regarding the chemicals on the initial list.

ACC encourages DTSC to confer with Washington State and Maine regarding the data collection challenges faced during implementation of the Children's Safe Product Reporting Rule, and the Regulation of Chemical Use in Children's Products, respectively. What will be clear is that to maximize the efficiency and utility of data and its collection, the regulatory need for specific data should be the driver for regulatory requirement for submission, not perceived gaps in the data DTSC possesses.

3. Information certification requirements are not necessary.

ACC is troubled by the proposed requirement to have all information submitted to DTSC signed and certified not only the responsible individual in charge, but also by the owner or an officer of the company, or an authorized representative (§69501.3(a)). While the requirement will certainly draw the attention of upper management, as DTSC no doubt intends, it is also unreasonable and unnecessary. DTSC proposes to review each submission, from Alternatives Analysis Exemption Notifications to Final Alternatives Assessment (AA) Reports. The additional certification requirement is superfluous in the situation where an AA is conducted by a certified assessor, according to DTSC's certification and accreditation process.

4. Key statutory prioritization factors must be included.

As proposed, the regulation identifies a vague, subjective process by which DTSC will prioritize and establish a list of Priority Products. While ACC appreciates that the Priority Products list is apparently intended to be risk-based, as the regulation requires some consideration of exposure and the potential for harm, we also believe DTSC has not adequately represented the three criteria noted in the underlying statute (§69503.2(b)):

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.

DTSC should, at a minimum, include these three items as the "Key Prioritization Criteria."

5. An analytical method for establishment of an alternatives analysis threshold is not needed.

DTSC will require an analytical method for the establishment of each Alternatives Analysis Threshold ("AAT"). §69503.5)(c)(2)(A). It is not clear why the Agency will require this step for substances that already have an established *de minimis* threshold. At a minimum, DTSC should make a clear statement of the value derived from this requirement and the regulatory necessity for the mandate.

6. Additional alternatives assessment exemptions are required.

The proposed regulation indicates where alternatives assessments are not necessary or required. §69505.1(b)(1) – (3). ACC believes the proposed exemptions are consistent with the authorizing statute and recommends that DTSC identify two additional instances where alternatives assessments are unnecessary:

- An alternatives assessment is not required if the responsible entity determines that the Chemical of Concern is not necessary for the product to continue to meet function, performance, technical feasibility, and legal requirements and certifies within 60 days of notifying the Department of its determination, its intent to stop using the Chemical of Concern in the Priority Product and will not use a substitute chemical in place of the Chemical(s) of Concern that is the basis for the priority product designation. The manufacturer must confirm that it has begun the process of removing the Chemical(s) of Concern that is the basis for the priority product determination no later than 120 days after the date the manufacturer notified the Department of its intent; and
- An alternatives analysis is not required if the responsible entity replaces the COC that is the basis for the Priority Product determination with a substitute chemical that is not on the COC list, and thus does not exhibit the toxicity trait(s) that caused the Chemical of Concern to be on the Chemical of Concern List.

7. Sensitive information should not be required in alternatives analysis reports

ACC cautions against requiring information in §69505.5 Alternatives Analysis Reports that unnecessarily results in the submission of large quantities of potentially sensitive personal and business information that is not particularly germane to the core of alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program. *See* §69505.5(d).

8. Accreditation bodies and certified assessors are not necessary to achieve the object and purpose of the regulation.

ACC questions the need certification of accreditation bodies and certified assessors. The underlying statute neither explicitly nor implicitly mentions such a regulatory construct. Other chemical management programs across the globe have given rise to a network of sophisticated reputable firms and academic institutions capable of performing such work, thus eliminating the

need for certification and accreditation. The proposed regulation will create a large, bureaucratic process that is not necessary to ensure the conduct of rigorous alternatives assessments or to implement the statute.

9. The selection principles for regulatory responses should weigh multiple factors.

ACC urges DTSC to consider all of the factors outlined in §69506(c)(1-5) when selecting regulatory responses. Selecting a regulatory response is just as much a multi-dimensional process as the evaluation of alternatives. Therefore, it is necessary to weigh efficacy, cost-effectiveness, burden, effects on subpopulations, and enforcement.

B. Authority (Government Code §11349(b))[12]

1. DTSC should clarify its authority to require information generation.

The proposed regulation specifies the ways in which DTSC may collect information "that it determines is necessary" to implement this chapter. In §69501.4(a)(4) DTSC asserts its authority to "request a responsible party or a chemical manufacturer to generate new information and provide it to the Department, in accordance with a schedule specified by the Department." In support of its assertion that it has the sweeping authority to compel the generation of any and all new information "necessary to implement this chapter," DTSC cites to three statutory provisions, none of which in fact support the Department's assertion of such broad authority.

The Department cites to §58012 Health and Safety Code as a basis of its authority to compel the generation of new information. That general grant of authority to "adopt and enforce rules and regulations for the execution of its duties" does not appear to add to the specific grants of authority contained with the Green Chemistry statute (AB 1879), and it is those specific grants of regulatory authority that govern.

The Department additionally cites to Green Chemistry statute §§25252 and 25253 of the Health and Safety Code as authority for its regulation requiring the generation of new information, but

[12] The legislative analysis of the final version of AB 1879 prepared by the Senate Committee on Environmental Quality (August 20, 2008) recognized that a legislative grant of authority to develop a range of regulatory responses that DTSC "may" take does not actually give DTSC a grant of authority to impose the range of requirements on the affected community. The Committee Analysis notes that while the language found in HSC §25253(b) "appears to give the department the authority to take listed actions, this is not explicitly and clearly stated in the bill. Usually, an administrative agency is given authority by the Legislature to take some action and then the authority to adopt regulations to implement the authority" (http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080821_111017_sen_comm.html). The legislative grant of authority to DTSC to set forth a range of possible regulatory responses it may take gives the Legislature a chance to review those proposed regulatory responses before the Legislature expressly grants DTSC the authority to impose the regulatory responses on the affected community. However, Article 6 of the proposed regulation clearly assumes the presence of express authority that the legislative analysis cited above pointedly notes is missing. We recommend that DTSC obtain an opinion from the Attorney General's office on the scope of the legislative grant of authority to impose the identified regulatory responses, and then provide stakeholders with an understanding of how the Department will exercise its authority in compliance with the Attorney General's opinion.

those specific grants of authority are either silent with respect to, or contradict, the Departments asserted authority in §69501.4(a)(4).

Section 25252 is simply silent on this issue, stating only that DTSC is not limited to adopting regulations that reference and use "available information from other nations, governments and authoritative bodies." That section does not grant the Department the authority to compel a responsible party or chemical manufacturer to generate new information.

Section 25253 is also cited. That section appears to contradict the Department's claim that it may compel entities to generate any and all information that the Department "determines is necessary to implement (the Safer Consumer Products) chapter." Section 25253(b)(2) states only that the regulations adopted by the Department may impose "requirements to provide additional information needed to assess a chemical of concern and its potential alternatives."

There are two key points to be made about §25253. The section merely authorizes regulations that require "additional information," not the generation of new information. The logical reading of the word "additional" in this context is that it means existing information not otherwise available from other nations, governments and authoritative bodies. There is nothing to suggest a grant of authority to require the generation of new testing data or analyses.

Even if one reads "additional" information to mean the generation of new information, which ACC believes is incorrect, it grants authority only to require "information needed to assess a chemical of concern and its potential alternatives." The section is not, under any conceivable reading, a grant of authority to require any and all information that the Department "determines is necessary to implement this chapter," which could include virtually any type of new information.

ACC believes the Department should follow the three-step sequential, tiered process for collecting information set forth in §69501.4(a)(1) – (3). 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), 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)(4) beyond the scope of the cited authorizing statute.

2. DTSC should not establish the Chemicals of Concern List without public consideration.

ACC questions whether DTSC has the authority to establish a final list of "Chemicals of Concern" without public review and comment. §69502.3. Section 25252 of the Health and Safety Code (AB 1879) stipulates that the regulations are "to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern." Stakeholders and interested parties should be afforded the ability to review and comment on the initial Chemicals of Concern (COC) List.

A "list of lists" approach to establish the COC list may be justified by resource constraints, but DTSC must take "ownership" of the resulting list. A California list of COCs, developed by a California process, must also have a California-based process to remove substances from the list.

As proposed, the regulation permits petitions to delist a chemical from the COC list, and DTSC may do so, as long as that chemical is no longer listed on <u>any</u> of the underlying lists (those identified in §69502.2(a)) (emphasis added). Under the proposal, then, delisting is likely to be impossible. Substances would likely remain on the COC list indefinitely – even if they are used safely in consumer products or even if they are not used in consumer products at all. ACC urges DTSC to establish a California list-specific process for delisting chemicals.

3. *Consideration of occupational exposures in the prioritization step should be reconsidered.*

DTSC should reconsider its broad inclusion of workers and worker exposure as part of the product prioritization process. §69503.2. While it is appropriate to consider worker exposure in a retail setting, or perhaps worker exposure to products used in schools or hospitals or other institutional settings, we question whether DTSC has the authority to request information about workers in California or outside the State. At a minimum DTSC should understand how the information requirements may differ from CalOSHA requirements.

4. DTSC's disclosure requirements may put confidential information at risk.

The crux of the proposed regulation is to address "Chemicals of Concern" in specific "Priority Products." §69505.5(j)(2)(C). DTSC's authority to require the disclosure of all known chemical ingredients in the alternative that differ from the original composition will put confidential information regarding new uses of chemicals and new products at risk. Disclosure of the new alternative formulation or composition of the chemicals in the selected alternative is outside of the scope of the regulation, and thus is outside of DTSC's statutory authority to require.

5. Restrictions on trade secret claims threaten innovation.

DTSC's proposed approach to trade secret claims, and to confidential chemical identity in particular, is contrary to the Agency's objective to promote innovation in consumer products and to reduce or replace the presence of substances, in those products, considered to pose a risk of harm. As proposed, the regulation could actually hinder innovation.

In §69510(f) of the proposed regulations, DTSC impermissibly proposes an alteration to California trade secrecy law under the Uniform Trade Secrets Act that is not supported by the implementing statute. Under the proposed regulation, "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." Section 69510(f)(emphasis added). According to the Initial Statement of Reasons, the provision is intended to "effectuate the intent of Health and Safety Code §25257(f), which provides that trade-secret protection may not attach to 'hazardous trait submissions for chemicals and chemical ingredients under this Article [14]'."

Section 25257(f) does not state, however, that "trade-secret protection may not attach" to hazard trait information. It simply notes that "*[T]his section does not apply* to hazardous trait submissions for chemicals and chemical ingredients pursuant to this Article." (emphasis added). The mere fact that §25257 does not apply to hazard trait information does not mean that trade-secret protection may not attach to that information, it simply means hazard trait information is governed by pre-existing law (California Uniform Trade Secrets Act, Cal. Civ. Code §3426 *et seq.),* rather than the green chemistry statute. By restricting claims for trade secrecy protection for hazard trait submissions, the regulations impermissibly alter the Uniform Trade Secrets Act in excess of DTSC's statutory authority under §25257, and must be revised.

Even if §25257(f) were interpreted to mean that trade secret protection does not attach to hazard trait information, proposed §69510(f) still exceeds the scope of the statute. The proposed regulation does not merely ban trade secrecy protection for hazard trait submission information; it also eliminates trade secret protection for "any chemical identity information associated with a hazard trait submission." However, §25257(f) does state that it does not apply to chemical identity information associated with a submission, just that it does not apply to "hazardous [sic] trait submissions."

The problem with the Department's interpretation of §25257(f) is that it fails to differentiate between "hazard traits," which are specific hazards, such as corrosivity or ignitability, and "chemical identities," which are a separate type of information different than hazard traits. It would it be unreasonable to interpret §25257(f) as preventing persons from claiming trade secret protection for chemical identity information, because chemical identity and formula information is the core of most companies' legitimate trade secrets, as described below. Section 25257(f) speaks to are specific hazards, not chemical identity. A generic name for a specific chemical should be acceptable to DTSC as long as its specific hazard traits are disclosed. Section 69510(f) should be revised to expressly allow companies to claim trade secrecy protection for chemical identity information.[13]

In the chemical industry, trade secret chemical identities are among the most valuable intellectual property. The composition of formulations can be particularly vulnerable, especially for small and medium-sized businesses. The public disclosure of confidential chemical identities would make companies' substantial investments readily available to their competitors, both in and outside the United States.

Health and safety studies and hazard trait information are meaningful to the public without disclosing chemical identities. Structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Generic names allow linkage to the scientific literature on similar chemicals and permit an assessment of the suitability of study methods.

[13] Should DTSC decide to eliminate §69510(f) altogether, subsections (g) and (h) must similarly be eliminated as they have no effect independent of subsection (f).

ACC has tested whether generic names actually lead to relevant health and safety studies. In 2009, the U.S. Environmental Protection Agency changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential.[14] ACC searched the generic and the chemical identity names of a number of these previously confidential substances in Toxline, a common tool to search toxicological literature. What was found should be of interest to DTSC. In many cases, a Toxline search for a generic name for a classified substance identified more studies than did a search for the corresponding CAS number or CAS name.

Other international jurisdictions, such as Canada, have adopted similar solutions, protecting confidential chemical identity in health and safety studies. Australia and Korea also provide protection from disclosure for confidential chemical identities, apparently without regard to whether they are in a health and safety study.

It is critical to California commerce and broader U.S. business interests nationally and internationally that confidential chemical identity is afforded protection as a trade secret. This regulation should not force manufacturers to decide whether to sacrifice their market share in California or their intellectual property, presumably on a global scale.

6. DTSC must prevent the disclosure of supporting information claimed as trade secret.

Under §69510(a), a person "who asserts a claim of trade secret protection" must furnish the department with twelve elements of "supporting information." Assuming that the supporting information would itself contain trade secrets, and not wishing to require the submission of additional information for supporting information claimed as secret, DTSC stated that "if the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation . . . shall not itself require further supporting documentation." DTSC cannot adopt this provision because it conflicts with the California Public Records Act in a manner not supported by §25257 of the Health and Safety Code.

There is a simple solution to this problem. Rather than require entities to submit supporting documentation that is trade secret, DTSC should require that no trade secret information be submitted as supporting documentation under §69510(a). DTSC should be able to make most trade secret determinations without receiving additional trade secret information. If additional trade secret information is not submitted, DTSC will not be obligated to ascertain its validity and protect it against accidental disclosure. Without the added expense of handling unnecessary trade secret information, this approach should reduce costs and lead to more efficient trade secrecy determinations.

In the unlikely event that DTSC is unable to make a trade secrecy determination with the initial round of non-trade secret supporting documentation, DTSC should amend the regulation to allow a specific request for additional information. The regulation should clearly state that the information being acquired is privileged under §1040 of the Evidence Code as "Official Information" because it is being acquired confidentially by DTSC in the course of its public duty

[14] 74 Fed. Reg. 37224 (July 28, 2009).

under the Green Chemistry law and its disclosure is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice. So long as DTSC makes clear in the regulation that the additional supporting information is privileged "Official Information," it will be exempt from public disclosure under §§6254(k) and 6255 of the Public Records Act without DTSC having to conduct an additional, costly trade secrecy determination.

ACC also cautions against requirements to submit large quantities of potentially sensitive personal and business information to support alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program.

C. Clarity (Government Code §11349(c))

The proposed regulation is rife with uncertainty. The uncertainties, in turn, make implementation and compliance a challenge. This lack of clarity directly contradicts the Office of Administrative Law's standard of clarity, which mandates that regulations be "written or displayed so that the meaning . . . will be easily understood by those persons directly affected by them."[15] Below are examples of this lack of clarity.

1. DTSC should clarify the use of lists developed by other bodies.

Objective chemical selection criteria for the COC list should be used in the regulation, rather than adoption of a "list of lists" developed by other bodies. If DTSC nevertheless decides to adopt a list-based approach as suggested in §69502.2, it is critical that any such lists be developed by authoritative bodies. As proposed, it is unclear what criteria DTSC used to select the underlying lists for COC identification. It is also unclear how DTSC will characterize the chemicals on the COC list. In ACC's view, authoritative bodies include government agencies and formal scientific organizations that:

- Characterize chemicals in an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- Are widely perceived to be objective, scientifically based, and do not engage in advocacy.
- Base chemical characterizations on a weight-of-the-evidence approach. To the extent available, authoritative bodies consider multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and give full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
- Publish their characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

[15] California Government Code, §11349(c).

The confidence of the public and the regulated community in the regulation will be enhanced if DTSC can assure that appropriate processes and the best scientific data available inform the list.

ACC suggests that DTSC list chemicals on the COC list by their individual Chemical Abstract Services numbers (CAS RN). The regulation should specify unique CAS RNs and cannot utilize generic chemical categories. For instance, the perfluorinated chemical category contains hundreds of different unique CAS RN chemicals, each with its own properties. Compliance and the ability to enforce the regulation require clarity regarding the COCs characterization.

Upon the effective date of the proposed regulations, a chemical would qualify as a Chemical of Concern if it (1) exhibits one of 25 environmental or toxicological hazard traits established by OEHHA in its *Toxics Information Clearinghouse* (22 CCR §§69401- 69407.2)*;* and, (2) it appears on one of the lists specified in §69502.2(a) of the proposed rule. Several of the lists are inappropriate indicators of hazard.

1. Category 1 Endocrine Disruptors Identified in the European Commission DG Environment Report. For example, §69502.2(a)(1)(C) references 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*. The preface of the report makes clear that the report was intended as "*a first step towards the establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption….*[16]Indeed, the "working list" of 564 chemicals proposed in the 2000 report has been modified substantially over time. 575 chemicals were ultimately screened and evaluated as to their endocrine effects. [17] Of that total:

> 109 substances were not retained in the priority list due to insufficient data on ED effects or insufficient scientific evidence. 147 substances have been excluded from the evaluation during the process as they were identified as double entries, mixtures or of doubtful relevance. [18]

The 2000 report has clearly been superseded by subsequent chemical evaluations, and should not be included as a trigger for hazard classification. For this reason, we urge the Department to delete §69502.2(a)(1)(C) from the proposed rule.

Most importantly, the potential to interact with the endocrine system does not necessarily constitute a health risk. As captured in the widely adopted Weybridge Definition, "[a]n endocrine disrupter is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary (consequent) to changes in endocrine function."[19] The International Programme for Chemical Safety (IPCS – which includes WHO, UNEP and

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[16] BKH Consulting Engineers, in association with TNO Nutrition and Food Research, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, November 10, 2000.
[17] European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.
[18] European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.

[19] European Workshop on the Impact of Endocrine Disruptor on Human Health and Wildlife (Weybridge UK; 1996). European Union Report EUR17459.

ILO), utilizes a similar definition, "[a]n endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effect in an intact organism, or its progeny, or (sub)populations."[20]

Endocrine-mediated effects have already been captured by other lists, selected by DTSC that include reproductive, developmental and other adverse outcomes.

2. Group 2B carcinogens identified by the International Agency for Research on Cancer (IARC). The IARC Group 2B list is composed of substances for which there is limited human evidence and insufficient animal evidence of carcinogenicity.[21] It is possible that chemicals classified as IARC 2B will have some evidence or carcinogenicity based on animal models, but stronger evidence against carcinogenicity from available human epidemiology studies. ACC strongly suggests that the IARC 2B characterization be removed from §69502.2(a)(1)(I).

Under IARC guidance, there are a number of issues when evaluating chemicals with "limited evidence of carcinogenicity," and therefore a definitive evaluation of cancer hazards cannot be made. For example, a definitive evaluation may be difficult due to the following: the evidence of carcinogenicity is restricted to a single experiment; there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or, the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.[22]

3. National Toxicology Program, Office of Health Assessment and Translation Reproductive or Developmental Toxicant. Another list that is inappropriate for purposes of qualifying COCs is proposed in §69502.2(a)(1)(L). That provision refers to "reproductive or developmental toxicants identified" in monographs produced by the National Toxicology Program, Office of Health Assessment and Translation (OHAT). OHAT is the successor to the Center for the Evaluation of Risks to Human Reproduction (CERHR).

A brief background on how CERHR/ OHAT monographs are structured demonstrates why §69502.2(a)(1)(L) is an inappropriate factor in designating Chemicals of Concern under the California Green Chemistry Program. CERHR/OHAT monographs classify chemicals based on:

> (1) the weight of scientific evidence on adverse effects, expressed on a seven-part scale ranging from "clear evidence of adverse effects" to "clear evidence of no adverse effects"; and

[20] World Health Organization International Program on Chemical Safety, "Global Assessment of the State-of-the-Science of Endocrine Disruptors," WHO/PCS/EDC/02.2, Chapter 1: Executive Summary.
[21] World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, p. 23 (http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf).
[22] World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble to the IARC Monographs, B. Scientific Review and Evaluation, 6. Evaluation and rationale (b) Carcinogenicity in experimental animals (http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php).

(2) the agency's level of concern that a chemical is associated with various reproductive and developmental effects, expressed on a five-part scale ranging from "serious concern for adverse effects" to "negligible concern for adverse effects.

In the second analysis, the agency may also find that "insufficient hazard and/or exposure data" exists.

A CERHR monograph can therefore determine that a particular chemical presents "clear evidence of no adverse effects" and express "negligible concern for adverse effects." Nevertheless, under a plausible interpretation of §69502.2(a)(1)(L), that chemical could be qualified as a Chemical of Concern because it was "identified" in a CERHR/OHAT monograph. We respectfully recommend that §69502.2(a)(1)(L) be eliminated from the proposed rule, or alternatively, that DTSC make clear that *only CERHR/OHAT monographs indicating high levels of evidence and concern* regarding reproductive and developmental effects be considered as the basis for addition to the COC list.

2. DTSC should make clear how it will use the key criteria to identify priority products.

As proposed, it is unclear how DTSC will objectively utilize the "Key Criteria" to assess and prioritize products based on a list of over twelve hundred potential chemicals of concern. §69502.3(b). An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint, as it leaves the door open for political decision-making.

The incorporation of "the ability of the Chemical of Concern in a product *to contribute to or cause* adverse public health and/or environmental impacts," (emphasis added) as criteria for prioritization is unclear. This phrasing is contrary to a risk-based approach in the implementation phase of prioritization and strays from the statutory use of the term "potential to cause." ACC suggests DTSC revise this phrase to read, "The *potential* for the Chemical(s) of Concern in a product *to cause* adverse public health and/or environmental impacts…".

The proposed "narrative standard" for the prioritization process (§69503.3 of the proposed rule) also creates significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the proposed rule does not articulate a clear, step-by-step process for doing so. The proposal indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC, in fact, might use to reach a decision.

The proposed regulation lays out multiple criteria to be used in prioritizing products for review, with products meeting "one or more" of the key criteria to be considered priorities. The

regulation should be clarified to focus, at least in the first few years of the program, on products that meet all three statutory criteria (as high priorities).[23]

From the proposal, it appears that the key prioritization criteria are secondary to the longer list of other criteria that precedes the "Key Criteria" (§69503.2). DTSC should clarify the relationship between the key criteria and what is better characterized as supporting evidence.

Other information DTSC proposes to use, however, is too ambiguous and may not be appropriate as part of this exercise, or may be claimed as confidential information. The proposed rule states, "[t]he Department shall consider the potential adverse public health and environmental impacts…" associated with a number of hazard and exposure scenarios. This information may be extremely diffuse, poorly defined or difficult to obtain, reliably, for the department to consider.

For example, the proposal specifies that DTSC shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for children, pregnant women, and other sensitive subpopulations. ACC agrees that certain demographics, primarily children, should be given distinct consideration. However, the term "sensitive subpopulations" as defined by DTSC in the proposed regulation is a vague and highly subjective term ("including but not limited to" §69501.2(a)(72)) that may include different demographics or conditions depending on the context. See "sensitive subpopulations" under Clarity, Definitions above.

In many cases it will be difficult to obtain product exposure information relating to "manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices." The proposed regulation seems to expect consumer product manufacturers to have comprehensive manufacturing, use, distribution, and disposal data for every unit of its product. This is not a practical expectation. It becomes increasingly difficult to monitor the exact movement of products once they are sold to distributors and to primary and secondary retailers.

Similarly, with the exception of a few product categories, most consumer products find their way to a landfill or recycle stream at the end of their useful life, although it is often difficult to track the exact path of the product. As DTSC is surely aware, end of life management practices are commonly predisposed by municipalities in which the products reach the end of their useful lives, rather than by manufacturer or retailer plans. A manufacturer would clearly not know that location at the time of production or sale. The regulation should hold regulated entities accountable only for information that it can be reasonably expected to obtain.

The proposed rule indicates DTSC will consider the availability of reliable information to substantiate potential adverse impacts and exposures in the prioritization process. ACC believes that DTSC should also consider reliable evidence that refutes potential adverse impacts or exposures.

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[23] Three statutory criteria: 1) The volume of the chemical in commerce in this state; 2) The potential for exposure to the chemical in a consumer product; and, 3) Potential effects on sensitive subpopulations, including infants and children.

3. 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. §69503.2(a)(1)(A)1.b./c.[24] 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.

It is impractical to require an assessment of aggregate and cumulative risk for all chemicals of concern or all priority products. Assessing aggregate risks from the total exposure to a specific chemical from <u>all</u> different sources and routes requires considerable data, about each and every use of a substance, information that manufacturers of individual products do not have and cannot readily obtain. Aggregate assessments should only be required for those chemicals that meet specific criteria, such as cases that present a very narrow margin of exposure.

The assessment of cumulative risk – the evaluation of a common toxic effect from a concurrent exposure to a group of chemical and non-chemical risks that act in the same way poses even greater challenges. Similar to aggregate risk assessment, cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. Cumulative risk assessment may require manufacturers to look at all the adverse effects caused by the chemical in question, and to evaluate all other chemicals that potentially cause the same adverse effects (not just those in humans, but also in animal studies where doses are typically hundreds, thousands or even tens of thousands of times higher than humans ever experience). In the context of consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

ACC urges DTSC to adopt the best available framework regarding combined exposure to multiple chemicals, developed and endorsed by the World Health Organization (WHO)/ International Program on Chemical Safety (IPCS) (see attached). The framework is designed to aid risk assessors in identifying priorities for risk management for a wide range of applications where co-exposures to multiple chemicals are expected; and, it builds on previously published guidance for priority setting and assessment of combined exposures.[25] A framework assessment would provide DTSC with a problem formulation process for each combined exposure situation. Roughly, DTSC would begin by asking a series of questions to formulate the problem, and then for example, the initial Tier 1 assessment would begin with the upper-bound levels of daily intake for the majority of the identified population (exposure), and, potency for the most sensitive endpoint (hazard). Based on necessity, DTSC may then revise the exposure and hazard assumptions, replacing with increasingly detailed data and models.

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[24] The proposed regulation refers to "aggregate effects" and "cumulative effects," whereas typically these are referred to as "aggregate risk" and "cumulative risk."

[25] M.E. (Bette) Meek, Alan R. Boobis, Kevin M. Crofton, et al, "Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework," Regulatory Toxicology and Pharmacology, v 60 (2011) S1-S14, p 51.

4. Minimum Detectable Concentrations should not be the alternative analysis threshold.

Language in the ISOR suggests that the default Alternatives Analysis Threshold (AAT) will be the minimum detectable concentration for intentionally added chemicals:

> **Section 69503.5**, in its entirety, provides an exemption from the requirement of conducting an alternatives analysis for a Priority Product when specified criteria are met. 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.

Functionally speaking, the detectable concentration or limit of detection is the lowest possible level of the chemical in the product. Beyond the limit of quantitation, detection may only be a binary (present/not present) outcome, rather than a quantitative amount. If this is the case, DTSC has not been clear about how the AAT will be used to demonstrate reductions of COC in the Priority Products. AB 1879 establishes that both limiting exposure to the COC(s) or reducing the level of hazard posed by a COC are goals of the regulation.[26] What is less apparent, however, is how a responsible entity will be able to demonstrably reduce the level of a COC in the Priority Product below the limit of detection. ACC asks that DTSC clarify whether the limit of detection will be the preferred AAT.

Satisfying DTSC's AAT exemption requirements will be a significant analytical burden for product manufacturers. At a minimum considerable product testing will be necessary to substantiate the exemption, and that the AAT will likely be at the level of detection. Most industrial chemicals are not pure; in essence many are mixtures.

As proposed, the regulation does not distinguish between intentionally-added constituents and contaminants, and every product <u>might</u> have a trace amount of a COC and would require analysis. Furthermore, responsible entities cannot control the state or pace of analytical chemistry. Establishing the limit of detection as a regulatory threshold effectively sets a moving target. The degree to which small and medium sized businesses, much less importers and retailers, would have access to and resources to put toward this level of analytical chemistry is questionable and impractical.

Furthermore, the proposed AAT threshold and the process for establishing the AAT are not consistent with the processes used by federal and international agencies. ACC strongly recommends that DTSC set numerical thresholds that are harmonized with those applied by federal and international agencies. This would be consistent with the enacting statute that specifies

> [T]he department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have

[26] Assembly Bill 1879, Section 1.

undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.

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 *de minimis* threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens and reproductive toxins. Further, ACC urges DTSC to distinguish between intentionally-added chemical ingredients and contaminants, and subject contaminants to a higher threshold.

The AA process also warrants other clarifications. Section 69505.4(a) does not make clear what criteria will be used to judge when an when an alternative makes a "demonstrable contribution" to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product. Section 69505.5(d)(5) fails to articulate what bearing the proximity of the place of product manufacture to virgin or recycled resources has on a DTSC decision. At a minimum, this information could very well be commercially sensitive, pertaining to the costs of doing business, and it will likely be claimed as trade secret.

5. Many definitions should be clarified.

- "Adverse air quality impacts" (§69501.1(a)(3)). It is unclear what is meant by "air emissions of any of the air contaminants . . . *that have the ability* to result in adverse public health, ecological, soil, or water impacts," (emphasis added). It is not clear what this means in practice. For example, it is not clear what DTSC intends by referencing air contaminants with an "ability" to produce adverse impacts. "Alternative" (§69501.1(a)(11)(C)). The meaning of "redesign of a Priority Product and/or manufacturing process, *using different materials* to reduce or restrict exposures to Chemicals of Concern in the Priority Product," (emphasis added) is not clear. DTSC should consider eliminating the phrase "using different materials." "Hazard trait submission" (§69501.1(a)(33)). The proposed regulation states that "[W]hen any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission." According to OEHHA's Green Chemistry Hazard Trait Characteristics, every chemical will manifest some hazard trait. This provision, therefore, is meaningless.
- "Homogeneous material" (§69501.1(a)(34)).DTSC proposes to identify and prioritize specific materials, regulating specific uses of a material. The definition of "homogenous material" is taken directly from the European Union's Restriction of Hazardous Substances Directive (RoHS). "Homogeneous material" is not well-defined, however, as it may be "one material of uniform composition" or "a material, consisting of a combination of materials." Attempting to harmonize with a problematic term will make compliance difficult for both DTSC and responsible entities.

  ACC suggests that DTSC remove the term from the regulation and make a consequent revision in the definitions of "component," as well as "consumer product" or "product" as suggested below:

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

(A) Is required to complete or finish an item

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

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

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

1. A "consumer product" as defined in Health and Safety Code §25251;
2. A component, or uniquely identifiable material within a component, that is identified under §69503.4(a)(2)(B), as the minimum required focus of an AA.

- "Reliable information" (§69501.1(a)(52)). The definition of "reliable information" lacks rigor and lacks a weight-of-the-evidence evaluation. However, the ISOR discussion of "reliable information" includes a number of internationally-accepted testing guidelines and protocols. It is not clear why these guidelines and protocols not been included in the regulatory language. [27] ACC urges DTSC to include these guidelines, practices and protocols in the regulation, and to specifically note:
- Whether the study has been replicated;
- Whether the study provided was conducted according to generally accepted principles, including test protocols:
    - US FDA Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations)
    - US EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines
    - TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations)
    - TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations)
    - OECD Guidelines for Testing of Chemicals
    - OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring
    - OECD Manual for Investigation of High Production Volume Chemicals
    - REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council
    - CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

- "Responsible Entity" (§69501.1)(a)(54)). For clarity and consistency with other existing regulations ACC suggests that DTSC adopt a definition of "manufacturer" that is consistent with the Fair Packaging and Labeling Act (FPLA; 15 U.S.C. §§1451-1461).

[27] *See*, however, Initial Statement of Reasons: Safer Consumer Products, R-2011-02, http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf, p. 33-34.

For products manufactured in a foreign country and imported into the U.S., FPLA requires that the entity that receives the product shipment in the U.S. must assure that the product carries U.S.-compliant labeling that identifies the entity for which the product is "manufactured for" or "distributed by." It is practical for DTSC to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the duty to comply to a foreign manufacturer or retailer.

- "Sensitive subpopulations" (§69501.1)(a)(58)). It is not clear what DTSC means by sensitive subpopulations representing "a meaningful portion of the general population?" The definition of "sensitive subpopulations" is too broad and may present significant issues of compliance for responsible entities depending on how this term is interpreted. There is likely broad agreement that infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness should be included within the definition. However, the use of the phrase "including, but not limited to…" inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of "sensitive subpopulations" in ways that the regulated community cannot anticipate. DTSC should carefully review the proposed regulation for such instances of open-ended language such as the definition of "sensitive subpopulations" in this and other sections, giving careful consideration to the inability of product manufacturers, importers, and retailers to comply with such vague regulatory language that could give rise to shifting interpretation over time.

  It is similarly not clear why the proposed regulation include workers and their occupational exposures as a "sensitive subpopulation?"
- "Technically and economically feasible" (§69501.1)(a)(59)). It is not clear what DTSC means when it indicates that "[t]he 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," (emphasis added). ACC believes a better articulation would be that the information "are sufficient." ACC supports DTSC's incorporation of consumer acceptance as part of the overall feasibility of a potential alternative.

6. The bulk chemical exemption should be restored.

The goal 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 Product Regulation" is the "Chemical(s) of Concern" in a particular "Priority Product." Therefore, ACC is unclear why DTSC has included bulk chemicals within the scope of a "consumer product." Federal agencies and federal statutes regulate chemicals and materials; and federal statutes and agencies, such as the Occupational Safety and Health Administration (OSHA) regulate the manufacturing workplace, as well as the Division of Occupational Safety and Health (Cal/OSHA), within California. Furthermore, the Department of Transportation and Department of Homeland Security also regulate the movement and transport of chemical goods.[28] ACC recommends that the exemption be restored.

[28] See attached list of federal statutes that currently regulate chemicals in U.S. commerce.

7. DTSC should clarify certain information submission and retention requirements.

The purpose of §69501.3(d) is unclear, and DTSC should clarify its intention. The provision states:

> A person who is subject to a requirement to obtain or prepare information, but who is not required to submit the information to the Department or has not yet been requested to submit information to the Department, shall retain the information for a period of three (3) years following the date the person was required to obtain or prepare the information.

A literal reading of the provision would require persons not subject to the regulation (those not required to submit information) to retain information for up to three years. All required information will be submitted to DTSC in some format. ACC requests that DTSC provide an example of the type of information referenced in the provision and the type of person expected to be affected.

Similarly, Section 69501.4(a)(1-4) also fails to make clear who may be responsible for information submissions in the future. In addition, §69501.4(d) does not make clear what information DTSC would consider "helpful" to the Department. ACC suggests using the term "reliable information" in this instance.

8. Additional clarity on the standard for demonstrating an inability to respond should be provided.

The last provision of §69501.5(c) describes the process by which the responsible entity, chemical manufacturer or importer may find itself on the Response Status List. The responsible party in this case must demonstrate to DTSC's "satisfaction that it does not have and is unable to produce the requested information" or, DTSC may post the responsible party's identifying information on DTSC's web site. However, it is unclear how a responsible entity, chemical manufacturer or importer may demonstrate to the Department's satisfaction that it <u>is not</u> able to produce the requested information. For example, DTSC might better articulate the objective standard of proof for such demonstrations.

9. *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. See, e.g., §69502.3(d). The success of DTSC's regulation depends in large part on the degree to which the compliance and decision making processes are transparent. It is good practice to require DTSC to respond to any and all substantive public comments, but the proposal lacks this basic process protection. For example, the COC listing process allows DTSC the discretion to respond to "some or all" public comments received on revisions to the list. Regulated entities materially affected by DTSC's decisions, and the public, should be able to understand the basis for the decisions, and DTSC's

reasoning in accepting or rejecting particular recommendations, data, and/or information. ACC strongly recommends that DTSC's default approach be to respond to all public comments.

10. DTSC's requirement to apply for an exemption from the response requirement places a significant burden on the regulated community, and appears inconsistent with the statute.

Section 69506.11 is intended to implement the provision in §25257.1 of the statute. Subdivision (b) of the statute provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides requires the Department to reform from duplicating or adopting conflicting regulations for product categories already regulated or subject to pending regulation.

Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response "substantially duplicates" one or more requirements of another California or federal regulatory program, "without conferring additional public health or environmental protection benefits." ACC requests that the Department clarify this section based on the following three points:

- Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The Legislature imposed the responsibility on the DTSC to implement that provision. It does not contemplate imposing the burden on responsible entities.
- With respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. This provision exceeds the Department's authority. Nothing in the section contemplates that DTSC or the Department may duplicate other regulatory programs solely on the Department's contention that greater public health or environmental protection will result.
- The Department has ignored the fact that subdivision (b) of §25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, may well supersede the other agency's regulatory program.

D. <u>Consistency (Government Code §11349(d))</u>

As noted in earlier sections, elements of the proposed regulation appear to be inconsistent with the Uniform Trade Secrets and Public Records Act, certain CalOSHA worker safety requirements, and certain federal OSHA and international standards. ACC strongly recommends that DTSC ensure that these inconsistencies are resolved in the final regulation.

E. <u>Nonduplication (Government Code §11349(d))</u>

Two areas of the proposed regulation appear to duplicate other regulatory programs. Section 69501 does not exempt food contact materials from the scope of the regulation, and thus

duplicates the Federal Food, Drug and Cosmetic Act (FFDCA). The federal Food and Drug Administration regulates food contact materials through a comprehensive, science-based regulatory framework. Any DTSC regulation of food contacts materials would necessarily be duplicative of the federal regulatory effort. 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. Per the agreement between the State of California and OSHA, the state plan "applies to all public and private sector places of employment in the state, with the exception of Federal employees, the United States Postal Service, private sector employers of Native American lands, maritime activities on the navigable waterways of the US, private contractors working on land designated as exclusive Federal jurisdiction, and employers that require Federal security clearances." See also, 29 CFR 1952.172. At a minimum, DTSC should explain how the inclusion of workers as a potentially sensitive subpopulation does not duplicate CalOSHA's authority.

american cleaning institute®
for better living

April 25, 2013

Jackie Buttle, Acting Regulations Coordinator
Department of Toxic Substances Control
Regulations Section
P.O. Box 806
Sacramento, CA 95812-0806
(*via e-mail: gcregs@dtsc.ca.gov*)

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

Dear Ms. Buttle:

The American Cleaning Institute (ACI)[1] appreciates this opportunity to provide comments on the revised text of the *Proposed Safer Consumer Products Regulations* released for public comment on April 10, 2013 by the California Department of Toxic Substances Control (DTSC or the Department). The revised regulation had few changes included however we offer the following detailed comments.

Alternatives Analysis Threshold
There were several changes made to the regulation related to the Alternatives Analysis (AA) Threshold. In Section 69503.5(c), the Department has included the ability for it to specify an AA Threshold concentration for an intentionally added ingredient, and the Department may specify an AA Threshold concentration greater than the applicable Practical Quantitation Limit (PQL) for any Chemical of Concern (COC) that is a contaminant. We agree with these additions to the regulation and the revision of the definition for *Alternatives Analysis Threshold* under Section 69501.1(a)(12). However, we reiterate our objection to the requirement that individual manufacturers determine the PQL of a COC that is a contaminant. This is well beyond the capability of most manufacturers and will result in a lack of standardization of the PQL level for any particular product-chemical combination. It would be better for DTSC to lead the effort to identify appropriate methods for measuring contaminant COCs in products and determining the appropriate PQL.

[1]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.

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Definition of Reliable Information and *Quality of Available Information in Determining Product-Chemical Combinations*

We do not agree with the proposed changes to the definition of *Reliable Information* under Section 69501.1(a)(57). First, the only information that would be defined as reliable information would be "a scientific study or other scientific information." There are many other kinds of information that could be outside of those boundaries that could be important in the regulatory process that would not be subject to the same level of scrutiny, for example, data on product market volumes or use of products by consumers. Such information should not be excluded.

All of the sources mentioned are certainly appropriate for consideration in making decisions. Some include deliberative scientific bodies that actually review the information in studies and judge weight-of-evidence and other factors, e.g. National Academies and reports from government agencies. Such cases can be considered reliable. However, defining everything from every other sources as de facto "reliable" is scientifically inaccurate and has the potential to drive controversy into a program that is intended to be science-based. In particular, subparagraph (A)1. Information "(p)ublished in scientifically peer reviewed reports or other literature" is problematic. "Other literature" is open-ended and could include all manner of unreliable information. Also, it is well established that individual published peer-reviewed studies can be unreliable.

This problem is carried through to the definition "Reliable information demonstrating the occurrence or potential occurrence of exposures to a chemicals" (Section 69501.1(a)(58)), which includes a variety of sources of exposure information, but again includes a determination of the sources as reliable, independent of the actual reliability of any specific studies.

The need for a mechanism to judge the reliability of studies is widely recognized by Federal agencies with health and safety responsibility and in international fora. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology has been used for determining data quality and reliability on tens of thousands of studies for over 2000 chemicals in US and OECD High Product Volume Chemical programs. Hundreds of thousands of studies on over 5000 chemicals have been submitted to REACH and were rated according to this approach. The same is to occur for additional thousands of chemicals in future years. The methodology is published as Chapter 3 in the OECD's Manual for the Assessment of Chemicals (http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html). The Department should use the principles found in the OCED Manual for evaluating whether data is reliable for the purposes of the SCP regulation.

Likewise, the SCP regulations have been revised to include a requirement that the Department "consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts and potential exposures" (Section 69502.2(b)(3) and "potential adverse waste and end-of-life effects" (Section 69503.2(b)(1)(C)). The factors for evaluating the quality of available information have been extracted from the definition of *Reliable Information* and included in Section 69503.2(b)(1)(C). We object to this evaluation being restricted to these particular aspects of the regulation. Any influential information used to make decisions under the regulation should be subject to a high level of scrutiny (and pass). While some elements of the factors for evaluating the quality of information proposed are

consistent with the OECD approach, we believe it would be best for California to harmonize its regulations with the International approach under the OECD Manual.

Candidate Chemical Lists – Endocrine Disruptors
In Section 69502.2(a)(1) of the revised regulation, the Department has attempted to specify a number of lists from authoritative bodies from which to assemble their Candidate Chemical List. Subparagraphs (B), (C), (G) and (I) are cited as being classified by or included as Substances of Very High Concern (SVHC) Candidates "by the European Commission". While these processes are conducted under European Union laws, both Classification and SVHC approaches are conducted by the European Chemicals Agency (ECHA), which works together with Member States, but has ultimate responsibility for both regulations. The proper citation would be "...by the European Chemicals Agency".

Also, subparagraph (C) as revised states "Chemicals included as Category 1 endocrine disruptors by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006" (that is, the European chemicals law known as REACH). The revision to (C) indicates that there are "Category 1" endocrine disruptors in the SVHC Candidate list. There is no process under SVHC categorization or in any other part of the REACH regulation for categorization of endocrine disrupting chemicals. As such the reference to "Category 1 endocrine disruptors" should be eliminated from the SCP regulations. However, Article 57f of the REACH regulation does identify chemicals as "Equivalent level of concern having probable serious effects to human health or the environment under Article 57f" and specifies

> *those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.*

There are presently 16 chemicals and Groups that are Candidates under the Article 57f rationale, some but not all of which are based on potential endocrine disruption.

Identification of Factors Relevant for Comparison of Alternatives
We agree with the addition of language to identify factors relevant for comparison of alternatives (Section 69505.5(c)). The authorizing statute (AB1879) specifies a broad list of life-cycle factors that should be considered as part of the alternatives analysis (the A-M factors). There is probably no situation where all of the A-M factors would have material differences among alternatives that are under consideration, and the reality is that in most cases there will probably only be a few relevant factors. The addition of a step to identify only the relevant factors that are necessary for comparison during the alternatives analysis is very pragmatic and should add to the efficiency of the program without diminishing protection of public and environmental safety.

Public Comments on AA Reports
We agree with the addition of language describing the public comment on Alternatives Analysis reports under Section 69505.8. We also believe it is appropriate for the Department to screen the comments and identify which elements are necessary to be addressed.

Chemical Identity Masking When a Patent is Pending
We note changes to the language in Section 69509(g) regarding masking of chemical identity of a chemical that is the subject of a hazard trait submission of a proposed alternative. The change *does* appear to provide more clarity to the Department's intent – that is, it appears the Department is requiring that it be notified when the identity of a chemical that is considered as an alternative in an Alternatives Analysis is no longer trade secret. This seems like added bureaucracy that provides little value to the public and potentially results in additional burdens to innovators of safer products and chemicals. We believe that this will only serve as one of many disincentives to makers of safer products and chemicals and the entire subparagraph should be removed from the section.

* * * * *

ACI would like to express, once again, its appreciation in being able to comment on the revised Safer Consumer Product regulations. Unfortunately, we must also note that a great number of the changes we recommended in two previous comment letters have been largely ignored. Likewise, many similar comments from dozens of other stakeholders also have been ignored by the Department. We remain disappointed in what appears to be the final version of the regulations.

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.

Sincerely,

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

Cc: The Honorable Matt Rodriguez, Secretary, CalEPA (MRodriguez@calepa.ca.gov)
Miriam Ingenito, Deputy Secretary, CalEPA (mingenito@calepa.ca.gov)
Kristin Stauffacher, Assistant Secretary, CalEPA (kstauffacher@calepa.ca.gov)
Nancy McFadden, Cabinet Secretary, Office of the Governor (Nancy.McFadden@gov.ca.gov)
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AmericanCoatings
ASSOCIATION

April 25, 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 gcregs@dtsc.ca.gov

Re: ACA Comments on the April 10, 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 Toxics 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.

Respectfully Submitted,

Alexandra Whittaker, Esq.
Counsel, Government Affairs

Stephen Wieroniey
Specialist, Health, Safety and Environmental Affairs

Priority Products List (Section 69503.5(c))

ACA is encouraged that DTSC will be providing Alternative Analysis Thresholds for certain product – chemical combinations and contaminants. ACA insists that an Alternative Analysis Threshold is necessary for every product - chemical combination and contaminant.

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" threshold, rather than a "Practical Quantitation Level" (PQL) or an "alternative analysis threshold." Again, defining this threshold as "de minimis" more clearly acknowledges that the risk is not actionable.

The addition of the PQL is extremely problematic for the regulated community. Use of a PQL gives DTSC the authority to mandate an alternatives analysis simply because there is an ability to measure a small amount of contaminant in a product. DTSC acknowledges in the definition of contaminant, that certain chemicals are present due to manufacturing processes and cannot be removed because of their natural occurrence. Forcing the responsible entity to perform an alternatives analysis on a contaminant is an impermissible expansion of original purpose of the California Green Chemistry Initiative.

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

The new language in the draft describing the "Alternatives Assessment" process and subsequent 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)

In Sections 69506.3, 69506.4, 69506.5, DTSC states that labeling requirements, use restrictions, prohibitions requirements, and engineering controls can be placed on selected alternatives that contain either "Candidate Chemicals" or "Chemicals of Concern." And, in Section 69506.7, DTSC states that end-of-life management requirements can be placed on a selected alternative, even if it does not contain 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 use restrictions, labeling requirements, and engineering controls on products that use "safer alternatives" is effectively regulating alternatives. DTSC's priority should focus 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.

Given that the Candidate Chemical List is extensive, it will be increasingly more difficult for the responsible entity to pick an unlisted "safer alternative". If, while finalizing an Alternatives Assessment,

DTSC decides to list a company's selected "safer alternative" as a Candidate Chemical, a company could be subject to regulation based on the "safer alternative". This places a nearly impossible burden on the responsible entity, as the functionally acceptable, technically feasible, and economically reasonable alternative could continually change based on a simple update to the Candidate Chemical List. Moreover, this makes any chemical ever listed as a Candidate Chemical a 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 must regulate within the authority outlined in the California Green Chemistry Initiative. DTSC should focus on Chemicals of Concern in Priority Products, not "safer alternatives". The Department should allow and encourage reformulation, as ACA has suggested several times before.

Public Comments on AA Reports (Section 69505.8)

The addition of this section is extremely problematic and has the potential to violate important intellectual property rights. Releasing this information to the public will allow competitors access to trade secrets and confidential information. This section adds another step to an extremely arduous process. Ultimately, this new section 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. This section creates more bureaucracy and red tape to the Alternative Analysis process.

American Forest & Paper Association

April 25, 2013

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
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 regulation issued in April 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, more changes are needed for this to be a viable program for our industry.

The January 2013 proposal essentially stated that intentionally added chemicals are subject to an alternative 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 (or above the Practical Quantitation Limit (PQL)). This was a meaningless distinction and would treat intentionally added chemicals identical to contaminants. AF&PA, therefore, supports the clarification that DTSC can set an Alternative Analysis Threshold (threshold) either at the PQL, or greater than the PQL, for Chemicals of Concern (COCs) that are

contaminants in a Priority Product. AF&PA also supports the DTSC setting thresholds for COCs in Priority Products that are intentionally added ingredients.

We remain concerned, however, that a threshold for a contaminant in a Priority Product can be set at the PQL. The thresholds that are set by DTSC should be based on risk posed by the COC in the product and not simply whether the COC can be detected in the Priority Product. AF&PA believes that if the DTSC sets thresholds at the PQL, it will be expensive, administratively difficult, overly burdensome, and essentially a precautionary approach. Most importantly, the PQL is a laboratory procedure and has no health or exposure elements. DTSC's focus should be to set thresholds so that manufacturers have the direction needed to focus on real changes that could have some health and safety improvements in products.

Although we believe that change to set thresholds higher than the PQL for a contaminant is an improvement, AF&PA believes DTSC should go a step further and focus solely on COCs that are intentionally added ingredients in Priority Products. The goal and intent of the California Green Chemistry Initiative is to provide better, safer options to California consumers, in terms of products they use on a daily basis. Chasing unintentional trace levels of COCs that have no adverse impact on public health or the environment will diminish the benefits of the program. AF&PA recommends that prioritization be focused on COCs in Priority Products that are intentionally added ingredients that have a function in the product. Washington State has adopted an approach in its Children's Safe Product Act (70.240 RCW) that allows product manufacturers the option of not reporting contaminants. Washington recognizes that intentionally added chemicals offer the best opportunity for substitution with a safer alternative, and intentionally added chemicals is where Washington plans to focus most of its attention.[1] We believe it would serve California well to have the same focus.

DTSC should have provided a revised Initial Statement of Reasons (ISOR) with the April 2013 proposed rule. Failing to release a revised ISOR with a revised proposed rule appears to be contrary to the spirit of California's administrative procedure law. For stakeholders to be informed, and therefore able to give valuable feedback to DTSC, the proposed regulations should be accompanied by the explanatory document, the ISOR. AF&PA requests the ISOR be made available for comment before the regulations are finalized.

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.

---

[1] Washington Department of Ecology, *Children's Safe Product Act Reporting Rule*, May 4, 2011.

Sincerely,

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

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

April 25, 2013

SUBMITTED VIA GCREGS@DTSC.CA.GOV

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

Re: Safer Consumer Products; Text of Proposed Regulations – Additional Post-Hearing Changes, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (R-2011-02, April 10, 2013)

Dear Ms. Raphael:

The Technical Affairs Committee of the Association of Global Automakers, Inc.[1] (Global Automakers) appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) on the Additional Post-Hearing Changes to the Proposed Safer Consumer Products Regulations, released on April 10, 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 the

[1] 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 Suzuki Motor 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.

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 additional refinements that have been made in this April 10, 2013 version of the proposed regulations but also believe that these very limited changes do not address the uncertainties inherent in the overall approach that DTSC has adopted and in particular in the degree of flexibility that DTSC has afforded itself in setting priorities, listing chemical/product combinations, determining regulatory duplication, exempting replacement parts, and setting alternative analysis thresholds. We 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.

We 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 or (202) 650-5559.

Sincerely,

Julia M. Rege
Senior Manager, Environment & Energy

Comments Submitted by
The Association of Global Automakers

Regarding the Additional Post-Hearing Changes to the Proposed Regulations for Safer Consumer Products
Division 4.5, Title 22, California Code of Regulations
Chapter 55. Safer Consumer Products Regulations (R-2011-02, April 10, 2013)

On April 10, 2013, the California Department of Toxic Substances Control ("DTSC" or "Department") released the "Text of Proposed Regulations - Additional Post-Hearing Changes" (April 2013 Additional Post-Hearing Changes) for 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 and health profile. Throughout this lengthy development process 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.[1]

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[2] in these regulations, there is a compelling need to provide the maximum degree of clarity, as well as concise definitions, exemptions and regulatory requirements.[3] We remain concerned that the proposed regulations create an unworkable regulatory scheme for complex durable goods. In numerous public forums, DTSC reiterates 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.

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 likely to be unworkable, and we urge you to listen to the concerns we are raising. As currently drafted, this

[1] In addition to Global Automakers' written comments, we adopt the comments submitted by the Durable Goods Coalition by reference.
[2] The meaning of a "highly durable product," or complex durable goods as we refer to it, is based on the definition of "complex durable product" from § 69503.5 Priority Products List found in the "Text of Proposed Regulations – Additional Post-Hearing Changes," dated April 2013.
[3] 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.

proposal builds so much uncertainty into the regulatory process that it will be impossible to predict the outcome of any DTSC regulatory response. DTSC has also recognized this uncertainty, to a certain extent, by deferring action on both the economic analysis and California Environmental Policy Council (CEQA) analysis pending selection of priority products. 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 Products 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.

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 in the April 2013 Additional Post-Hearing Changes:

- We appreciate that DTSC has expanded the applicability of the Alternative Analysis Threshold (AAT) Exemption to include not only contaminants but also intentionally-added chemicals. This revision recognizes the negligible risk that may be posed by chemicals present in concentrations below the AAT.
- We are pleased to see that DTSC has focused the public comment process on final Alternative Analysis (AA) documents and that DTSC will design and implement the process itself. However, it is not clear from the current proposal how DTSC will determine which public comments merit additional input from the preparer of the AA. Providing the criteria that DTSC will use will add rigor and consistency to the process.
- We support the relocation of the “identification of relevant comparison factors” from Stage 2 to Stage 1 of the AA process. While this will create more work at the beginning of the process, we are hopeful that it will give DTSC the opportunity to provide guidance early on in the AA process rather than after the development of the final AA report.
- A number of changes to the “End of Life Management” requirements will make any end of life program more workable. We support the removal of the requirements that a collection program must include the collection mechanism and compensation requirements. DTSC’s recognition that these types of arrangements are best developed between manufacturers and retailers, as is currently done, is a positive step that recognizes the value of letting the marketplace address these types of issues. We remain concerned about DTSC’s approach to contaminants in recycled products and believe that if contaminants in recycled products can trigger an AA requirement, recycling will be discouraged.
- We support DTSC’s determination to request that confidential business information be deleted from documents rather than masked. This approach will circumvent any unintended disclosures and aligns with current practices implemented at the federal level.

While these changes are positive ones and move us a little closer to a workable program, there still remain a number of areas where we have significant concerns. We have provided detailed comments on each of these areas in previous comments, most recently in Global Automakers' February 28, 2013 comments on the Post Hearing Changes.[4] In brief, we believe the following areas continue to create an uncertain regulatory environment that will not focus on areas of highest consumer risk, that will force investment in redesign and remanufacture of products that will have a relatively short continued presence in commerce, and ultimately may result in regrettable substitution and the serious consequences that entails.

1. Regulatory Uncertainty and Lack of Clarity
    a. §69506.1(f)(4) Replacement Parts
    b. §69501.1(a)(15) Definition of Assemble and §69501.1(a)(16) Assembler
    c. §69501(b) Duplicative Regulatory Requirements
    d. §69503.6(b) Initial Priority Products List
    e. §69501(b) Up-Front Applicability Exemption for Certain Products
    f. §69501.1(a)(12) Alternatives Analysis Threshold Exemption
    g. 69501.1(a)(59) Replacement Candidate Chemical
    h. 69504.4 Alternative Analysis Process and Options
    i. 69505.7 Alternative Analysis Reports
    j. §69501.1(a)(62) Safer Alternative

2. Compliance with Administrative Procedures Act (APA) requirements
    a. ISOR Availability
    b. Economic Analysis for First Priority Product List

1. Regulatory Uncertainty and Lack of Clarity

a. §69506.1(f)(4) Replacement Parts

The ability to repair complex durable products continues to be one of the primary areas of concerns for complex durable goods assemblers. In each of our prior comments on these regulations, Global Automakers has identified as a priority issue the critical need to allow the continued availability of replacement parts for complex durable goods. DTSC addresses 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 §69506.1(f)(4) that would allow DTSC to exempt replacement parts from any particular regulatory response requirement on a case by case basis, but this allowance does not go far enough. In this current version of the regulatory text, DTSC revises the definition of "Assembler" to now include "repair, refurbish, maintain or make non-materials

[4] "Public Comments on 30-Day Notice: Public Comments A – C," p. 106-125. http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Reduced-A-C-30-Day-CONSOLIDATED-LIST-OF-COMMENTS.pdf (last accessed 4/23/13).

alterations," which could inadvertently subject anyone repairing, refurbishing, maintaining, or making non-material alterations subject to the rule, even a consumer at his/her own home.

DTSC has often stated that they want the SCP regulation to be "forward-looking" and not focused on products placed in the stream of commerce prior to the implementation of a selected regulatory control option. The current treatment of replacement parts and the inclusion of the new language in the "Assembler" definition take us further from this goal and introduce additional uncertainty about how the regulations will apply to replacement parts and repair facilities. 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 have provided additional comment on the treatment of repair and refurbishment businesses under Section 1b of these comments.

b. §69501.1(a)(15) Definition of Assemble and §69501.1(a)(16) Assembler

In our February 28, 2013 comments, Global Automakers provided extensive comment on the proposed definitions of "Assemble" and "Assembler." Obtaining the necessary clarification and certainty regarding these definitions are a high priority for us, because they greatly impact how the regulation is implemented and/or interpreted and the treatment of domestic and international assemblers. We believe that it was DTSC's intent to provide some regulatory relief to complex durable goods assemblers, which we support, by adding the 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 do not provide the needed relief for the complex durable goods assembler and instead, 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 can be 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 criteria in the definition of "Manufacturer" ("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 complicated combination of definitions and exclusions would allow an automobile assembler to fall under the 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 components of the vehicle or assembled vehicle from oversees (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. In fact, this scenario unfairly applies separate criteria to domestic and international assemblers. Based on the hierarchy of responsibility explained in the regulation, the manufacturer of the component, who controls the overall design and production of the component, should be the first in line of responsible parties for compliance with DTSC's regulations. However, without clarification that the definition of "Importer" does not apply to assembled products, DTSC is inappropriately placing the burden to comply directly on the importer of the assembled product. Based on the designated roles and responsibilities in DTSC's regulations, DTSC should provide clarification on this point, since the responsibility would fall on the manufacturer first, then the importer of the assembled product in the event the manufacturer fails to comply.

In order to address this critical issue, we request that DTSC revise the regulatory text as indicated below:[5]

[5] First and foremost, Global Automakers recommends that DTSC reconsider our earlier requests to exempt the automotive sector from this regulation. The automotive sector is a complex and already highly regulated community. We appreciate that DTSC intends for the terms "assembler" and "assemble" to carve out exclusion for the automotive sector and other manufacturers of complex goods, however the complexity of the sector and the supply chain necessitates a more explicit exemption.

1. *Move the definition of "complex durable product" now contained in Section 69503.5 (c)(2) to new §69501.1(a)(23), and renumber subsequent sections accordingly*.

2. *Revise §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.

In addition, we continue to believe that it is an inappropriate expansion of authority for DTSC to include businesses that "repair, refurbish, maintain or make non-materials alterations" to a consumer product in the hierarchy of entities with a duty to comply. By modifying the definition of "Assemble" to include these activities, DTSC has placed an obligation of compliance on a group of businesses that will be hard pressed to meet any of the AA obligations should that responsibility fall to them. We request that DTSC reconsider this issue and provide for an up-front exemption for these activities and those that perform them. Specific language to accomplish this goal should be as follows:

1. *Revise §69501.1(a)(43)*:

   "Manufacture" means to make or produce. "Manufacture" does not include:
   (A) acts that meet the definition of "assemble;"
   (B) repair or refurbishment of an existing consumer product;
   (C) installation of components to an existing consumer product;
   (D) making non-material alterations to an existing consumer product.

2. *Revise §69501.1(a)(15):*

   "Assemble" means to fit, join, put or otherwise bring together components to create~~, repair, refurbish, maintain or make non-material alterations to~~ a consumer product. "Assemble" does not include activities to repair, refurbish, maintain or make non-material alterations to a consumer product.

3. *Add to §69501.1(a)(24)*:

   (D) "Consumer product" does not mean replacement parts used to repair, refurbish or maintain existing consumer products.

c. §69501(b) Duplicative Regulatory Requirements

Although DTSC did not address §69501(b) Duplicative Regulatory Requirements in the April 2013 Additional Post-Hearing Changes, we would be remiss to not mention the ongoing concerns with these areas and the need for additional regulatory clarity on this topic. As currently proposed, DTSC has given itself wide latitude in determining whether or not a priority product is adequately regulated under another California statute or a federal statute. By including the end of life effects in their scope of consideration for this exemption, DTSC has essentially ensured that this exemption will be very narrowly applied. The proposed regulatory language leaves the regulated community 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).

d. §69503.6(b) Initial Priority Products List

We believe it is appropriate to reiterate our previous concerns regarding the scope of the initial list, since it will impact how the regulations are implemented, even though DTSC did not address §69503.6(b) Initial Priority Products List in the April 2013 Additional Post-Hearing Changes. Global Automakers supports DTSC's commitment to keeping the initial Priority Products list small in size, as provided in §69503.6(b),[6] allowing DTSC, 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 of Concern (COC) per product. This allowance is problematic, because it will require a separate AA to be developed for each chemical in the priority product, which will be costly and time-consuming. For example, California currently has a law in place that regulates the content of copper, as well as asbestos fibers, cadmium, hexavalent chromium, lead, and mercury in brake pads. In the event an AA was required by this law,[7] it would not be possible to conduct a single AA for all constituents. Instead, five separate AAs would be necessary, and each may have to be redone to accommodate formulation changes that may result from the selection of any one alternative. This expansion undercuts the very rationale for keeping the initial list small and imposes an unmanageable

[6] §69503.6(b) reads:

> *(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*.

[7] This law, SB346 passed in 2010, does not require any AA to be performed. This law exists independently of and regulates copper and the other constituents separately from the Safer Consumer Product regulations.

burden. We ask that DTSC reconsider the reasoning behind keeping the initial list to a manageable size and ask that DTSC limit the number of chemicals per listed product.

e. §69501(b) Up-Front Applicability Exemption for Certain Products

DTSC also did not address §69501(b) Up-Front Applicability Exemption for Certain Products in the April 2013 Additional Post-Hearing Changes, but we continue to support the need for additional regulatory certainty and clarity for these products. This current proposal does not include an up-front 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. In the absence of a current Statement of Reasons, it is difficult to understand the reasoning behind DTSC's determination to include products intended for use in exempted products. This approach appears to be an attempt to circumvent the very exclusions provided for in §69501. The product prioritization factors in §69503.3(b)(3) include considering whether the product is manufactured or stored in California solely for use outside of California or whether the product is used only to manufacture a product exempted from the rule,[8] but it would be more appropriate to include these two factors as up-front exemptions for regulatory certainty and clarity. Global Automakers reiterates our request from our February 2013 comments that DTSC retain the language and exemption for these particular products as reflected in the July, 2012 Proposed Regulations.

f. §69501.1(a)(12) Alternatives Analysis Threshold Exemption

As indicated earlier in these comments, we are pleased that DTSC has determined to adopt an approach to the Alternatives Analysis Threshold (AAT) Exemption that had been proposed in an earlier iteration of these proposed regulations. By expanding the applicability of the AAT Exemption to include not only contaminants but also intentionally-added chemicals, this revision recognizes the negligible risk that may be posed by chemicals present in concentrations below the AAT.

However, the current proposal does not identify 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) with additional language that indicates that DTSC can propose a different AAT, if appropriate. While we believe that providing DTSC with the authority to propose something other than the PQL is a marginal improvement, we remain concerned that DTSC will not have the resources necessary to identify AATs on a case by case basis and the default will become the PQL. We continue to request that DTSC adopt a default 0.1% AAT for COCs in Priority Products and exclude recycled products from the AA process if it is a contaminant that triggers the AAT and the AA requirement. If DTSC continues to move forward with the case by case

[8] Prioritization factors found in §69503.3(b)(3) include:

> *(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".*

approach they have proposed for developing alternate AATs, we request that DTSC provide the process details they will use to develop the alternate AAT.

g. §69501.1(a)(59) Replacement Candidate Chemical

We find this definition to be very confusing and request clarification of DTSC's intent with respect to §69501.1(a)(59) in the April 2013 Additional Post-Hearing Changes, which states:

> "*Replacement Candidate Chemical" or "replacement chemical" means a Candidate Chemical or other chemical, whichever is applicable, that replaces, or is under consideration to replace, the Chemical(s) of Concern, in whole or in part, in an alternative to the Priority Product, and that is one of the following:*
>
> *(A) A chemical that is not present in the Priority Product; or*
>
> *(B) A chemical that is or would be present in the alternative at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern.*

The revised language in §6950101(a)(5)(B) appears to be the opposite of the definition as it was revised in the January 2013 Revised Regulations, and furthermore this language is confusing. Does DTSC mean that a chemical that is present at a higher concentration than other chemicals in the Priority Product would be considered as a potential replacement chemical? As currently written, this language does not make sense to us. DTSC should revise this text further so that the meaning and intent of the language is clear and provide an additional opportunity for public comment on the definition.

h. 69504.4 Alternative Analysis Process and Options

As we have indicated earlier in these comments, we support the relocation of the "Identification of Relevant Comparison Factors" from Stage 2 to Stage 1 of the AA process. While this change will create more work at the beginning of the process, we are hopeful that it will give DTSC the opportunity to provide guidance early on in the AA process rather than after the development of the Final AA Report. Even with this improvement however, we believe that the AA process is still unclear, creates many areas of uncertainty, and creates the potential for different interpretations of the same requirements. Many of those who will be subject to the AA requirement have limited experience in developing AAs and will need as much clarity as possible. We encourage DTSC to release the required AA guidance for a public comment process to ensure that the guidance is as clear and consistent as possible.

We request that DTSC give serious consideration to adopting concepts laid out in the proposed AA guidance that has been developed by the Interstate Chemicals Clearinghouse (IC2) and published for comment on March 7, 2013.[9] We strongly support the flexibility that has been built into that process, most notably the

[9] Interstate Chemicals Clearinghouse, "Guidance for Alternatives Assessment and Risk Reduction (draft version)." http://www.newmoa.org/prevention/ic2/aaguidance.cfm (last accessed 4/25/13).

ability of the user to select the modules and levels appropriate for the assessment that needs to be performed. We also support the collaborative approach that the eight participating states have adopted. California has been an active participant in this IC2 effort, and in order to avoid a patchwork of AA programs that will lead to confusion and regulatory instability across states, it would be beneficial to adopt one standard approach. One uniform AA process will provide for predictable and certain outcomes. We will be submitting comments separately to IC2 on the draft guidance.

i. 69505.7 Alternative Analysis Reports

We appreciate that DTSC is attempting to add as much structure as possible to the reports they will be required to review. However, in keeping with our previous comment on the AA process and options, we encourage DTSC to allow flexibility for the preparer of the AA in designing the appropriate summary of information.

j. §69501.1(a)(62) Safer Alternative

DTSC also did not address §69501.1(a)(62) Safer Alternative in the April 2013 Additional Post-Hearing Changes, but we continue to be concerned about the additional burden this places on the manufacturer and the limitations it imposes on the universe of chemicals that can be considered as candidates for replacing COC. The definition of "Safer Alternative" in §69501.1(a)(62) creates two significant areas of concern.

First, it creates an overly broad universe of determinations that need to be made by the manufacturer, including comparison to other products for which the manufacturer may have no reliable information. When compared to the definition of safer alternative in earlier proposals, 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 is 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. The second and equally troublesome concern is that DTSC has also narrowed the universe of chemicals that a manufacturer can consider when looking for viable alternatives. In earlier versions of these proposed regulations the focus was on COC, 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 COCs 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.

We request 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 as suggested by the following strikeout of the text:

"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.

2. Compliance with Administrative Procedures Act (APA) requirements

a. Initial Statement of Reason Availability

The ability to assess the changes made in both this most recent revision of the proposed SCP regulations and the January 29, 2013 revisions has been made difficult because we do not have a current and corresponding Statement of Reasons. The changes made between the July 27, 2012 proposal, the January 29, 2013 revised regulatory proposal and this most current 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. While a revised Statement of Reasons is not a mandatory requirement under California's APA, it would be helpful to have a revised Statement of Reasons so that we could better understand the intent behind many of the changes and comment appropriately. We request that DTSC issue a revised Statement of Reasons and provide for a public comment period prior to finalization of these regulations. We believe this would be beneficial to all stakeholders and would help to better understand the changes that have been made.

b. Economic Analysis for First Priority Product List

We believe that it is DTSC's intent to develop the Initial Priority Product List through a notice and comment rulemaking process. We also understand that DTSC intends to do an economic analysis along with the proposed Initial Priority Products List. We request that DTSC include specific language in the regulatory text that reflects that intention.

Conclusion

We recognize that this document may be the last iteration of DTSC's SCP proposals before DTSC moves forward to finalize them. We do appreciate that DTSC has worked to engage stakeholders in the development of these regulations, but we remain concerned that as written they create an unworkable system for manufacturers, importers and assemblers of complex durable goods.

As we have pointed out in all of our comments, the regulations as proposed do not reflect the unique needs of the manufacturing, production and life cycles for complex durable products. The current proposal continues to put forward a process that may be workable for less complex, simple and/or formulated consumer products, such as personal hygiene products, cleaning products and similar

consumer goods that can be modified in short periods of time and that have a very narrow shelf life as compared to complex durable goods that are manufactured to provide service for decades.

DTSC's unwillingness to recognize and address that very fundamental difference has resulted in the insertion of language intended to work around the issues of complex durable goods rather than address them head on. For example, rather than recognize the complexity of complex durable goods and the unsuitability of the current proposed approach, DTSC has limited the number of components of a complex product that can be the subject of review at any given time. While this regulatory limitation is a marginal improvement over having no limitations, it does not address the fundamental difference between complex durable goods and simple products. In similar vein, DTSC recognizes that replacement parts for complex durable goods must be available for repair and refurbishment of complex durable products, but rather than provide an up-front exemption, DTSC has attempted to address this issue by allowing themselves flexibility in the regulatory response options. In its efforts to create a one size fits all regulation, DTSC has made the regulation more complicated than it needs to be for more simple consumer products and inadequate to effectively assess and address complex durable goods such as automobiles. DTSC has received hundreds of constructive comments from the makers of complex durable goods providing workable solutions to the concerns that have been raised and for no clear reason has chosen not to adopt the majority of those recommendations. We strongly urge DTSC to take this issue seriously and defer inclusion of complex durable goods until the fundamental problems with the current approach can be rectified.

If DTSC determines to move forward based on this latest proposal, we request that the recommendations we have outlined earlier in this set of comments, as well as recommendations from Global Automakers' previously submitted comments throughout the regulatory process, be reflected in any final regulation.

ASSOCIATION OF HOME APPLIANCE MANUFACTURERS

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April 25, 2013

Jackie Buttle
Acting 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. Buttle:

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) April 10, 2013 revisions of the 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. AHAM has provided comments to previous drafts of the regulations; however, the most recent draft changes that were published on April 10, 2013, do not address the concerns that AHAM has expressed in its previous comments which are provided again below.

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 "[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.

The definition for "assembler" has been revised in the April 10, 2013 draft regulations. "Assemble" is defined to mean "means to fit, join, put, or otherwise bring together components to create, repair, refurbish, maintain, or make non-material alterations to 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 definition of “assemble” is unnecessarily broad, and the distinction between a manufacturer and an assembler is confusing. This makes 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

AAIA® Automotive Aftermarket Industry Association

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April 25, 2013

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RE: Comments on Revisions to Text of Safer Consumer Product Regulations Released on April 10, 2013 (R-2011-02/OAL File No:Z-2012-0717-04)

Dear Ms. Buttle:

On behalf of the Automotive Aftermarket Industry Association (AAIA) and CAWA- Representing the Automotive Parts Industry (CAWA), we would like to provide comments regarding the most recent revision of the proposed text of the Safer Consumer Product Regulations (SCP) (22 CCR, div 4.5, ch. 55). AAIA, as a member of the Complex Durable Goods Coalition, also supports the comments of that group and has included those as an extension of this document.

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:

Comments on behalf of our organizations have previously stated on multiple occasions the unworkable structure of the draft Safer Consumer Product Regulations. We recognize that the Department of Toxic Substances Control (DTSC) has made several attempts to address industry concerns; however, the current draft continues to include areas that are capable of demonstrating measurable harm to the automotive aftermarket. Our industry in California accounts for $33.8 billion in sales, employs more than 194,000 people, and is a significant contributor to State tax revenue.

In addition to those stated in the comments submitted by the Complex Durable Goods Coalition, AAIA and CAWA have the following concerns:

- The proposed regulation still does not properly address the treatment of repair, maintenance and refurbishment parts. These types of parts are created with specific functionality considerations in order to extend the useful life motor vehicles while helping reduce their environmental impacts. Many of these repair and maintenance items are also generated from recycled or reused vehicle components. Including these types of products in the SCP could ultimately create more waste,

increase energy use, and potentially further damage the environment. Repair, maintenance, and refurbishment parts for motor vehicles should be exempted from this regulation.

- Businesses that perform repair, maintenance, and refurbishment activities and automotive parts retail establishments are ill-equipped to fulfill the requirements of any position within the responsible entity hierarchy created by the regulation. Therefore, we urge that repair, maintenance and refurbishment-based automotive aftermarket entities and automotive parts retailers should be exempted from the regulation as a responsible entity.

Further details and recommendations for these items are below:

Recommendations:

The AAIA and CAWA recognize the effort by DTSC to address the confusion over unclear definitions for entities within the regulatory response hierarchy. However, including activities to "repair, refurbish, maintain" within the definition of "assemble" remains problematic for the automotive aftermarket industry. The fundamental concern is that businesses offering these services, along with motor vehicle parts retailers, have no control over the previous manufacturing processes and, therefore, have no control over the levels of chemicals of concern contained within those items.

Moreover, the proposed regulation should be aimed at the manufacturing processes and the manufacturers of consumer products being the primary entities responsible for the regulation. Therefore, the goal of the regulation should not be to target business that provide a service, but do not actually provide a consumer with a product. Repair, maintenance, and refurbishment organizations are service companies, not product manufacturers and should not face the same potential consequences.

Additionally, motor vehicle repair, maintenance, refurbishment and parts retail locations are, for the most part, small businesses that will struggle to adhere to the overly burdensome inventory reporting standards, let alone the potential full regulatory response process. Leaving these companies open to the threat of millions of dollars in testing and analysis will seriously harm and possibly destroy small businesses and the automotive aftermarket in the state.

Motor vehicle repair, maintenance, and refurbishment parts are not single-use products with brief lifespans. These products are intended for long-term use in order to extend the life of motor vehicles. These services further help reduce emissions of greenhouse gases and toxic pollutants by maximizing fuel efficiency of the vehicle as well as maintaining the performance of emissions control systems. Further, the repair and maintenance also helps cut down on environmental waste due to the reuse by our industry of many components from a vehicle. This remanufacturing process results in a reduced depletion of resources and in the energy used to produce replacement components. Any harm done by the SCP regulation to the automotive aftermarket may have the unintended opposite effect of the DTSC's original goal.

Therefore, we recommend that activities including repair, refurbishment, maintenance of vehicles and motor vehicle parts retailers be exempted from the proposed SCP regulation through the following:

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)(15)*:

"Assemble" means to fit, join, put or otherwise bring together components to create~~, repair, refurbish, maintain or make non-material alterations to~~ a consumer product. "Assemble" does not include activities to repair, refurbish, maintain or make non-material alterations to a consumer product.

3. *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.

4. *Revise Section 69501.1(a)(61) to add:*

"Retailer" means a person to whom a product that is subject to the requirements of this chapter is delivered or sold for purposes of sale or distribution by that person to a consumer. "Retailer" does not include entities selling only products intended for the repair, maintenance, or refurbishment of motor vehicles as defined in California Vehicle Code §415(a) – (c).

The AAIA and CAWA again thank the DTSC for the opportunity to comment on the revised draft of the SCP regulations. We hope these comments, along with the included extension from the Complex Durable Goods Coalition are helpful in guiding the agency to a workable regulation that helps satisfy the goals of both the DTSC and the automotive aftermarket industry.

Sincerely,

Aaron Lowe
Vice President, Government Affairs
AAIA

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April 25, 2013

VIA EMAIL AND OVERNIGHT MAIL

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

Re: Comments of the Complex Durable Goods Coalition on the April 2013 Revised Proposed Safer Consumer Products Regulations

Dear Ms. Raphael:

I am pleased to submit the comments of the Complex Durable Goods Coalition (the "Coalition")[1] on the revised proposed Safer Consumer Products ("SCP") Regulations (sometimes referred to as the "Proposed Regulations") released by the Department of Toxic Substances Control ("DTSC") on April 10, 2013 for public comment.

The Coalition acknowledges DTSC's attempts to render the SCP Regulations more practicable, including revising the scope of the Alternatives Analysis Threshold Exemption to encompass intentionally added ingredients. However, too many aspects of the Proposed

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[1] 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 Alliance of Automobile Manufacturers, the Association of Global Automakers, the Automotive Aftermarket Industry Association and the Motor and Equipment Manufacturers Association.

Regulations remain uncertain and confusing and, overall, the Proposed Regulations remain unworkable.

DTSC's proposed program is the first of its kind in the United States, with the ambitious goals of promoting "benign by design" approaches to consumer product design and manufacture, and of creating a new green economy in California. The program's implementation will be scrutinized closely by the public and executive level agencies in this and other jurisdictions. The Coalition is perplexed that four years into this regulatory process the SCP Regulations remain an unwieldy muddle. If DTSC does not revise, improve and incorporate real-world guidance from numerous industry experts charged with complying with the Proposed Regulations, its program is destined to very publicly fail.

The Coalition has five key concerns:[2]

- The failure of the SCP Regulations to address replacement parts and the inappropriate inclusion of repair/refurbishment/maintenance activities in the definition of "assemble";
- The failure of the SCP Regulations to address appropriately the importation of components and assembled complex durable goods;
- The continued lack of clarity about the Alternatives Analysis Threshold Exemption, including the absence of any criteria by which DTSC will develop an Alternative Analysis Threshold, and the continued use of the Practical Quantitation Limit as a cap on the maximum level of a chemical of concern ("COC") as a contaminant in a Priority Product;
- The continued deficiencies in the proposed public comment process for Final and Abridged Alternatives Analysis ("AA") Reports; and
- The confusing revisions to the definition of "Replacement Candidate Chemical" and "replacement chemical."

The Coalition discusses its five concerns in greater detail below.

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[2] The Coalition attaches and hereby incorporates by reference its prior comments on earlier versions of the Proposed Regulations, submitted on October 10, 2012 and February 28, 2013.

I. THE SCP REGULATIONS STILL FAIL TO ADDRESS REPLACEMENT PARTS AND INAPPROPRIATELY INCLUDE PERSONS WHO REPAIR, REFURBISH AND/OR MAINTAIN CONSUMER PRODUCTS WITHIN THE SCOPE OF RESPONSIBLE ENTITIES

In each of its prior comments to the iterations of the Proposed Regulations, the Coalition has pointed out the critical need to allow the continued manufacture of replacement parts for complex durable goods, and the critical need to ensure that persons undertaking repair, refurbishment and maintenance activities are not deemed "responsible entities." Those persons have no involvement in developing products and merely come in contact with those already in existence – at a point where chemical composition control is long past. Rather than ensuring such persons will not bear the burdens of DTSC's proposed program, the Proposed Regulations do precisely the opposite, thereby threatening California's economy, environment and consumer choice.

Ensuring that replacement parts remain available for complex durable goods is critical. Numerous unique factors interact to make the supply of replacement parts a challenge in any scenario, and the constraints to be imposed by the SCP Regulations promise to make those challenges insurmountable. Some of these unique factors are described below:

- 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 must remain available for years, even for products that are no longer being manufactured.

- Frequently, replacement parts must meet specific legal requirements and/or regulatory approvals or certifications. In these circumstances, it is not possible to simply substitute newly designed parts – not without substantial investment of time and resources, and certainly not in the short time frames contemplated by the SCP Regulations. As evidenced by multiple global COC-type regulations, replacement parts are designed and manufactured to the relevant regulatory requirements in effect at the time in which the product originally was sold. These other regulatory programs recognize that there is no feasible scenario in which resources could be adequately allocated to the re-engineering and re-development of parts associated with legacy products no longer being manufactured. Further, such efforts would drain resources from other efforts to "green" current and future products currently or imminently entering commerce – contrary to DTSC's stated goal.

- The lead-time necessary for product design, development and validation of complex durable goods is on the order of years, not months or weeks. At a minimum, this means that design changes to replacement parts also require substantial lead-time. And, for complex durable goods no longer being manufactured, there may be little

incentive to invest the resources for re-design of replacement parts to comply with the SCP Regulations. While DTSC's intentions may be noble, no evidence exists that DTSC understands the timing, design, sourcing, manufacturing or sale of complex durable goods, nor the inherent regulatory and timing roadblocks in the Proposed Regulations, which virtually assure failure. This apparent lack of understanding is made even more perplexing because multiple industries and associations have spent nearly five years working with DTSC to explain the unique issues surrounding the assembly of durable goods and to provide workable solutions toward a successful program. DTSC, to this day, either ignores or skews those solutions.

- With the multi-tiered, multi-faceted global supply chain inherent in the assembly of complex durable goods, replacement parts may be available only from overseas manufacturers. Such manufacturers may not provide re-designed replacement parts to fulfill demand for a single market, i.e., California, within the constraints of the SCP Regulations. In such circumstances, severe supply chain disruptions will result, with the ultimate victims being California's consumers and economy.

If implementation of the Proposed Regulations results in the unavailability of replacement parts meeting all applicable requirements, the net and ironic result could very well be detrimental impacts on the environment and sustainability. Greater waste will be generated as consumers discard broken and (now) unrepairable complex durable goods and buy new ones (also unnecessarily draining their financial resources); those broken goods will end up in landfills. With the repair of goods being discouraged by DTSC's proposed program, more virgin material will be used to manufacture goods to meet supply needs and comply with the program. These consequences will be exponentially exacerbated by the Proposed Regulations' inclusion of contaminants as triggers for the new program's burdensome regulatory requirements. The Coalition does not believe that DTSC intends the SCP Regulations to result in such environmentally detrimental consequences.

Nor does the Coalition believe that DTSC intends to encompass, within the hierarchy of responsible entities, persons who are ill-equipped to take leading roles in the sophisticated and costly AAs required by the SCP Regulations. Yet that is precisely the consequence of including repair, refurbishment and maintenance activities in the definition of "assemble." With this new definition, businesses that merely offer repair and maintenance services will be captured as assemblers within the hierarchy of responsible entities.

Aside from the fact that such businesses do not even sell or lease ***consumer products*** within the meaning of the authorizing statute, but merely offer ***services***, these entities are primarily small business owners that lack the expertise and financial resources to undertake AAs. The Coalition fails to see the logic in causing such damage to businesses, many of them part of a multi-billion dollar industry in California, whose only actions, at worst, would be to replace an existing part with a similar one. These businesses' only recourse may be to stop purchasing parts

– which will put them out of business. This will have an enormous economic impact and will create an uneven playing field vis-à-vis non-California businesses. DTSC has undertaken no economic analysis that would demonstrate otherwise and again has demonstrated a lack of understanding of industry and business needs within its own state.

The Coalition acknowledges that DTSC may have intended the new definition of "assemble" to clarify that persons providing repair, refurbish and maintenance services are not "manufacturers." The Coalition agrees that such persons should not be in the highest tier of responsible entities. Indeed, because such entities sell services rather than consumer products, it is far from clear that DTSC has ***any*** authority to regulate such persons under AB 1879. Aside from that threshold issue, DTSC's proposed approach would impose on a family-owned repair shop the same resource-intensive regulatory burdens as are imposed on national and global corporations. DTSC's approach has created a new problem that must be fixed by clearly removing from the responsible entity hierarchy altogether those persons offering such services.

The Coalition urges DTSC to make all of the following revisions (additions in underline; deletions in strikethrough):

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)(15)*:

   "Assemble" means to fit, join, put or otherwise bring together components to create~~, repair, refurbish, maintain or make non-material alterations to~~ a consumer product. "Assemble" does not include activities to repair, refurbish, maintain or make non-material alterations to a consumer product.

3. *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.

II. THE SCP REGULATIONS MUST APPROPRIATELY ADDRESS ASSEMBLERS OF COMPLEX DURABLE GOODS

The Coalition previously has described to DTSC the challenges arising from the global nature of supply chains for complex durable goods, and acknowledges DTSC's effort to appropriately assign the regulatory obligations of assemblers to a lower tier in the responsible entity hierarchy. Nevertheless, the SCP Regulations miss the mark regarding the importation of assembled complex durable goods and their components.

Assemblers of complex durable goods sometimes may import the components that they assemble and/or in some cases may 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. Yet, if such assemblers are considered "importers," they will be more likely to be called upon to conduct the sophisticated and resource-intensive alternatives analyses for the assembled products or components that they import. It is unrealistic to assume that these entities can acquire and maintain the level of chemical ingredient knowledge which DTSC apparently believes is readily available.

If the goal of the responsible entity hierarchy is to ensure that the most knowledgeable entity conducts the AA, then the SCP Regulations in their current form fail to achieve it. The Coalition therefore urges DTSC to adopt all of the following revisions (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 current proposed 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.

III. THE SCP REGULATIONS MUST CLARIFY THE ALTERNATIVE ANALYSIS THRESHOLD EXEMPTION

The Coalition acknowledges the changes to DTSC's treatment of the "Alternatives Analysis Threshold" ("AAT") Exemption, e.g., including intentionally added ingredients within its scope. However, many uncertainties remain and DTSC must clarify its approach to this component of the SCP Regulations.

At the outset, the Coalition makes one more attempt to urge DTSC to adopt a clear numerical value to the AAT, such as 0.1%. A "hard" number approach has been successfully used in the global regulations from which DTSC itself has drawn inspiration. A "hard" number provides clarity and certainty to the regulated community and vastly improves supply chain communications regarding product and ingredient specifications. Such clarity and certainty are key factors to the success of DTSC's program.

In addition, the continued inclusion of contaminants as a category of chemicals targeted under the overall SCP Regulations is the wrong approach for achieving the goals of DTSC's proposed program. Targeting contaminants results in confused priorities for eliminating "chemicals of concern" in California commerce. In a program as broadly scoped as this one, it is a better investment of resources to target intentionally added ingredients. Targeting contaminants in any manner also threatens the viability of recycling efforts and undermines other legitimate approaches to protecting the environment and promoting sustainability. Had sound, science-based reasoning been the primary driver for an effective regulatory solution, this proposition would be self-evident. Otherwise, the SCP Regulations may the first regulatory program in history that discourages reuse, recycling and recoverability. The Coalition cannot discern any rationale justifying such a result.

Beyond that, the Coalition is very concerned that the Proposed Regulations specify no criteria at all by which DTSC will develop AATs. No member of the public has any understanding of how DTSC will implement this aspect of its program. This is far from the transparent process that DTSC has aimed to create in the SCP Regulations and that is mandated by statute under Health & Safety Code section 25253(c). ***DTSC must identify objective, science-based criteria for developing AATs, and must allow the public another chance to provide input on those criteria via another round of public comments.***

Finally, the Coalition remains concerned about the viability of using the Practical Quantitation Limit ("PQL") as an AAT alternative for contaminants. PQLs are a moving target. They depend on the analytical method, the instrumentation, and even the laboratory in which a PQL is developed. PQLs rely primarily on the substrate being tested. Reliance on PQLs as AATs will cause inconsistent regulatory outcomes affecting responsible entities manufacturing, importing, assembling and/or selling the same Priority Products. Relying on a PQL based on the capability of a testing methodology, rather than the reality of testing a sample's unique

properties, continues to highlight that a science-based understanding and approach to the SCP Regulations is lacking. If PQLs are to be used at all as a component of AATs, they should set a widely accepted, science-based floor, rather than the cap, for the level of contaminants in Priority Products.

IV. THE PROPOSED PUBLIC COMMENT PROCEDURE FOR AA REPORTS STILL IS DEFICIENT

The Coalition understands that, through the public comment process set out in proposed Section 69505.8, DTSC seeks to establish a transparent quality assurance procedure for Final and Abridged AA Reports that shifts some burdens away from the agency. The Coalition also acknowledges DTSC's revisions to the public comment process for AA Reports, so that DTSC takes the lead role in collecting and reviewing public comments, rather than the private responsible entity. This lead role is the correct and appropriate one for any regulatory agency. However, the revisions to Section 69505.8 do not go far enough because the responsible entity, rather than DTSC, must respond to public comments via an Addendum.

The Coalition cannot find any precedent for a California public comment process in which a regulated private entity, rather than the regulatory agency, directly responds to public comments in a regulatory proceeding like the one being proposed. This procedure is not a lawful one under the Administrative Procedures Act and is contrary to Health & Safety Code section 25253(c) (requiring that tools for evaluating chemicals of concern be "in a form that allows ease of use and transparency of application"). DTSC must revise Section 69505.8 so that DTSC, and not the responsible entity, responds to public comments.

Proposed Section 69505.8 also fails to establish any criteria by which DTSC will filter what public comments warrant a response. It falls short of the statutory mandate that the tools for evaluating chemicals of concern be "in a form that allows…transparency of application." *See* Health & Safety Code section 25253(c). ***DTSC must identify objective, science-based criteria for reviewing and responding to public comments on Final and Abridged AA Reports, and must allow the public another chance to provide input on those criteria via another round of public comments.*** In this regard, DTSC must provide more than 15 days for comments on a proposal that will have such an extensive potential impact on the AA process. Indeed, this current 15-day comment period was insufficient to fully digest this new approach.

Finally, the Coalition remains concerned that this public comment procedure establishes an AA process with no finality discernible at the front end of the AA exercise. AAs already will be resource-intensive and time-consuming to prepare. The proposed public comment proceeding at the back end of the AA process will add more uncertainty and will increase the resources and time to necessary to finalize AAs – with as-yet-unknown benefits, if any.

V. THE REVISED DEFINITION OF "REPLACEMENT CANDIDATE CHEMICAL" AND "REPLACEMENT CHEMICAL" MUST BE CLARIFIED

Proposed Section 69501.1(a)(59) is incomprehensible. That section now defines "Replacement Candidate Chemical" and "replacement chemical" completely opposite to its original meaning. In light of the significant impact of this definition on implementing the Proposed Regulations and, particularly, the AA process to be undertaken by responsible entities, DTSC must revise the definition to make its meaning clear and must provide the public with a further opportunity to comment on the revised definition. If DTSC keeps the definition as is, DTSC must explain its rationale in detail and provide illustrations of its application in DTSC's final statement of reasons. This is critical for regulated entities to properly understand and implement the program's requirements.

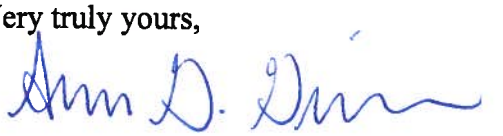
VI. OTHER ISSUES

Beyond what is described above, the Coalition remains concerned that the implementation of the AA process is still unclear. Among other things, DTSC has not clarified whether the AA guidance materials it posts will be mandatory requirements, whether they will establish some sort of baseline level for AAs, or whether they are merely recommendations. *See* Section 69505. And there is little confidence that the AA process will be a disciplined, science-based one that still contains sufficient flexibility to appropriately encompass the vast spectrum of products it will address. The AA process apparently will be an iterative one, with each round revealing its strengths and weaknesses. As implementation of the SCP Regulations proceed, the Coalition strongly urges DTSC to heed the voices of those actually in the trenches and undertaking these AAs.

Finally, once again the Coalition expresses its disappointment in the piecemeal approach of this entire regulatory process. The fragmented process has made it difficult for members of the public, and members of the regulated community in particular, to provide meaningful input.

Thank you for this opportunity to comment on the Proposed Regulations.

Very truly yours,



Ann G. Grimaldi

AGG

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)
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February 28, 2013

VIA E-MAIL (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.[1] 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.

[1] *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. 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) 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.[2] 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~~.

[2] 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 ± 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 copyt 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.[3] 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.

[3] 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.

1 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.

Thank you again for this opportunity for the Coalition to comment on the Revised SCP Regulations.

Very truly yours,

Ann G. Grimaldi

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October 10, 2012

VIA E-MAIL (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 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;

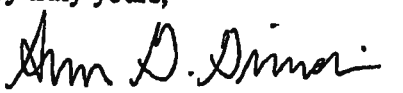
c. The amount of time that the Chemical(s) of Concern in the product is/are in contact with the body of the intended user during reasonably foreseeable use of the product; and

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.

Thank you again for this opportunity for the Coalition to comment on the Regulations.

Very truly yours,



Ann G. Grimaldi

Attachments

cc: Matthew Rodriquez, Cal/EPA Secretary (w/ attachments, via first class mail and email: 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)
Jeff Wong, Chief Scientist (with attachments, via email: jwong@dtsc.ca.gov)
Krysia von Burg, Regulations Coordinator (with attachments, via first class mail and email: gcregs@dtsc.ca.gov)

April 25, 2013

Debbie Raphael, Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95812-0806

Dear Ms. Raphael,

We are pleased that DTSC is finally bringing the SCP regulation-writing process to closure and will move to implementation. On behalf of BizNGO, we have the following comments on the Safer Consumer Product Proposed Regulations, R-2011-02 (April 2013):

§ 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.~~

DTSC's decision to include this definition of "economically feasible" means that there will be no public opportunity to review this section of an AA. The DTSC definition of "economically feasible" is inconsistent with, or certainly not supportive of, public review of AAs as economic feasibility. This means a key criterion in the evaluation of alternatives will be judged by criteria that will be blocked from public review by confidential business information claims. Furthermore, the definition of economic feasibility complicates any effort on the part of industry consortia to submit AAs – as competitors will not want to share this information, assuming the sharing of such information among competitors is even legal.

§ 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.

The failure to specify a time period for updating of the list means that DTSC cannot be held accountable for updating the Candidate Chemicals List. The likely outcome of this failure is that the list will quickly become outdated.

§ 69505.6. Alternatives Analysis: Second Stage

BizNGO supports the revised streamlining of (a)(1) Adverse Impacts and Multimedia Life Cycle Impacts.

BizNGO is still concerned with (a)(3) Economic Impacts and recommends the following change:

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.)

§ 69505.8. Public Comments on AA Reports.

BizNGO supports the public review of the "Final AA Report" and "Abridged AA Report", and recommends adding back in the public review of the "Preliminary AA Report." Preliminary AAs are a critical step in the AA process, including the identification of alternatives as well as the screening out of possible alternatives. The deletion of the preliminary AA report removes a key step in providing outside eyes on the direction of an AA. The selection of alternatives to review and the initial assessment of hazard traits are significant steps in an AA. Now review of these evaluations will only be performed on the final AA Report – a point in time in which the preferred alternative(s) is/are close to being set for the responsible entity.

§ 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 …

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.

Sincerely,

Mark S. Rossi, PhD
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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.

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April 25, 2013

Ms Jackie Buttle
Acting Regulations Coordinator
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Comments on Regulations for Safer Consumer Products Department – April 10 Additional Post-Hearing Changes
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 earlier comments submitted by Boots on the Proposed Regulations for Safer Consumer Products. We do, however, wish to draw your attention to the following additional comments concerning the Additional Post-Hearing Changes made to the Proposed Regulations:

Sec. 69505.8: Public Comments on AA Reports

The Additional Post-Hearing Changes now provide for public comment after a Final AA has been submitted rather than after submission of the Preliminary AA, and this change could negatively impact business-planning cycles. A responsible entity is likely to begin work on an alternative product during the AA development process, and the ability to address potential public concerns at the Preliminary AA stage provides a firmer basis to plan for product launch around submission of the Final AA. Now a responsible entity not only faces uncertainty as to the timing of the ability to place an alternative product into the stream of commerce in California, there is also uncertainty as to whether further development work will be required on the alternative product based on the DTSC's review of public comments submitted on the Final AA. We would note that expediting the launch of an alternative product would be in the best interests of the public and the fundamental regulatory purpose of the Proposed Regulations.

Sec. 69503.5(c) Alternatives Analysis Threshold

The Additional Post-Hearing Changes raise an issue as to the fundamental purpose of this section of the Proposed Regulations. If the chemical of concern in a Priority Product meets the Alternative Analysis Threshold provision, then the product is exempted from

the AA process. The exemption apparently would be granted because the chemical of concern would be present at a level that does not pose a health concern to the public. If that were the basis for the exemption, then logic would dictate that the product containing the chemical of concern at a level that does not pose a health concern should also be exempted from the Priority Products List – but that is not the case. We therefore recommend that the Proposed Regulations be further amended to exempt from the Priority Products List products with chemicals of concern that meet the Alternatives Analysis Threshold provision.

Sec. 69501.5. (b)(3) - Availability of Information on the Department's Website.

The Additional Post-Hearing Changes raise an issue as to the need to further amend the Proposed Regulations to ensure the removal from the DTSC's website of information such as the name and address of a company whose product was exempted from the AA process because the chemical of concern met the Alternatives Analysis Threshold - or the company placed into the stream of commerce in California an alternative product pursuant to an approved Final AA that does not require Regulatory Response requirements. Failure to do so would result in a situation where a company that complied fully with the requirements of the Proposed Regulations – once finalized – would still in effect be penalized because it would continue to be publicly and incorrectly identified as marketing a Priority Product.

69506.1. Applicability and Determination Process (for Regulatory Responses)

The Additional Post-Hearing Changes also raise an issue as to the need to further amend the Proposed Regulations to ensure that a product is explicitly exempted from the Regulatory Responses provisions of the Proposed Regulations in the case where the chemical of concern in a Priority Product meets the Alternative Analysis Threshold provision. The current Regulatory Responses provision is unclear in that regard.

Sincerely,

Ansis M. Helmanis

cc: Steve Lloyd, CEO, Boots Retail USA

CPSC
California Product Stewardship Council SM

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Sacramento, CA 95811
916-706-3420

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April 22, 2013

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

RE: CPSC SUPPORT of 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 February 25, 2013, on the previous version of the regulations, to ensure the program sufficiently captures HHW products and the manufacturer's end-of-life management plans allow for public stakeholder input.

We strongly support the proposed regulations, and urge DTSC to move forward with implementation of the Safer Consumer Product Regulations.

However, in order to ensure the end-of-life management programs established under these regulations are effective and transparent, we urge DTSC to address the following issues during the implementation process:

(1) In order to ensure the end-of-life management programs have meaningful and reasonable performance goals, we urge the Department to ultimately establish the performance goals, in consultation with the manufacturers or stewardship organizations and affected stakeholders. With any product stewardship program, the performance goals should be established by the State, and the manufacturers/stewardship organizations identify how to attain the performance goals in their stewardship plans, and report on their progress annually.

(2) In order to support resource conservation and highest and best use of materials, the end-of-life management programs should support the waste management hierarchy, and encourage source reduction activities as well as beneficial use (e.g., energy recovery) of any hazardous materials which cannot be reused or recycled.

(3) In order to ensure full transparency, we strongly suggest the Department conduct annual reviews of the independent financial audits of the end-of-life management programs, to make certain that funds raised to implement these stewardship programs are not used inappropriately such as to fund litigation against the State.

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. We look forward to working with you as the Safer Consumer Product Regulations are implemented in California!

Thank you for your consideration.

Sincerely,

Heidi Sanborn

California Product Stewardship Council

CHANGE
Californians for a Healthy & Green Economy

COMMENTS ON THE
CALIFORNIA SAFER CONSUMER PRODUCTS PROPOSED REGULATIONS OF APRIL, 2013
April 25, 2013

CHANGE Coalition
Californians for a Healthy and Green Economy

Californians for a Healthy and Green Economy (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, environmental, and occupational health. We have closely tracked the development of the DTSC's regulations to implement a Safer Consumer Products program under the authority of AB 1879 from the beginning. We are grateful DTSC has provided CHANGE the opportunity to provide the public interest perspective of our member organizations on this important effort.

Sincerely,

Kathryn Alcántar
CHANGE Campaign Director

As we near the end of a long process to develop these regulations (with the current estimated effective date 2.75 years late), we hope that DTSC will now move expeditiously to finalize the rules governing the Safer Consumer Products (SCP) program. It is past time to get this started and see how it works. As we monitor the program's progress, we will not hesitate to go to the legislature to work for improvements if they become necessary.

The current SCP proposal has significant weaknesses which we have noted before. CHANGE takes note that DTSC did not incorporate many of our suggestions in its development of these regulations, including in the last round. But these are important recommendations that would enable the SCP program to better achieve its potential to protect human, environmental, and occupational health.

With this letter, CHANGE incorporates by reference all of its prior comments on the draft SCP regulations, including but not limited to those comments submitted on formal drafts of the regulations dated October 11, 2012 and February 28, 2013; and those comments submitted on informal drafts dated December 30, 2011 and May 28, 2012. We attach these four letters here. We also incorporate by reference CHANGE comments submitted to DTSC on the plans to implement AB 1879 prior to the Brown Administration in letters dated 10/23/07; 1/16/09; 4/23/09; 5/29/09; 8/18/09; 9/28/09; 10/19/09; 11/4/09; 6/4/10; and 1/25/11.

Below, we provide two examples of the most significant weaknesses in the proposed SCP regulations; raise two issues from the January 2013 draft; and point out what we believe to be an editing error that needs to be corrected.

Contact: Kathryn Alcántar, CHANGE Campaign Director - changecalifornia@gmail.com or 510.655.3900 x315

"Candidate Chemical" list

One important example of where the regulations fall short that we must again emphasize is the addition of a "Candidate Chemicals" list. This is a significant weakening of the regulations, and goes against the language of the statute.

We are still perplexed as to why DTSC has changed the name of the list of the initial 1200 chemicals to "Candidate Chemicals" from "Chemicals of Concern." As we have said in previous comments, these 1200 chemicals have been identified as hazardous by respected authoritative bodies – this is not in dispute. Calling them "Chemicals of Concern" is scientifically accurate.

Moreover, the "Chemicals of Concern" language has been a part of every draft of the regulations until this unexpected 11th hour change.

"Chemicals of Concern" is the language used in the authorizing statute. We had thought that DTSC was building a program that was legally defensible by paying close attention to the language in the statute.

The central rationale for a large Chemicals of Concern list is that it will ignite market forces that will proactively remove listed chemicals from consumer products because manufacturers, importers or retailers would not want to sell a product that contained a chemical that was identified by California as hazardous and therefore "of concern."

In addition, it would catalyze innovation and create green jobs as entrepreneurs devote resources to bringing safer chemicals to market.

This was supposedly one of the key goals of the program - stimulating the market to act because it would effect change more quickly, and wouldn't cost DTSC anything. It was a smart strategy that acknowledged the extreme shortfall of resources that DTSC has to implement the program.

By this last-minute action, DTSC is saying that "hazard" is not a "concern" for the health of the public, the environment, or workers. The Department is deceiving the public about the threats to health from these chemicals, and denying the consumer the opportunity to use the list as a guide to buying inherently safer products.

DTSC is ensuring that the goal of removing hazardous chemicals from consumer products will take much longer and do much less. As we have commented before, this change is a serious misstep by the Department and the Brown Administration, and puts a cloud over the entire program. Sadly, it must be seen as a capitulation to lobbying by the chemical industry.

Starting the Safer Consumer Products program with a 1200 Chemicals of Concern list is the best way to launch this program with some momentum, and generate immediate action that will protect Californians.

We again strongly recommend that the initial list of 1200 chemicals be referred to “Chemicals of Concern.”

Definition of "Economically Feasible"

§ 69501.1 (a)(29)
Current language defining "economically feasible":
"Economically feasible" means that an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin."

This definition of "economically feasible" essentially gives a responsible entity the freedom to opt out of replacing a chemical of concern by simply stating that its operating margin will be significantly reduced. How will DTSC define a "significant" reduction, and how will it be measured and validated? Does DTSC expect to audit a responsible entity's internal documents to compare profit margins?

This definition is an invitation to responsible entities to continue with business as usual. It will do nothing to ensure that the public, workers, and the environment experience significant reductions in their exposures to hazardous chemicals of concern. Instead, the message is: profit lines cannot be touched, but the tab for society's compromised health will be borne by the public and government.

DTSC should ensure that "economically feasible" fairly accounts for the externalized costs that toxic chemicals always bring. But the Department has failed to do so with this flagrant loophole and give-away.

Merits Review of Petitions

§ 69504.1 (b)(5)

This new language from January 2013 inserts a new criterion into the decision-making matrix for delisting an entire list of chemicals. It provides another opportunity for opponents of a comprehensive list of chemicals, whether "candidate chemicals" or "chemicals of concern," to inappropriately challenge the work of authoritative bodies. If nothing else, it will inject another layer of review into the program which will hamper DTSC's ability to move forward. We recommend this language be stricken from the regulations:

"For a petition to remove an entire existing chemicals list from the lists specified in section 69502.2(a), whether the entity responsible for the underlying list still conducts its scientific assessments of chemicals in a manner that is substantially equivalent to, or as rigorous as, the manner in which it conducted its scientific assessments at the time of the initial adoption of these regulations."

Priority Products Listing Process

§ 69503.5 (a)(2)
The language here is new since the January 2013 draft of the regulations. It requires DTSC to establish a Priority Products list through rulemaking under the Administrative Procedure Act. The result of this provision will be to dramatically slow down the listing process.

Previous versions of the regulations required a public hearing but not formal rulemaking. This new provision would waive the requirement for DTSC to hold a public workshop for the initial list of Priority Products but still go through formal rulemaking.

DTSC should retain the prerogative to list Chemical of Concern-Priority Product combinations based on the criteria already included in previous drafts of the regulation. Requiring the listing of a Priority Products to be developed under the APA is unnecessary and a recipe for significant further delays in protecting the public, workers, and the environment from potential adverse effects from hazardous chemicals.

Definition of "Import"

§ 69501.1 (a)(38)
In what we assume must be an editing error, the current definition of "import" incudes this language:

"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.

From our reading, this means that anyone located in the United States could order a product manufactured abroad and this by itself would exempt the product.

We suggest aligning the language in § 69501.1 (a)(38) with the language in § 69501.1 (a)(39) re "Importer" so it would read:

"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 solely for use in that person's workplace if that product is not sold or distributed by that person to others."

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CHANGE
Californians for a Healthy & Green Economy

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

Asian and Pacific Islander Obesity Prevention Alliance * Bayview Hunters Point Community Advocates * Black Women for Wellness * Breast Cancer Action * Breast Cancer Fund * California Healthy Nail Salon Collaborative * California Latinas for Reproductive Justice * California Pan-Ethnic Health Network * Californians Against Waste * Californians for Pesticide Reform * Center for Environmental Health * Center for Race, Poverty and Environment * Clean Water Action * Coalition for Clean Air * Commonweal * Communication Workers of America- District 9* Communities for a Better Environment * East Yard Communties for Environmental Justice * Environment California * Environmental Working Group * Forward Together (formerly Asian Communities for Reproductive Justice) * Green Schools Initiative * Green Science Policy Institute * Healthy 880 Communities * Healthy Child, Healthy World * Healthy Children Organizing Project* Instituto de Educación Popular del Sur de California * Just Transition Alliance * Making Our Milk Safe (MOMS) * Movement Strategy Center * Pesticide Action Network North America * Physicians for Social Responsibility – Los Angeles * Science and Environmental Health Network * Silicon Valley Toxics Coalition * United Steel Workers – Local 675 * Worksafe

Contact: Kathryn Alcántar, CHANGE Campaign Director - changecalifornia@gmail.com or 510.655.3900 x315 www.changecalifornia.org

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

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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 <u>than the general population, due to the nature of their occupation and specific duties.</u>

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 reasonably 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 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 <u>or relied upon or referenced in any submission to</u>

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 3rd 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.

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CHANGE
Californians for a Healthy & Green Economy

COMMENTS ON THE
CALIFORNIA SAFER CONSUMER PRODUCTS
DRAFT REGULATIONS OF JULY 27, 2012

October 11, 2012

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 Campaign Director

Contact: Kathryn Alcántar, CHANGE Campaign Director - changecalifornia@gmail.com or 510.655.3900 x315

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. 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 chemical regulations are attempting to incorporate cumulative exposures, which are a key public health concern and 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, in which toxic chemicals can be replaced with non-toxic alternatives. Such an approach focuses on public, occupational, and environmental health, maintaining the essential concept of primary prevention.

Two components of the draft proposal are essential in our view and must be retained. The first is a large Chemicals of Concern (CoC) list that is unranked. The second is the requirement that the Department set science-based, case-by-case alternative analysis threshold levels. Detailed comments about these two issues are below.

However, as we have observed before, some portions of the draft regulations contain deep flaws that need to be fixed. In particular, there are two critical aspects to the program that require improvement: the standard of causation DTSC is requiring of itself to consider action; and the lack of transparency and oversight in the generation of Alternative Assessment reports. Our detailed comments about these issues also appear below.

Beyond these content issues, funding must be found so DTSC can carry out the program. 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 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. However, as a first step, we urge DTSC to build permitting and licensing fees, which would not rely on legislative action, into the regulations.

Furthermore, 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.

CHANGE's view of the draft regulations is that there are important improvements that still need to be made so they can be as effective as possible. But it is now time for DTSC to quickly bring this program online and see how it works in the real world.

A comprehensive Chemicals of Concern list is critical to the SCP program's success.

CHANGE strongly supports DTSC's plan to post a robust list of Chemicals of Concern (CoC) within 30 days of the effective date of the regulations that relies on the work of authoritative science bodies. 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.

The language of AB 1879 explicitly requires DTSC to identify chemicals of concern in Section 25252 (a). There is no mention in the statute of a category called "chemicals under consideration" and therefore CHANGE believes retaining the term "chemicals of concern" in the regulations is appropriate and legally required.

A large CoC 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 CoC 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, in fact it represents 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 health and safety effects before reaching the market.

CHANGE also strongly supports DTSC's intent not to rank chemicals on the CoC 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.

DTSC should specify that when any lists it relies on are updated, the updated list becomes the version that DTSC uses in its own CoC list.

We support the addition of the Priority Chemicals list of the California Environmental Contaminant Biomonitoring Program.

The proposed CoC list needs some additions. DTSC should ensure that all hazard traits identified by OEHHA are captured in its CoC list, including neuro-developmental hazard traits.

DTSC should also augment the list with substances of particular relevance to workers and consumers: asthmagens, respiratory sensitizers, skin irritants/sensitizers. OEHHA lists these hazard traits already (e.g., Chapter 54, s. 69403.16 Respiratory Toxicity) and there are lists available from 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. California already plans to follow suit, adopting the federal changes at a minimum.

For asthmagens and other sensitizers:

- 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 -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
  - http://www.cleanproduction.org/library/greenScreenv1-2/Green_Screen_v1-2_Supporting_Lists.pdf

Other lists CHANGE recommends including are the following:

- Washington State Department of Ecology *Reporting List of Chemicals of High Concern to Children* at 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;
- California's 303(d) list of impaired waterways: http://www.waterboards.ca.gov/water_issues/programs/tmdl/303d_lists2006_epa.shtml.
- The Skin Disease portion of the Haz-Map database from the U.S. National Library of Medicine, http://hazmap.nlm.nih.gov/types-of-diseases; and
- The Green Chemistry & Commerce Council's *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

We are alarmed that the proposed list of CoCs does not include the 303(d) list of the federal Clean Water Act for contaminants impacting California waterways. 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. 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 CoC/Priority Product combinations. Without it, we do not see a pathway for DTSC to address water quality concerns. Furthermore, the regulations should indicate that Department will review the list each time it is updated by the California State Water Resources Control Board.

§ 69502.2(b)

In addition, it is important to provide a mechanism for additions to the CoC 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. As written in the current draft, CHANGE supports DTSC having the authority to identify new CoCs based on their hazard traits or environmental or toxicological endpoints. 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.

§ 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 CoC list.

§ 69502.3(a)

DTSC needs to specify how often the CoC list will be formally updated. As currently written, DTSC will do

this "periodically." CHANGE urges that the CoC list be updated at least every two years.

§ 69502.3(c)
CHANGE supports the opportunity for formal public input on proposed revisions to the CoC list.

CHANGE strongly supports the removal of default alternative analysis (*de minimis)* threshold exemptions.

One of the most important improvements in the new proposed regulations is the removal of the alternative analysis threshold (AAT), or what was termed a "*de minimis*" level in previous drafts. 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 are 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 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 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 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 chemical-specific alternative analysis thresholds for each product category 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.

Illegal standard of causation language

The proposed regulations employ a burden of proof for causation that is higher than that specified by AB 1879. That burden should be conformed to the requirements of AB 1879.

We believe that DTSC has strayed so far from the clear provisions of AB 1879, the intent of the law and the Green Chemistry Initiative and the earlier drafts of the regulations that we request that DTSC provide a full written explanation of its decision on this issue, including answers to the six questions we pose below, at the end of this section.

This erroneous causation standard carries enormous consequences for the program. It will in practice disable the program from its goal of encouraging industry and society to begin to avoid early warnings of harm. It also causes the regulations to diverge from DTSC's goal of making them legally defensible. This destabilizes the program because not only may NGO's legal challenge the validity of the regulations, but one can expect an individual industry to do so as well whenever DTSC attempts to enforce the regulations or a regulatory response against that industry. Moreover, the erroneous causation standard destabilizes the initial COC list by potentially opening an avenue for removing chemicals from that list. For all of these reasons, we hope DTSC will take this issue very seriously.

AB 1879 explicitly requires DTSC to establish a process for identification of chemicals of concern that must include evaluation of the "potential" effects of a chemical on sensitive subpopulations, including infants and children, HSC § 25252 (a)(3), and evaluation of the "potential" for exposure to the chemical in a consumer product, HSC § 25252(a)(2). It requires DTSC to develop a process for evaluating alternatives to a COC that must include evaluation of all the "potential" hazards of the alternatives. HSC § 25253(a)(2); 25253 (a)(2)(K). Finally, AB 1879 instructs DTSC "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern" in fashioning a regulatory response after the alternatives assessment process is complete. HSC §25253(a)(1). The requirement for DTSC to determine how best to limit exposure or reduce the level of hazard is consistent with the concept of reducing even potential exposures and hazards wherever reasonably possible.

Thus, AB 1879 requires DTSC to develop a process to evaluate the "potential" hazards of and "potential" exposures to chemicals when identifying them as COCs, and then a process to evaluate the "potential" hazards of any potential alternatives before DTSC may then fashion a regulatory response to best limit exposure or reduce the level of hazard.

In contrast to these unambiguous requirements of AB 1879, the objective of the current regulatory proposal is to evaluate and respond only to hazards that a chemical is shown to have the "ability" to cause or contribute to. The "potential" standard of earlier draft regulations has been replaced by the "ability" standard virtually throughout this version. As one example, §69502.2(H)(b)(1)(A) provides that in order to list a chemical as a chemical of concern, DTSC must consider the "ability of the chemical to contribute to or cause adverse public health and/or environmental effects." (This and similar standards of causation used at various places in the proposed regulations that recite or imply the word "ability" are referred to herein as "ability" standards of causation.) "Ability" rather than "potential" is now used in the provisions relating to whether a chemical can be identified as a COC (see, for example, p. 23, line 12; p. 23, line 23; p. 23, line 34; p. 23, line 40). It is used in the provisions relating to identification of a priority product (see, for example, p. 25, line 32; p. 26, line 2; p. 26, line 5; p. 26, line 17; p. 27, line 9; p. 27, line 27; p. 27, line 27). It is used or implied in the provisions relating to preparation of an alternatives analysis (see, for example, p. 42, lines 3-7; p. 42, lines 14-16; p. 43, lines 8-12). It is similarly implied in the very definition of a safer alternative (see p. 13, line 14). It is explicitly used in

some of the provisions relating to regulatory responses (see, for example, p. 55, line 13; p. 55, line 38) and effectively by implication in others (see, for example, p. 52, line 8; p. 52, line 12; p. 54, line 5).

In the paragraph above we have sometimes said that a provision uses the "ability" standard by implication. Let us explain that. Take, as an example, the regulatory response section §69506(a). That section provides that DTSC shall implement regulatory responses designed to protect public health and the environment and maximize use of alternatives of least concern. There is no explicit reference to the term "ability" (or "potential" or any other particular standard) in that section. But, if COC's and alternatives are identified and compared in AA's that consider solely evidence that meets the "ability" test, with any lesser evidence showing only "potential" adverse effects discarded from the analysis, then any regulatory response by DTSC could only protect public health from adverse effects from COC's or alternatives that can be shown to meet the "ability" test. DTSC will not be able to protect the public or environment from "potential" hazards because DTSC will have no evidence of any such potential hazards in the record for it to consider. Similarly, in maximizing use of alternatives of least concern, the only evidence DTSC will have before it in AA Reports will be any evidence that the COC and alternatives meet the "ability" test, with all lesser evidence of potential harm removed from its consideration. Thus, the "ability" test is impliedly employed in this section.

The same issue arises in §69506(b), which instructs DTSC to focus on "avoidance or reduction of adverse impact or exposure" by a COC in a product. Again, the section does not explicitly recite the "ability" test. But the only evidence of any adverse impact or exposure that will be present in the AA Report being considered by DTSC will be that rising to the level of meeting the "ability" test. Evidence not rising to that level will not be part of the record for DTSC to consider. Again, the "ability" test is impliedly employed in this section.

While the proposed regulations use the "ability" test explicitly in numerous places, the impact of that test is felt even more broadly and, indeed, infects every aspect of the proposed regulations. The pervasive use of the "ability" standard explicitly and by implication means that potential hazards cannot be considered by DTSC in identifying COCs, by alternatives assessors comparing alternatives to COC's, or ultimately by DTSC in fashioning a regulatory response. This approach, which contrasts with that mandated by AB 1879, would not fulfill the requirements of the law.

The bottom line: the use of the "ability" standard of causation in the proposed regulations is illegal under AB 1879.

One potential contradiction in the proposed regulations in particular should concern DTSC. That is that many of the authoritative bodies relied on for identification of the initial COC list very likely use a standard that is less stringent than the "ability" test of these proposed regulations. Does use of the "ability" standard in the regulations undermine DTSC's ability to rely on those authoritative bodies? Will it be used by industry to have COC's removed from the initial COC list where the evidence used by an authoritative body does not rise to the level of the "ability" test? How can DTSC justify these contradictions?

There is an enormous difference between a chemical that presents a "potential" hazard and one that has the "ability" to contribute to cause an adverse effect. The scientific reality of the impact of toxic chemicals on the environment and human health is that often the best evidence available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. The difference between the standards is that between acting on early warnings of harm and waiting for proof of harm before acting. The former is the goal of all modern chemical policy reform efforts, including the Green Chemistry Initiative. The latter represents the discredited approach urged and sought by the chemicals industry as it seeks to externalize the damage from its chemicals onto society. As compared to a "potential" standard,

because it would remove early warnings of harm from consideration under the regulations, the "ability" standard disables DSTC from acting on early warnings of harm and therefore is essentially deregulatory in effect.

There was a time in the not too distant past when DTSC clearly understood this issue and the requirements of the law. Draft proposed regulations as recent as the October 31, 2011 version, after 3 years of drafts and regulatory development, were directed to "potential" adverse effects. It is only recently under the Brown administration that DTSC has lost its way on this issue.

We understand there to be several reasons offered for adopting the "ability" standard. One is that the "potential" standard could allegedly be met by any chemical, even those for which there is no data at all. We disagree. Establishing that a chemical has the "potential" to exhibit a hazard trait requires a body of reliable information. In our view, words other than "potential" can carry the same meaning, such as the word "may," as in the "may present" standard of TSCA Sections 4 and 5. In the case of TSCA, no one has ever suggested that TSCA's "may present" standard can be satisfied in the complete absence of evidence.

DTSC should be clear that use of the "potential" standard is not the same as switching the burden of proof onto industry (which would mean that chemicals are assumed hazardous until proved otherwise). A complete absence of information cannot establish that a chemical is potentially hazardous. The "potential" standard is a lower, but not a switched, burden of proof.

To remove any confusion about this issue, if that is the problem, we suggest DTSC provide a simple definition of "potential" to exhibit a hazard trait and clarify that any finding of a "potential" hazard requires reliable information to substantiate the finding.

A second reason suggested is that the term "ability" is allegedly "less ambiguous" than the term "potential." We emphatically disagree. There is nothing inherently more ambiguous about the term "potential" than about any other term defining a burden of proof. Even TSCA contains legal standards such as whether a chemical "may" present an unreasonable risk. See TSCA, Sections 4, 5. Standards such as "may present" or "potential" are not vague as compared to more stringent standards such as "ability" or "beyond a reasonable doubt"; they establish lower burdens of proof but are not more vague. Whatever standard is chosen, whether "ability" or "potential," there will undoubtedly be disputes over its precise meaning until some content is given to it through experience or a clear definition is provided. But there is nothing inherently more vague about "potential" as compared to "ability."

Indeed, just the opposite. Substantial confusion has emerged as to exactly what is meant by the "ability" standard. If anything, it is the vaguer term. Does it mean that a chemical must be proved to be able to cause adverse effects under any circumstances, regardless of whether those circumstances exist in the real world (such as through high dose tests)? Or does it mean that a chemical must be shown to be able to cause adverse effects as it is used in practice? In law, this is the distinction between specific and general causation – which is meant by the "ability" standard? DTSC should ask itself and answer the questions: has BPA been shown to have the "ability" to contribute to or cause an adverse effect? Have brominated fire retardants? Has mercury? Is DTSC going to be able to regulate any chemical hazard under this standard?

For all these reasons, CHANGE believes that the "ability" causation standard is illegal under AB 1879, and is also bad policy that flies in the face of the purpose of the California Green Chemistry Initiative. The regulations should be reoriented toward "potential" hazards by pervasive substitution of the "potential" standard for the "ability" standard in at least the places identified above.

In the event that DTSC does not reorient the regulations to the "potential" standard, then CHANGE requests that the Department explain in writing the following:

a. Why does AB 1879 not require the regulations to employ the "potential" standard?

b. What standard does AB 1879 authorize and what is the evidence for that?

c. If the Department insists on adopting the "ability" standard, what is the legal basis for adopting that standard rather than some other standard that would provide more public health protection than the "ability" standard, such as a "reasonable likelihood" standard, "likely" standard or "probable" standard?

d. If the Department chooses to retain the "ability" standard, what is the policy basis for adopting it, including an explanation of (1) the balance the Department is seeking to strike between protecting public health / environment and vested commercial interests and (2) the reason it must be applied throughout the regulations rather than in some places but not others?

e. If the Department chooses to retain the "ability" standard, what exactly does it mean? Does it refer to the inherent ability of a chemical to cause an adverse effect, or to proof that the chemical does cause such effects as used in the real world, or to something else?

f. Do all of the chemicals on the initial COC list all meet the "ability" standard of causation, and if they do not, must they be removed from the COC list; and why or why not?

Minimize regrettable substitutions by prioritizing classes of chemicals.

The draft regulations may result in regrettable substitutions as companies switch out of chemicals of concern before their product is designated as a priority product. Past proposals for implementing regulations have included: (1) a no data, no market requirement for all or most chemicals in commerce; or (2) detailed, admittedly cumbersome reporting requirements anytime a CoC is altered in any product. The current regulations do not address this, although the large number of CoCs may help somewhat with this problem.

Prioritizing classes or groups of chemicals or products, rather than taking them up individually or relying on authoritative body listings, would minimize regrettable substitutions. DTSC should consider building in a mechanism to do this when appropriate.

We suggest that at the very least, DTSC should try to collect information about the extent of this problem to inform the design of future elements of the GCI. In these regulations, DTSC could and should develop regulatory provisions to help accumulate information as to whether and how often companies switch out of CoCs prior to entering the formal AA process. For example, companies could be required to report to DTSC if they switch out or reduce the amount of a CoC in any product once the CoC list is finalized. A simple, non-burdensome program could provide information of great value in the further development of the regulations.

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 note 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 commits 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) Page 23 line 16
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)(A)(1)(c) Page 25 line 38
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**.

§ 69503.5 (d) Page 32 line 26
CHANGE strongly supports this section so that if multiple Chemicals of Concern exhibit the same hazard trait and/or environmental or toxicological endpoint(s) that have been identified as the basis for the products being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such CoCs.

Environmental impacts are neglected in the first round selection of Priority Products and should be included.

CHANGE has consistently advocated that environmental endpoints be prioritized along with human health impacts when establishing both a Chemicals of Concern (CoC) list and choosing Priority Products. Our concern has been that environmental issues are often not as readily apparent or seen as urgent as hazard traits such as carcinogenicity or the known ability of a chemical to cause reproductive harm. However, environmental protection is critical for a variety of reasons:

- A healthy environment is essential to the overall well being of society and is in and of itself worthy of protection.
- Environmental impacts, such as those to wildlife and ecosystems, are often first indicators or early warnings of adverse impacts on human health and safety.
- Human exposure, including those that can result in serious health impacts, is often due to environmental exposure (as opposed to exposure by direct use of or contact with a product), such as through the air, drinking water, and contaminated food sources.
- Continued introduction of chemicals into the environment places heavy technical, regulatory, legal, and financial burdens on local communities and agencies that must meet certain environmental standards or be in violation of the law. For instance, investing in higher levels of wastewater treatment to remove the many toxic substances from today's consumer products would cost California's more than 300 treatment plants hundreds of billions of dollars and, in the end, may not be technologically feasible.

§ 69501.1 (19)(A)2. and **§69503.2(a)(1)(A)h.** In earlier comments to DTSC, CHANGE offered suggestions to ensure and strengthen the consideration of environmental endpoints for the CoC and Priority Products lists. We support the addition of "degradates, metabolites, and reaction products" in the definition of a chemical, and consideration of a CoC's ability to degrade, form reaction products, or metabolize into another CoC or chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

As already stated, CHANGE is deeply concerned by the omission of California's 303(d) list of impaired waterways and related contaminants. Other concerns regarding environmental endpoints include the following:

§ 69503.3 (g) CHANGE strongly opposes the language in this section and urges that it be stricken. There is no reason to restrict the universe of CoCs to be considered in the first round of the Priority Products categories as the program gets underway. In fact, by requiring that chemicals in consumer products on the initial Priority Product list(s) (those prior to 2016) meet criteria described in BOTH sections §69502.2 (a)(1) and (2), DTSC effectively ensures that water pollutants will not be included because there are no ecotoxicity lists that are equivalent to the human PBT and CMR lists described in section §69502.2(a)(1). Consequently, pollutants on the 303(d) list, solvents, metals such as copper or zinc, and other common surface water and groundwater contaminants will be omitted. If a chemical appears on the CoC list, this should be sufficient for a consumer product containing that chemical to be considered for prioritization.

What DTSC does in the first few years that these regulations are implemented will be critical to setting the stage for their future effectiveness and that of the Green Chemistry Initiative as a whole. For this reason, limiting the Priority Product list in this way is both inappropriate and sets a troublesome precedent for decision-making by future DTSC staff and leadership. It also substantiates concerns that many in the water community – public advocates and water agency personnel – have expressed over the years, namely that environmental concerns will not be addressed with adequate vigor. For these reasons, CHANGE strenuously urges DTSC to strike §69503.3(g).

§ 69501.1(a)(3)
It should be made explicitly clear that the definition of "adverse air quality impacts" includes both indoor and outdoor air quality impacts.

Occupational health and worker protection of workers must be more consistently incorporated into the regulations.

§ 69501(b)(2), Page 4, lines 17-21
This section of the draft exempts products placed into the stream of commerce "solely for the manufacture" of a consumer product exempted from AB 1879. There is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes certain exempt products, not all chemicals used in their manufacture. This is an example where workers, who should be granted equal protection in the regulations, would be exposed to CoCs that others would not. We strongly object to this section and recommend that it be deleted.

§ 69501 (b)(3) Page 4, lines 22 – 23
Workers in California face hazards related to the manufacture, storage, or transport of products in the state, regardless of where those products are eventually sold. Hence, the regulations must apply to all products manufactured, stored, or transported in California, whether they are sold here or not.

The ISOR argues that the regulations are meant to design "consumers" from harmful chemicals in products. But consumers are not only individuals – businesses are consumers as well, buying chemicals and other products for manufacturing purposes in the state.

CHANGE has consistently objected to this section that exempts products that are manufactured or transported in California, but not sold here. This will expose workers who make the products and communities through which the products are transported to hazards that the regulations are meant to prevent. Workers and fenceline communities are members of the public and entitled to equal protection from harmful substances.

Any product that is manufactured here, whether it is sold here or not, will have an impact on the environment and public health. This section as drafted subverts the statute's goal of incorporating life cycle thinking. Life cycle is defined in 69501.1 (a)(39) to include manufacture, transport and distribution. In 69503.2 (a)(1)(B)4.a., "manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices" as Product Prioritization Factors.

We support the earlier comments from GRSP member Julia Quint, who has pointed out the unethical nature of excluding a consumer product that is "passing through" California. She wrote: "In contrast to customers, clients and members of the public who may be exposed for short periods of time to low concentrations of consumer products when they are in workplaces on an infrequent basis, workers who use the products are typically exposed to much larger quantities, on a daily basis, for years."

§ 69501.1(a)(6), Page 6, lines 4-5
CHANGE supports the language that states, "Public health includes occupational health." This is consistent with the definition, understanding, and practices of public health.

§ 69501.1 (a)(22)(A), Page 8, line 32

DTSC should ensure that the definition of "Consumer Product" makes clear that chemicals and products used in the workplace, including bulk purchases, are included.

Add language under a new 69501.1(a)(22)(A)4. to read: Chemicals and products used in the workplace, including bulk purchases.

§ 69501.1(a)(53)(A)2., Page 12, lines 14-15
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 the home of places of employment."

§ 69501.5 (entire section) Pages 18 – 20)
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 (IIPPs) their employers must prepare.

Unfortunately, the information only will 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).

§ 69505.5 (f)(2)(B)
This section requires a description of how safeguards provided by other federal or state regulations were considered in AAs. DTSC should add language here that does not permit AAs to rely on outdated and inadequate occupational exposure limits in the development of a safer alternative chemical or product.

§ 69506.4, Page 54
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. They have as much right to know about hazardous chemicals and products as others, including other consumers.

Workers are appropriately included in the definition of "sensitive sub-populations" .

§ 69501.1(a)(58) Page 13 lines 19-25
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.

The wording in this section could and should be improved, however because 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.

We also believe women of child-bearing age should be 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 fathered by men who work in some occupations with high chemical hazards 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."

The draft regulations give preference to information that is already "available." Furthermore, prioritization and other decisions are influenced by, and are in fact dependent on, the current availability of safer alternatives. This sends the wrong signal to the marketplace and in fact runs counter to the goals of the SCP program by deterring innovation and the development of new alternatives. It could be interpreted to mean that no information implies a CoC is "safe." DTSC should not unnecessarily limit their decisions based on the availability of a safer alternative, especially in the regulatory response phase.

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, frequently lack the data sets that the definition of "safer alternative" could be interpreted to require.

There are many 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 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 hazards, not on the companies making the chemical or product containing the chemical to demonstrate it will not cause harm.

The SCP program should formally identify chemicals with little or no toxicity information as lacking adequate safety data. Furthermore, DTSC should use its call-in authority under AB 1879 to require the generation of new health and environmental data in order to accurately identify CoCs and safer alternatives and to make appropriate regulatory responses. DTSC should exercise this authority as early as possible in the program's implementation.

§ 69501.4(a)(3)
§ 69501.4(a)(4)
§ 69501.4(a)(3)(b)
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 DTSC's effort to obtain existing or new information is laudable, the language should be strengthened so it is a requirement for responsible entities. Throughout these sections, "request" should be replaced with "require."

§ 69502.2(b)(3)
This is an example where DTSC could, instead of merely considering "the availability of reliable information to substantiate the potential adverse impacts and exposures," require responsible entities to provide or produce the needed data for additions to the CoC list. This would reverse the burden of proof and bring more information forward sooner.

§ 69503.2(a)(2)
Rather than rely on availability of information, DTSC should use this as an opportunity to require responsible entities to provide or produce information needed to make an informed decision.

§ 69506.2(a),(b)
CHANGE strongly supports the language in these two sections that gives DTSC authority to require the provision or development of needed additional information. This information would be even more useful earlier in the process.

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 toxicity information can reasonably be considered CoCs 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" or non-toxic.

The draft regulations rely too often on an over-reliance 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 hazards as the highest priority. That is, if a substance is dangerous, this is 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 workplaces where workers still have to handle toxic chemicals and limiting harm is the most common solution, rather than eliminating a hazard. Moreover, safety standards are generally inadequate and often out-of-date.

Moreover, "containment" or "control" fails to drive the development and use of less toxic chemicals, one of the overarching goals of both the SCP regulations and California's broader Green Chemistry Initiative.

While 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, CHANGE has consistently advocated that engineering safety measures or administrative controls be viewed as *interim actions*, not permanent solutions to reduce danger to the public and the environment while inherently less hazardous alternatives are developed.

§ 69506.7 (a) Page 57
CHANGE recommends that any engineered safety measures or administrative controls imposed by DTSC in in this section be considered ***an interim action*** until a more sustainable solution is found.

Current language for § 69506.7 (a)
The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts.

Suggested language for § 69506.7 (a)
The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts <u>as an interim action while a solution to eliminate the hazard is found.</u>

§ 69501 (a) Page 4, lines 8-12
Current language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to limit exposure to, or the level of adverse impacts posed by, the Chemical of Concern in the product.

Suggested language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to <u>reduce the use of toxic chemicals</u>, or the level of adverse impacts posed by the Chemical of Concern in the product.

§ 69501.1 (a)(11)(D) Page 7 line 24

Current language: Any other change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

Suggested language: If Removal, Reformulation, or Redesign is not feasible, a secondary strategy of another change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

§ 69505.3 (b)(2)(A)1 Page 41, lines 30-35

Current language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of "alternative" under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce or restrict exposures to the Chemical(s) of Concern in the Priority Product.

Suggested language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of "alternative" under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product. If a responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, they should then seek to reduce or restrict the potential for release of the Chemical(s) of Concern, leading to human or environmental exposures, as an interim action until a less or non-hazardous alternative is developed.

Definition of "technically and economically feasible alternative"

We agree with others who have asked for greater clarification about the definition of "technically and economically feasible alternative," and that they should be defined and evaluated separately.

If something is technically possible, this should be the standard for whether it should be considered.

§ 69501.1 (a)(59) Page 13, Line 27-32

CHANGE strongly objects to the language in the definition of "technically and economically feasible alternative." Even if "significant reduction in a manufacturer's operating margin" and "meeting consumer demand" are defined, it requires numbers that can easily be manipulated to give an off-ramp to any responsible entity.

We urge § 69501.1 (a)(59)(B) be stricken: "The manufacturer's operating margin is not significantly reduced."

We urge the language in § 69501.1 (a)(59)(A) be amended by deleting "and to meet consumer demand after an appropriate phase-in period." Requiring a company to demonstrate consumer demand would limit timely options for alternatives especially if companies request delays to conduct consumer research.

Definition of "functionally acceptable"

This definition suffers from the same flaw as the definition of "technically and economically feasible alternative." The current draft would enable a responsible 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)(31)(B) Page 9, Lines 35-36
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"

These important terms derive from AB1879. One goal in properly defining them is to ensure that they will reach complex nanomaterials in the event the Department identifies such materials as CoCs. Another is to ensure that the two statutory terms can both be used to identify chemicals of concern.

We appreciate the Department's response to our suggestions as to how to improve the definitions that were used in prior draft proposed regulations. The Department essentially has adopted CHANGE's recommendations, but with one discrepancy that can easily be fixed.

§ 69501.1(19)(A)(2)
The definitions currently provide that a chemical ingredient means "a substance comprising one or more of any **substance, element, ion, uncombined radical, degradate, metabolite, or reaction product**." The problem is that the terms in bold are now disconnected from the qualifiers that exist in the first part of the definition, and so are seemingly too broad and perhaps even essentially undefined.

We suggest that this can be easily fixed by amending the definition of chemical ingredient in §69501.1(19)(A)(2) to read:

"**a substance comprising one or more substances of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity."**

We believe this change, though minor, is important and that it will work. We appreciate the Department's attention to this important detail, and request that this suggestion be implemented.

Trade Secret Protection for Chemical Identify in Hazard Trait Submissions

CHANGE offers two comments on the proposed regulations in connection with trade secret protection for chemical identity in hazard trait submissions: one relating to the trade secret provisions and one relating to the definition of hazard trait submissions. Both of these comments are important to this issue.

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.

§ 69510 (g)
Unfortunately, however, the regulations also set forth an exception to this bar on trade secret protection for chemical identity. § 69510(g) provides that trade secret protection may be available for chemical identity in hazard trait submissions in the case of new chemicals or new uses of existing chemicals. CHANGE believes this exception is legally invalid and also unwise policy, and that it should be eliminated.

The exception is illegal under AB 1879. In that statute, the legislature struck a balance between the competing interests of the commercial importance of the confidentiality of chemical information on the one hand, and the need of the public and the broader market to have access to such information on the other. The balance struck by the law is that trade secret protection is available for most such information, but not health and safety information in hazard trait submissions. The latter is particularly important for public disclosure, because it is the very information most necessary to evaluate the safety and health effects of chemicals and chemical ingredients. There is no basis anywhere in AB 1879 for the Department to disregard the law in the particular case of new chemicals or new uses of existing chemicals. The law requires disclosure of health and safety information in all hazard trait submissions without exception, which must include chemical identity if the disclosure is to have any meaning or utility.

Moreover, the law is just good policy. The public and the market need access to hazard trait information for new chemicals and new uses just as much as they do for existing chemicals and uses.

The exception of § 69510 (g) should be eliminated.

Should the Department nevertheless conclude that this exception is legal and wishes to maintain it as a policy matter, CHANGE recommends the following modifications designed to give greater force to the competing interest in disclosure:

1. The exception should apply not to all proposed alternatives to a CoC, but only to those not chosen as preferred to the CoC. If an alternative is chosen as preferred to a CoC and is therefore going to be marketed in a consumer product, the public and the market need to know the safety properties of that alternative. That need for a marketed chemical outweighs the private need for confidentiality. If the alternative is not chosen and there shall not be marketed, then the commercial interest in that new, but NOT SELECTED alternative would be protected under this proposal. Though we believe an important oversight function of disclosure would be foregone by following this proposal, it would protect both the public when it is exposed to a chemical and industry's interest in keeping confidential new chemicals and uses that are not yet marketed.

2. All trade secret claims made under this exception should be time limited and subject to revalidation periodically, for example every 5 years. Because the legislature has clearly expressed the view that hazard trait submissions should be publicly available, it is particularly important in this case that they not be withheld on the basis of trade secret claims that could grow stale.

3. § 69510 (g)(2) permits a party to provide the Department with selective information about the properties and toxicity of the alternative. CHANGE suggests that this section require that ALL available data about the alternative, not just the information that is selected by the party seeking trade secret protection, demonstrate health and safety to the Department's satisfaction.

b. Definition of Hazard Trait Submission

§ 69501.1 (a)(33)

This provision by its terms only applies if a study or datum indicates "that a chemical manifests any hazard trait." It does not apply if a study indicates that a chemical does NOT manifest a hazard trait. CHANGE believes that hazard trait submissions indicating that a chemical is non-toxic are just as important as those indicating a chemical presents hazards. The market and the public need to exercise oversight of study claims that a chemical is safe. They also need to know which chemicals are safer in order for the market to be able to select safer chemicals over more hazardous ones.

Current language: "When any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission."

Suggested language: "When any study or datum <u>provides information relating to whether a chemical manifests any hazard trait,</u> chemical identity is part of any hazard trait submission."

<u>Trade secret claims should be minimized.</u>

DTSC is not providing any broad new leadership on transparency and trade secrets in the informal draft regulations, but instead relies on existing law in this area. CHANGE believes this will impair the program's ability to be fully trusted by all stakeholders. Nevertheless, DSTC can take some steps to reduce the amount of trade secret claims that will be allowed under this program, and CHANGE urges it to do so. One of the most valuable contributions this program can make is to make more information about chemicals available to the public and the marketplace.

Trade secrets should not be allowed for any health and safety or product ingredient information, nor for a

chemical's identification in hazard trait submissions; nor for other kinds of information such as AA methodologies that AA assessors might choose. Transparency of this information is important for accountability, for public confidence in the program and for the ability of the program to affect the market. Simply put, consumers, workers and other downstream users of chemicals have a right to know about and avoid the hazards found in the chemicals and products they purchase. Recent tests by Women's Voices for the Earth found that popular cleaning brands had hidden ingredients linked to cancer, reproductive harm and allergies. Workers and employers have had similar experiences with inadequate and inaccurate Material Safety Data Sheets.

Importantly, DTSC should not see transparency provisions as an effort to satisfy NGO's. DTSC itself should have acute concern with both the credibility and effectiveness of this program. Without enough transparency for the public and industry to understand the results of the AA Reports, the program will simply not convince the public that it is being properly protected, and hopes for broad impacts of analysis of "sentinel product/CoCs" will be unrealized because no lessons will be understood by the market.

We support the requirement 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.

We propose the following specific amendments to the regulations to implement these suggestions.

§ 69501.1(a)(60) Page 13, line 34
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.

§ 69505.5. (a)(6)(A) Page 45, lines 38-41
CHANGE strongly supports the language that, 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.

§ 69505.5(d),(e),(h)(2) beginning Page 46
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.

§ 69505.6(e) Page 51, lines 38-40.
All notices issued by the Department should also be posted on DTSC website.

§ 69508.3(e) Page 73, lines 21-22
CHANGE supports the inclusion of this provision, which reads: "An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach."

§ 69510 Page 75
Regarding the Assertion of a Claim of Trade Secret Protection, CHANGE supports the range of information DTSC will require to ensure that trade secret claims are in fact valid and are not made frivolously. We believe these requirements will discourage trade secret claims that are not warranted or are of little value to the responsible entity.

§ 69510 (a)(8) Page 75, lines 31-34
CHANGE strongly supports this requirement for trade secret justification: "The estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering."

§ 69510(c)(2) Page 76, lines 18-20
CHANGE fully supports making a redacted copy of the documentation related to trade secret claims, excluding the information being submitted for trade secret protection, available to the public. This will allow the public, local agencies, employers, workers, and other end-users to gauge the degree to which information is being kept confidential and allow them to make better consumer, business, or regulatory decisions. Since no trade secret information will be included, CHANGE recommends that DTSC make the documentation available in all cases, rather than "at DTSC's discretion."

§ 69510(f) Page 76, lines 32-34
CHANGE strongly supports the provision 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. This explicit language is derived directly from the enabling statute, and reflects the importance of making this information publicly available.

§ 69510.1 Page 77
CHANGE recommends that DTSC 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

The lack of transparency and oversight in the production and review of Alternative Assessment reports is breathtaking. Not only will DTSC permit responsible entities to claim substantial information about the chemicals in their products as confidential, shielding it from consumers, public researchers, and the marketplace, but the regulations will allow responsible entities to conduct their own AA reports with no public oversight or input. Instead, a cumbersome oversight structure is proposed for which DTSC does not have the resources.

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.

CHANGE has long maintained that Alternatives Assessments should not be conducted by the makers or users of toxic chemicals. Since AAs contain quantitative and qualitative data, the assessment can be easily "gamed" to arrive at a pre-determined outcome. We continue to believe that the best, unbiased 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. This 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 will be needed under the current draft regulations.

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 companies that conduct AAs with no trade secret claims and make the reports public could be exempt from third party oversight. Some BizNGO members have suggested a peer review panel to provide quality control on AAs. None of these suggestions is reflected in the formal draft regulations.

Rather, the department has decided that all AA reports may be done by manufacturers, so long as the person performing the AA meets certain requirements and has been certified by an accreditation body. While we understand that the Department hopes this certification will lead to unbiased outcomes, we disagree. Being certified by an independent body will not guarantee against mischief or even bias in AA reports. Moreover, the department does not have the resources required, nor the expertise, to fully review every AA report. The time and money required to do so will slow the pace of product prioritization and lead to consumer products containing CoCs remaining in the market for a longer period of time, increasing hazards for all Californians'. Requiring either independent AAs or third party review will allow the Department to spend its limited resources on prioritizing products and issuing the appropriate regulatory responses.

If DTSC proceeds with its proposed accreditation body model, CHANGE recommends the following changes:

§ 69508 (g)(1) Page 67, line 17

CHANGE supports the provision that a certified assessor may not be in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, if the certified assessor has an ownership interest in the responsible entity whose product is the subject of the AA. We believe, however, that there should be no permissible equity stake as any amount would increase the chance of conflict of interest. Accordingly, the $10,000.00 threshold should be eliminated.

§ 69508.1 (b) and (c) Page 70, lines 4-8

CHANGE supports the provision that any entity that seeks designation as an accreditation body must be independent of, and may not hold any stock or ownership interest in, any consumer product manufacturing, importation, distribution, or retail business (except colleges, universities, or their subdivisions as noted).

§ 609508 (b)(2)(A) Page 66, lines 22-27

CHANGE supports the requirement for at least 20 hours of continuing education during each two-year accreditation period for assessors, including two hours each period in professional ethics.

§ 69508.1(a)(5)(D) Page 68, line 26-32

CHANGE supports the requirement that accreditation bodies demonstrate expertise in public health among other skill sets. But we believe that "pollution prevention" and "maternal and child health" should not have been deleted from the previous drafts and recommend that they be reinstated.

§ 69508.1(a)(5)(E) Page 68, line 33-42

CHANGE supports the requirement that accreditation bodies demonstrate expertise in professional ethics.

Transparency must be maximized in Alternatives Assessment Reports.

CHANGE is very concerned that responsible entities can do their own AAs. While the proposed accreditation process builds in some accountability, the fact remains that a responsible entity will have a vested interest in a specific outcome of an alternatives assessment, and DTSC may not have the resources to adequately audit the many AA reports that will be generated. Moreover, the expected prevalence of trade secret claims is very likely to result in AA Reports that cannot be meaningfully evaluated by the public or other parties. Under these circumstances, the public is unlikely to have confidence in the decisions made by the program.

CHANGE has long advocated for the public's right to know about chemicals in the products they use and the impacts of those chemicals on human and environmental health. We recognize businesses may need to claim information about the ultimate makeup or formulation of some of their products as a trade secret to maintain a competitive advantage in the marketplace and to attract investment in new, innovative chemicals and products. We further recognize that *the Safer Consumer Products Regulations* must conform to current legal trade secret protections.

However, given that AAs will be prepared by manufacturers with a vested interest in the AA's outcome, as well as DTSC's limited resources to review those AAs, the Department should rely on the public, as well as a manufacturer's competitors, to ensure that the AA is factual and represents a good faith effort to reduce the use of toxic chemicals. Without reasonable limits on the information that can be claimed as confidential in AA Reports, there is no way for the public to maintain its critical role as watchdog over this important part of the program.

CHANGE strongly supports the department's explicit language that health and safety information and chemical identity in relation to health and safety data may not be claimed as confidential. We also support the fact that a version of submitted AA reports will be made public and that trade secret information will be masked only to the extent necessary to protect its confidential nature as specified in 69505.5 (a)(6)(A).

However, the language in 69505.5 (a)(6)(A).is 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 meet these provisions.

We therefore strongly recommend that the Department develop specific guidelines for masking strategies as part of the Alternative Assessment guidance published the adoption of these regulations. This guidance should clarify the types of information for which masking is acceptable and provide recommendations for compliance, including but not limited to using ranges to obscure specific formulations.

While a growing number of companies recognize that full public disclosure about their products actually creates competitive advantage, nothing in the regulations encourages this. Requiring companies to mask trade secret information in a way that promotes the public's understanding of AAs is a positive step. Still, DTSC should provide incentives for voluntary full public transparency. For example, manufactures could get a streamlined review process in exchange for forgoing all trade secrecy claims.

Importantly, since regulatory responses are based on the content of AA reports, it is essential that there be a mechanism for the public to register questions or objections to information in them. The Department should determine how the contents of AA Reports can be meaningfully shared with the public, and include a public comment period following the submission of AA Reports. A publicly available executive summary of both the Preliminary AA Report and Final AA report should be accompanied by a public comment period before DTSC accepts the findings of either document.

Ultimately, CHANGE believes that 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, successful balance requires proper guidance, a variety of options, and public input, so that both businesses and the general public can have confidence in the program.

§ 69505.1. (g) Page 38, Lines 17-21.
CHANGE strongly supports the requirement of notification when a Chemical(s) of Concern is/are removed from a priority product, even when a responsible entity reformulates without adding or replacing a substitute chemical. This notification is necessary for the public and the Department to assess the program's overall success in achieving its goal to spur innovation and develop safer consumer products. Without receiving notification, neither the public nor the Department will be able to assess the true and complete impact of these regulations which may come under budgetary scrutiny or attack in the future.

§ 69505.1. (g)(2)(F) Page 38, Lines 35-36.
CHANGE supports the requirement for the responsible entity to submit notification of the measures it will take to "ensure the product that contained the Chemical(s) of Concern is no longer placed into the stream of commerce in California." This is an important protection for EJ communities since companies often dump old products into dollar or discount stores located in poorer communities. In fact, CHANGE strongly encourages the Department to institute fines to companies who continue to sell products containing Chemical(s) of Concern after notifying the department that they have been removed. Experience with California's Proposition 65 program has demonstrated that a combination of on-going surveillance and fines are needed to ensure companies comply with the law.

§ 69505.1. (g)(2)(G)2. Page 38, Lines 40-42.
CHANGE supports the requirement in the regulations that requires responsible entities to submit "laboratory analytical testing, quality control, and quality assurance protocols used to detect and measure the Chemicals(s) of Concern in the product that ensures the Chemical(s) of Concern have been removed."

§ 69505.3 (b)(1)(C)1. Page 41, Lines 21-23
CHANGE strongly supports the requirement that the responsible entity shall determine if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's requirements. This analysis should be explicitly required in the AA Reports.

§ 69505.5. (d) Page 46, line 19
CHANGE supports the inclusion of comprehensive supply chain information in AA Reports.

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 can lead to frivolous delay tactics by those entities that are regulated. It is 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 (e) Page 30, Lines 35-38
Allowing 180 days to post the initial proposed list of Priority Products the effective date of the regulations is too long, especially since we have heard several times from DTSC that there will only be two to five product categories in the first round. CHANGE believes 90 days should be sufficient for the initial group of product categories to be identified and posted.

§69507.6 (d) Page 65, Lines 13-15
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.

"Economic Impacts" must capture all appropriate costs, including to public health, occupational health, and the environment.

DTSC should use consistent language about economic impacts throughout the document. When considering economic impacts, the regulations should ensure that all relevant impacts to public health, occupational health, and the environment are accounted for.

§ 69501.1 Page 4
We recommend re-inserting a definition of "Economic Impacts" using the following language: *"Economic Impacts means internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."*

§ 69505.4(a)(2)(A) Page 43, Lines 8-17
Too often, extraction is left out of the considerations when talking about 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.

§ 69503.2 (a)(1)(B)4.a. Page 26, Lines 35-36

This is another example where "extraction of raw materials" should be added so this section reads: ***Extraction of raw materials****, manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices.*

§ 69505.4(a)(2)(C) Page 43, Lines 28-41
This section requires responsible entities, during the second stage of an AA, to "take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered."

Cost impacts need to explicitly include externalized costs related to public health, occupational health, and the environment which will be borne by society and the taxpayer stemming from the life cycle factors cited in § 69505.4(a)(2)(A). These cost factors should be listed in (C) so there is a complete understanding of the economic costs to retain a Priority Product despite the continuing presence of a CoC.

§ 69501 (b)(1) Page 4, Lines 15-16
DTSC should specify that being placed "in the stream of commerce in California" includes internet / online purchases.

§ 69501.1(a)(36) Page 10, Line 16
Add the words "or entity" to the definition of "Importer" so it reads: *"Importer means a person **or entity** who imports a consumer product into the United States."*

CHANGE is not convinced that regulation automatically leads to negative impacts on a responsible entity's balance sheet.

For example, Market Watch -- http://www.marketwatch.com/story/regulation-may-have-little-jobs-impact-2012-08-06?pagenumber=1 -- reported on August 6, 2012 that it is not clear that regulation hurt a business's bottom line or leads to a loss of jobs. It was noted that while there are clearly people who lose jobs from regulations in the U.S., there are also people who gain jobs as some regulations have created entire new industries such as catalytic converter manufacturing. Similarly, we should have every reason to expect the *Safer Consumer Products Regulations* will spawn a new industry of alternative analysis and assessment that leads to innovative products and processes in California.

In fact, Cary Coglianese, a regulation expert at the University of Pennsylvania Law School, says: "The net effects of regulations on employment are generally rather negligible." Some studies about environmental regulation show that, on balance, regulation has had little or positive impact on overall industry employment. Data from the U.S. Department of Labor indicate that employers cite government regulations and intervention as the reason for layoffs as employers cited governmental regulations/intervention as the reason for less than 1% of layoffs.

There also is important evidence that the anticipated costs of regulation generally are overestimated, often substantially. For example, see *"Not Too Costly, After All: An Examination of the Inflated Cost-Estimates of Health, Safety and Environmental Protections",* by Ruth Ruttenberg and Associates, Inc. for the Public Citizen Foundation, 2004.

Beyond this, it is not in society's best interest to preserve a job that has more negative impacts than positive ones. We don't want to produce something that is toxic just because it provides a job. Regulations are meant to promote overall social welfare which can include a variety of important societal benefits, not just employment. The potentially substantial health and worker productivity benefits associated with regulations which should be

factored into any cost-related analysis. The *Safer Consumer Product Regulations* are stimulating the development of better jobs, not less jobs.

A key principle driving Regulatory Responses by DTSC gives preference to responses providing the greatest level of inherent protection.

§ 69506 (b) Page 52, lines 10-14

"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.

§ 69501.3 (a) – (c), Page 17, lines 1-21
We support these sections which require all information submitted to DTSC under the penalty of perjury to be signed by the person who prepared the information as well as the owner of the company or an official or authorized representative. It is an effective method to ensure the company's responsibilities under these regulations are integrated into the company's activities. This is consistent with requirements for California's workplace Injury and Illness Prevention Program rules and studies showing that programs are more effective with written management commitment that comes from the top.

In addition, CHANGE recommends that responsible entities be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

§ 69501.2(d)
If the most stringent or only punitive measure to address "Failure to Comply" is a DTSC website listing, this is inadequate 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.

A robust end-of-life management program is important and will contribute to positive changes in the marketplace.

§ 69506.8(a)(2) Page 57, Lines 38-41
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 provide DTSC with a copy of their product stewardship plan.

§ 69506.8(d) Page 59, Lines 14-17
CHANGE objects to this 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 have the job of deciding if the responsible entity had adequately "demonstrated" its claim. An end-of-life management program should be required in all cases, with the responsible entity providing limitations and mitigating factors in the end-of-life management plan.

An inventory recall mechanism should be included in Regulatory Reponses.

§ 69506.6 Page 55
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.

AA Report Supplemental Information Requirements

§ 69506.2 (a) and (b) Page 5, Lines 30-39
CHANGE supports these provisions allowing DTSC to require responsible entities to provide supplemental information or to take steps to fill data gaps.

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.

Dispute Resolution

§ 69507(b) Page 62, Lines 33-36
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. Instead, there should be a summary of why the chemical/product combination was prioritized, and a current update about how the dispute is being resolved. Without provisions like this, companies will have a green light to pursue frivolous disputes, wasting scarce DTSC resources and undermining the public's confidence in the process.

Dispute processes should include short timelines to minimize costs to both sides. The current draft allows for far too much delay by the responsible entity for a straightforward task.

Priority Product Work Plan will limit DTSC's ability to respond to new hazards.

§ 69503.3 (f)
This new provision requires DTSC to develop and issue a Priority Product Work Plan by 1/1/14 that describes the product categories that the Department will evaluate to identify products to be added to the Priority Products list during the next six (6) years.

This provision has several serious flaws. First, it unnecessarily commits DTSC to a small number of consumer products, allowing the vast majority of products to continue to be marketed without any incentives to move away from CoCs. Second, it would prevent DTSC from responding to new science about CoCs and the products that contain them. Third, it is predicated on the current level of DTSC resources that may change over time. In the initial pilot stage, DTSC will identify no more than 5 priority products, in large measure because of resource constraints. If budget forecasts improve, DTSC should be able to ramp up the program as much as possible.

CHANGE opposes tying DTSC's hands with this restrictive requirement.

If a Priority Product Work Plan remains in the regulations, DTSC should not be limited in the number of possible priority products it will list. Rather, an open-ended list of potential products should be posted, allowing DTSC the flexibility to initiate the search for safer alternatives as circumstances and resources permit.

A DTSC Priority Product Work Plan must include an opportunity for public comment.

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CHANGE
Californians for a Healthy & Green Economy

COMMENTS ON THE
CALIFORNIA SAFER CONSUMER PRODUCTS
INFORMAL DRAFT REGULATIONS OF MAY 18, 2012

May 28, 2012

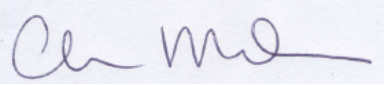
CHANGE Coalition
Californians for a Healthy and Green Economy

Californians for a Healthy and Green Economy (CHANGE) offers the following comments on DTSC's second informal 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,



Christina Medina
CHANGE Coordinator

Due to the short window for feedback on DTSC's second informal draft regulations, we have limited our comments to only a few critical areas where we believe the current draft falls short and also where it has strong provisions which we support and must be retained.

We acknowledge 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. 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.

As we have observed before, the draft regulations suffer from the limitations in the enabling statute. As such, the Green Chemistry Initiative (GCI) is incomplete. The California Legislature will have to pass further legislation to complement AB 1879 if the GCI is to fulfill its promise. At the same time, strong support from the Governor for green chemistry is an essential ingredient for the success of this ambitious undertaking.

In particular, 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.

CHANGE's view of the draft regulations is that there are important improvements that still need to be made so they can be as effective as possible. But it is time to bring them online and see how they work in the real world, despite the shortcomings which they will undoubtedly contain.

CHANGE strongly supports a large Chemicals of Concern (CoC) list.

The listing of an estimated 2,100-2,500 chemicals as Chemicals of Concern within 30 days of the program's implementation date represents a significant effort to identify and prioritize chemicals which have already been recognized as threatening public health and the environment. CHANGE supports DTSC's reliance on the prior work of authoritative bodies to generate the initial CoC list, as well as a petition process to add additional chemicals to the CoC list.

Because of the resource constraints that DTSC faces, it is imperative that the regulations send market signals that will stimulate and encourage efforts by forward-thinking entrepreneurs and businesses to voluntarily act before subsequent regulation compels them to do so. The size of this list will help reduce the problem of regrettable substitutions.

At the same time, it must be recognized that even though 2,500 chemicals may seem like a large number, it is in fact only a small fraction of the more than 80,000 chemicals currently registered for use in the United States which are not adequately tested for safety before reaching the market. As we learn more about chemicals in commercial use in the coming years, we expect the Chemicals of Concern list will need to expand significantly.

CHANGE supports DTSC's intent not to rank chemicals on the CoC list in what would be a misguided effort to identify and prioritize the "worst" chemicals. Such an effort would be 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.

DTSC should specify that when any of the lists it relies on is updated, the updated list becomes the version that DTSC relies on for its own CoC list.

We support the addition of the Priority Chemicals list of the California Environmental Contaminant Biomonitoring Program.

Cumulative exposure 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.

California EPA is engaged in an ongoing process that is studying cumulative impacts (OEHHA's Cumulative Impacts and Precautionary Approaches Workgroup). While more tools for evaluating cumulative exposure need to be developed, tools are never developed unless they are needed, and so 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 "with other environmental factors."

We recognize that this is 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.

Regulatory Responses Article is improved.

§ 69506
CHANGE supports the wide range of regulatory responses DTSC can apply. The revised draft is significantly improved over the earlier draft.

§ 69506 (b)
CHANGE strongly supports that DTSC shall give preference to regulatory responses providing the greatest level of inherent protection.

§ 69506.4 (b)(2)
Internet purchasers need to be provided the same information as consumers who buy products as retail outlets. Adding language to include internet purchases should be added here.

§ 69506.8

CHANGE strongly supports the proposed End-of-Life Management Requirements, especially the requirement for the responsible entity to "fund, establish, and maintain an end-of-life management program for the product;" the financial guarantee mechanism; and the required annual report.

Occupational health and worker protection must be clearly and consistently incorporated into the regulations.

As written, the inclusion of occupational health and worker protection is mostly invisible in the current draft regulations. Because workers in California experience exposures related to the manufacture, storage, or transport of products in California regardless of where those products are eventually sold, the regulations must apply to all products manufactured, stored, or transported in California, whether they are sold here or not. Occupational exposure should be one of the criteria to be considered when prioritizing a chemical or consumer product. All exposure pathways must be examined if exposure analysis is needed.

For these and other reasons, we recommend the following amendments.

§ 69501(b)(2)
This section exempts products placed into the stream of commerce "solely for the manufacture" of a consumer product exempted from AB 1879. There is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes certain exempt products, but not all chemicals used in their manufacture. This is an example where workers, who should be granted equal protection in the regulations, would be exposed to CoC's that others would not.

As such, the entire language of 69501(b)(2) should be stricken.

§ 69501(b)(3)
The provision states, "This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California."

Workers, and those living near and around manufacturing sites, will be exposed as products are manufactured, stored, and/or transported in the state, even if they are not sold here. Workers are members of the public who are entitled to equal protection from harmful substances. This provision has no basis in AB 1879 and subverts the statute's goal of promoting life cycle reviews, including hazards to workers and fenceline communities within the state.

The entire language of 69501(b)(3) should be stricken.

§ 69501.2(a)(23)
DTSC should ensure that the definition of "Consumer Product" makes clear that chemicals and products used in the workplace are included.

The definition of "sensitive sub-populations" must include workers.

§ 69501.2(a)(60)
Workers should be explicitly mentioned in the definition of sensitive subpopulations. There are many examples where they are at greater risk for adverse health effects when exposed to chemicals that exhibit certain hazard traits. Exposures to workers are often different from other members of the public, and can be larger and of longer duration.

We support the addition of the phrase "or greater exposures" in the new draft's definition of Sensitive Subpopulation.

Trade secret claims should be minimized.

DTSC is not providing any broad new leadership on transparency and trade secrets in the informal draft regulations, but instead relies on existing law in this area. The flaws in the enabling statute also present a problem. Yet one of the most valuable contributions this program can make is to make more information about chemicals available to the public and the marketplace.

Transparency of the information generated by these regulations is important for accountability, for public confidence in the program and for the ability of the program to affect the market. Simply put, consumers, workers and other downstream users of chemicals have a right to know about and avoid the hazards found in the chemicals and products they purchase.

Importantly, DTSC should not see this as an effort to satisfy NGO's. DTSC itself should have acute concern with both the credibility and effectiveness of this program. Without enough transparency for the public and industry to understand the results of the AA Reports, the program will simply not convince the public that it is being properly protected, and hopes for broad impacts of analysis of "sentinel product/CoC's" will be unrealized because no lessons will be understood by the market.

That said, we support the following provisions which attempt to bring information forward despite the limitations of the enabling statute:

§ 69508.3 (e)
CHANGE supports that an accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach.

§ 69510
CHANGE supports the requirements here 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.

§ 69510 (a)(8)
CHANGE strongly supports this requirement for trade secret justification: The estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed

as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering

§ 69510 (f)

CHANGE strongly supports the provision 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 (except in (g).

§ 69505.5. (b)(3)
CHANGE strongly supports the new language in this draft that 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.

DTSC is breaking new ground in proposing an Alternative Analysis Threshold (a.k.a. *de minimis*) exemption, but more should be done to reflect current science.

CHANGE acknowledges that DTSC is proposing an Alternative Analysis Threshold (AAT) level that is 10 times more protective than any agency has proposed before for certain health endpoints such as carcinogens, mutagens and reproductive toxins, persistent bioaccumulative toxins, and endocrine disruptors - 0.01 % instead of 0.1%; and that DTSC will retain the authority to set a lower or higher chemical-specific level if evidence warrants.

DTSC should be mindful of the incentives created by an AAT exemption: it will motivate product manufacturers to continue to use CoC's (and other dangerous chemicals) as long as they are below the AAT thresholds, or to replace a CoC used at levels above the threshold with multiple CoC's each at levels below the threshold. These counter-productive incentives undermine the intent and central goal of AB 1879, which is to prompt a search for safer alternatives.

CHANGE's position is that the regulations should not have any AAT exemptions for Chemicals of Concern. There is now peer-reviewed research demonstrating that some chemicals, previously thought to be harmless, can in fact have adverse impacts at extremely low doses. Because DTSC is charting a new course in the arena of chemicals management, adopting a more protective standard would be a welcome contribution for other regulatory agencies, but more importantly, it would reflect current scientific understanding of what constitutes a "safe dose."

At the least, chemicals that are carcinogens, mutagens, and reproductive toxicants (CMRs), persistent bioaccumulative toxins (PBTs), and endocrine disruptors (EDs) should have no AAT exemption. These are known substances with adverse health effects, and increasingly seen at lower concentrations. For the endocrine disruptor bisphenol A, for example, effects can be observed in the parts-per-trillion range. A threshold of 0.01

percent would fail to be protective by several orders of magnitude. EDs in general will be under-recognized within DTSC's proposed structure.

Rather than grant exemptions, DTSC should consider using the measured concentrations of CoC's as a prioritization criterion for Priority Products.

DTSC should also consider requiring responsible entities to disclose chemicals of concern in their products at any level that can be detected using an existing analytical method. This could be required regardless of what AAT standard is ultimately finalized.

It goes without saying that an AAT standard of zero would save DTSC scarce resources that otherwise would need to be directed to the task of setting chemical-specific AAT levels and reviewing AAT exemption notifications. While the burden of proof lies with the responsible entity to be accurate, it's hard to imagine DTSC will be able to provide sufficient quality control over the large number of AAT exemption notifications that will come in the door.

If DTSC maintains the current two-tier AAT structure as outlined in the draft regulations, it is imperative that DTSC maintain the authority to set a chemical-specific AAT level where evidence warrants.

Priority Product Work Plan has major flaws.

§ 69503.3 (f)
This new provision requires DTSC to develop and issue a Priority Product Work Plan by 1/1/14 that describes the product categories that the Department will evaluate to identify products to be added to the Priority Products list during the next six (6) years.

This provision has several serious flaws. First, it unnecessarily commits DTSC to a small number of consumer products, allowing the vast majority of products to continue to be marketed without any incentives to move away from CoC's. Second, it would prevent DTSC from responding to new science about chemicals of concern and the products that contain them. Third, it is predicated on the current level of DTSC resources which may change over time. In the initial pilot stage, DTSC will identify no more than 5 priority products, in large measure because of resource constraints. If budget forecasts improve, DTSC should be able to ramp up the program as much as possible.

CHANGE opposes tying DTSC's hands with this restrictive requirement.

If a Priority Product Work Plan remains in the regulations, DTSC should not be limited in the number of possible priority products it will list. Rather, an open-ended list of potential products should be posted, allowing DTSC the flexibility to initiate the search for safer alternatives as circumstances and resource permit. And a DTSC Priority Product Work Plan must include the chance for public comment.

Delete "Historic Product" language.

§ 69501.1 (a)(23)(B)2
New language has been added re "Historic Product." According to this definition, a "historic product" is not considered a "consumer product" and therefore exempt from these regulations if it is manufactured prior to the date the product is listed as a Priority Product. Furthermore, its service, replacement, and repair parts are also exempt in perpetuity even if manufactured after the listing date.

Combined with the proposed new requirement for DTSC to forecast in a work plan which Priority Products will be considered for the next 6 years, the "historic product" provision would enable a manufacturer to make a product with CoC's in high volume up until the date of listing, and then be exempt from any product recall or other action to prevent exposure to the CoC's in the product after the listing date.

This creates an incentive for a responsible entity to continue to produce a hazardous product in high volume until a PP listing date, which it will know 6 years in advance.

Furthermore, exempting service, replacement, and repair parts will continue to expose workers to CoC's.

There is also uncertainty in the wording whether this new language intends to exempt all "historic products" from the regulations entirely; i.e., grandfather them without any regulation at all.

Clearly, a consumer product doesn't become a Priority Product until it is listed as such. The "historic product" language is unnecessary and should be deleted.

The standard for DTSC to demonstrate causation is too high throughout the regulations and will prevent DTSC from taking action.

DTSC is imposing on itself a high burden of proof to show that chemicals and products cause harm to human health and the environment. This is not required by AB 1879.

The new draft is significantly worse that the first informal draft in this regard. Whereas the first draft frequently referred to the "potential" for adverse effects or the "potential" for exposure, the new draft requires evidence that a Priority Product has the "ability to cause" adverse effects.

The modern reality of the impact of toxic chemicals on the environment and human health is that often the best proof available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. A requirement for DTSC to have more information than that is essentially a deregulatory requirement – since the absence of required evidence means no regulation is possible.

Reducing the existing burdens of proof on government is one of the central goals of chemicals policy reform as articulated by California's Green Chemistry Initiative and the national efforts to reform TSCA (Toxic Substances Control Act of 1976). The Safer Consumer Products regulation should enable DTSC to act on the evidence that is reasonably available and to act on early warnings of harm. Indeed, the authoritative bodies being relied on by DTSC in this draft proposed regulation often employ a lower burden of proof than DTSC is imposing on itself in these regulations.

Accordingly, the regulations should enable DTSC to act on evidence that exposures to toxic chemicals create "threats of," "may contribute to," or have "potential" adverse effects on human health and the environment. These recommendations should be employed throughout the document so consistency is maintained. In the CHANGE comments of 12/30/11, we provided several examples where this could be amended in the regulation.

DTSC will be hampered by dependence on "available information."

There are many instances where DTSC's decisions and regulatory actions will be limited by the lack of available information. By giving preference to, and relying, the current availability of chemical data, instead of exercising the Department's authority to request or require new information, DTSC will find itself in the position of perpetuating the data gap that continues to limit innovation and the development of green chemistry based alternatives. It also ensures that the burden of proof remains on the regulatory agency and not on the companies making the chemical or product containing the chemical. Finally, and importantly, it creates an incentive for industry to shield information and discourage dissemination of many data.

DTSC should do everything within its authority under AB 1879 to obtain the information it needs to identify CoC's and safer alternatives and to fashion appropriate regulatory responses. Preferably, the burden of proof should be reversed so that in the face of uncertainty because of a lack of adequate data, the responsible entity must provide information that demonstrates with reasonable certainty that the chemical/product does not cause harm. DTSC should assert its data call-in authority to require the generation of new health and environmental impact data wherever it is unavailable, and DTSC should exercise this authority earlier in the program's implementation.

The availability of alternatives should not limit decisions.

As written in the draft regulations, prioritization and other decisions are influenced by, and are in fact dependent on, the availability of safer alternatives. We believe this will send the wrong signal to the marketplace because it may deter innovation as well as run counter to the development of new alternatives which should be one of the goals of the program. DTSC should not unnecessarily limit their decisions based on the availability of a safer alternative, especially in the regulatory response phase.

The regulations are silent about how to treat chemicals for which we have insufficient or no information.

CHANGE continues to believe that chemicals for which there is little or no information demonstrating whether they are safe can reasonably be considered CoC's under AB 1879. This would give DTSC authority to request further information in the form of minimum data sets.

In the absence of a minimum data requirement, the regulations should at the very least create a mechanism to recognize these chemicals – a "yellow flag" that sends a message to the market and the public that they are under-studied and not necessarily safe.

There is potential for unnecessary delays in program implementation.

The draft regulations are overly generous in the allowed timelines.

§ 69503.4 (d)

Posting the initial proposed list of Priority Products 180 days after the effective date of the regulations is too long, especially since there will no more than 5 product categories in the first round. 90 days should be sufficient for the initial group of product categories to be identified and posted.

§ 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." A total of 90 days should be more than adequate for DTSC to act in this regard.

Assessors and Accreditation Body provisions.

§ 69508 (g)
CHANGE supports the provision that a certified assessor may not be in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, if the certified assessor has an ownership interest in the responsible entity whose product is the subject of the AA.

§ 69508.1 (b) and (c)
CHANGE supports the provision that any entity that seeks designation as an accreditation body must be independent of, and may not hold any stock or ownership interest in, any consumer product manufacturing, importation, distribution, or retail business (except colleges, universities, or their subdivisions as noted).

§ 609508 (b)(2)(A)
CHANGE supports the requirement for at least 20 hours of continuing education during each two-year accreditation period for assessors, including two hours each period in professional ethics.

§ 69508.1(a)(5)(D)
CHANGE supports the requirement that accreditation bodies demonstrate expertise in public health among other skill sets. But we believe that "pollution prevention" and "maternal and child health" should not have been deleted from the new draft.

Alternatives Analysis

There is no public review and comment period following the submission of AA Reports. This is a critical point in the process where the public should be involved to improve quality control. There should be a public comment period following the submission of AA Reports.

§ 69505.3 (C)1.
CHANGE strongly supports the requirement that the responsible entity shall determine if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's requirements. This analysis should be explicitly required in the AA Reports.

§ 69505.5. (d)
CHANGE supports the inclusion of comprehensive supply chain information in AA Reports.

Economic costs should include public health considerations.

§ 69505.4. (a)(2)(C)
Economic impacts should include both the environmental remediation and public health benefits or costs to be borne by society.

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CHANGE
Californians for a Healthy & Green Economy

COMMENTS ON THE CALIFORNIA SAFER CONSUMER PRODUCTS INFORMAL DRAFT REGULATIONS

December 30, 2011

CHANGE Coalition
Californians for a Healthy and Green Economy

Californians for a Healthy and Green Economy (CHANGE) is pleased to submit comments on DTSC's informal 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 are grateful for 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
Campaign Director

Contact: Kathryn Alcántar, CHANGE Campaign Director - changecalifornia@gmail.com or 510.655.3900 x315

We would like to begin by noting these regulations are in some ways historic. 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. 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. Exposure data will be considered, but the intention is to reduce exposure to hazardous chemicals rather than justify exposures through risk assessment. This is the first time regulations of chemicals will address cumulative exposures, which are a key public health concern and 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.

It also represents a focus on "public health", where the concept of primary prevention is essential -- whether the "public" is a worker, an employer or manufacturer, a consumer, or a community member.

DTSC is to be commended for responding to and trying to incorporate the many competing interests of stakeholders into a workable program that will accomplish meaningful reform. The new leadership at CalEPA, and in particular at DTSC under new Director Debbie Raphael, has breathed new life into this regulation-development process. The deeper involvement of the state's Green Ribbon Science Panel (GRSP) has been very welcome and the informal draft regulations reflect this.

DTSC has developed a draft that is in many ways far superior to previous efforts. One point CHANGE wants to make clearly at the outset is that the draft regulations suffer from the limitations in the enabling statute. As such, the Green Chemistry Initiative (GCI) is incomplete.

The California Legislature will have to pass further legislation to complement AB 1879 if the GCI is to fulfill its promise. Key issues that must be addressed by the Legislature, which we urge DTSC to acknowledge and support, include:

a. Funding from some source must be provided to DTSC to carry out the program.

It has been widely noted by nearly every interested party tracking the development of the regulations, including CHANGE, 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 to start, and a final alternative analysis report will take three years if all goes smoothly. Although it's important to start small and pilot how the program will actually function, the pace of work as outlined in the draft regulations will lead to unacceptably modest accomplishments. It would be impossible to argue that the program can generate any significant throughput without a budget.

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. However, as a first step, we urge DTSC to build permitting and licensing fees, which would not rely on legislative action, into the regulations.

b. 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 existing 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.

c. The problem of lack of transparency created by trade secret claims must be addressed.

Under the draft regulations, DTSC will permit consumer product manufacturers – the responsible entities – to claim substantial information about the chemicals in their products as confidential, shielding it from consumers, public researchers, and the marketplace. Trade secrets should not be allowed for health and safety and ingredient information relating to chemicals in products. This 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.

d. There is an obligation for the Legislature to act more quickly with chemical-specific bills when there is a threat of harm.

A fourth important challenge and responsibility for the Legislature is to recognize that because resources will seriously hamper the pace of the program, there is still an important role for chemical-specific bans that protect Californians quickly from chemicals for which we already have enough information to act to protect public health.

Despite these limitations in the Green Chemistry Initiative, CHANGE urges DTSC to move quickly to implement AB 1879 so the State of California can begin the process of substituting safer chemicals for more harmful ones, while at the same time frankly acknowledging the limitations of the program and the need for further green chemistry legislation.

CHANGE's view of the draft regulations is that they are on the right track but there are important shortcomings that can and should be addressed for the program to truly be protective of all Californians. The regulations should go further in some areas to strengthen California's leadership within this new regulatory environment.

In the sections that follow, CHANGE identifies these shortcomings (not necessarily in order of importance), and offer specific proposals for changes. These needed improvements are important, and it will be difficult for CHANGE to fully support the regulations unless they are implemented. We appreciate DTSC's willingness to discuss these concerns and look forward to continued conversations.

1. CHANGE strongly supports a large Chemicals of Concern (CoC) list posted within 30 days of the program's implementation date.

A large CoC list will support and encourage efforts by forward-thinking entrepreneurs and businesses to voluntarily act before subsequent regulation compels them to do so. In fact, the listing of an estimated 3,000 chemicals represents a significant effort to identify and prioritize those that threaten public health and the environment, given there are some 80,000 chemicals currently registered for use in the U.S.

A large list as proposed will also save DTSC resources.

CHANGE also supports DTSC's reliance on the prior work of authoritative bodies to generate the initial CoC list. Industry is already on notice that all of the chemicals DTSC will propose for its initial list of CoC's are problematic. Indeed many industries are already making efforts to move away from these very same chemicals. The size of this list will, as DTSC intends, help reduce the problem of regrettable substitutions. But it must be recognized that even though 3,000 chemicals or so may seem like a large list, it is not, given that as we learn more about chemicals in commercial use in the coming years, we expect that this list will have to expand significantly.

However, many of the hazard traits identified by OEHHA, which are to be used by DTSC in the Safer Consumer Products regulation, are not captured in the specific lists which appear in the draft regulations. DTSC should expand the lists it relies on so that existing scientific understanding about chemical links to all relevant health endpoints are included.

CHANGE also supports DTSC's intent not to rank chemicals on the CoC list in what would be a misguided effort to identify and prioritize the worst chemicals. We believe such an effort, which seems to be broadly supported by industry, 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; the identification out of all the tens of thousands of chemicals in commerce of about 3,000 chemicals already on authoritative body lists of problematic chemicals does constitute a thoughtful and reasonable process for the identification and prioritization of chemicals of concern, which is all AB 1879 requires.

In addition, it's important to provide a mechanism for additions to the CoC 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. As written in the current draft, CHANGE supports DTSC having the authority to identify new CoC's based on their hazard traits or environmental or toxicological endpoints. 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(a)(1)(A-O)
DTSC should consider adding to the CoC list:
* The California Environmental Contaminant Biomonitoring Program (also known as "Biomonitoring California") Designated Chemicals list.
* The California Environmental Contaminant Biomonitoring Program Priority Chemicals list.
* Berkeley Center for Green Chemistry PluM database.

* SIN list from ChemSec.
* Green Screen "Red List."

DTSC should specify that when any of the lists it relies on is updated, the updated list becomes the version that DTSC relies on for its own CoC list.

DTSC should ensure that a comprehensive list of asthmagens is included in the initial CoC list.

§69502.3(a)
CHANGE strongly supports DTSC's intent to generate a CoC list relying on existing authoritative bodies within 30 days of the effective date of the regulations.

§69502.3(e)
We recommend the CoC list be fully updated every two years instead of three. This will enable DTSC to stay as current as possible with emerging science that has been reviewed by authoritative bodies.

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2. Including cumulative exposure is an important component of the program, but DTSC's approach needs to be strengthened.

CHANGE strongly supports DTSC's efforts to build in cumulative exposure. Addressing this regulatory challenge is long overdue and is a fundamental concern in many environmental justice communities. 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 numerous chemicals.

California EPA is engaged in an ongoing process that is studying cumulative impacts (OEHHA's Cumulative Impacts and Precautionary Approaches Workgroup). While more tools for evaluating cumulative exposure need to be developed, tools are never developed unless they are needed, and so we encourage DTSC to maintain its commitment to this issue.

However, the scope of cumulative effects contemplated by the regulations (that is, cumulative with "other chemicals of concern with similar modes of action") is unduly limited and bears little relationship to the reason the concept is so important. The proposed scope also carries an analytical burden for DTSC (to determine "similar modes of action") that is beside the larger point. What is important is to consider the impact of chemicals as they accumulate with other broadly defined environmental factors. We recognize that this is 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.

Accordingly, we recommend that where "cumulative effects with other" factors is recited, this should refer to "other environmental factors," not just other "Chemicals of Concern," and should eliminate the phrase "mode of action." These sections in particular should be amended as follows:

§69502.2(b)(1)(A)(3)
Should read: *"The chemical's cumulative effects with other* ***environmental factors****;"*

§69503.2(a)(1)(A)(1)(c)
Should read: *". . . cumulative effects* ***with other environmental factors;****"*

We also recommend the following amendments.

§69501.2.
No definitions are included for "aggregate exposure" or "cumulative exposure." These should be added as they are used throughout the document.

§69503.4(c)(2)(A)1.
Do aggregate or cumulative exposures include synergistic effects? If yes, this should be stated.

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3. The phrase "chemical or chemical ingredient" should be used throughout the regulation rather than just the term "chemical."

The draft regulations use the term "chemical" throughout, in dozens of places. But AB 1879 uses the phrase "chemical or chemical ingredient" in almost all instances throughout the statute. For example, AB 1879 provides:

"25252. (a) On or before January 1, 2011, the department shall adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern . . ."

Thus, under the statute, "chemicals" in consumer products are distinct from "chemical ingredients" in consumer products and the statute grants DTSC authority over both. Under AB 1879, DTSC has the authority to designate not just chemicals, but also chemical ingredients, as chemicals of concern. It may also designate as priority products those containing either chemicals or chemical ingredients. Thus, the use in the regulations only of the term "chemical" is an unwarranted restriction of DTSC's statutory authority.

Therefore, DTSC should employ the term "chemical or chemical ingredient," or "chemical and chemical ingredient," as appropriate throughout the regulation in place of the term "chemical."

DTSC should also provide a definition of "chemical ingredient" that differs from that of "chemical" by reciting attributes in addition to just being in a consumer product as that definition now provides. In our proposal on nanomaterials, set forth below, we suggest definitions for "chemical" and "chemical ingredient" that we believe would be suitable.

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4. "Economic Impacts" must capture all appropriate costs.

DTSC should use consistent language about economic impacts throughout the document. We recommend language that says economic impacts includes "internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."

§69501(b)(1)
DTSC should specify that being placed "in the stream of commerce in California" includes internet / on-line purchases.

§69501.2(a)(27)(A-H)
The Economic Impacts definition is much too narrow. Later in the regulation, Section 69505.4(a)(2)(C) does require accounting of internalized and externalized costs. The definition should read: ***"Economic Impacts include "internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."***

§69501.2(a)(42)
Add the words "or entity" to the definition of "Importer" so it reads: "Importer means a person ***or entity*** who imports a consumer product into the United States."

§69501.2(a)(62)
Amend so it reads:
"Product function and performance" means the principal use(s) or application(s) of a product by a consumer, as intended ***or is anticipated*** by the manufacturer."

§69501.2(a)(74)(C)
DTSC should provide guidance on how to measure "aggregate externalized costs."

§69505.4(a)(2)(C)
CHANGE supports the requirements in the draft regarding the responsible entity's evaluation and comparison of economic impacts. To be consistent throughout the document, we recommend that this language be used here: "internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."

§69505.1(b)(1)
DTSC should specify that "placed into the stream of commerce" includes all products that are manufactured, imported, stored, sold, or used in California.

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5. Occupational health and worker protection of workers must be clearly and consistently incorporated into the regulations.

Several changes must be incorporated throughout the regulations. Because workers in California experience exposures related to manufacture of products in California regardless of where those products are eventually sold, the regulations must apply to all products manufactured, stored, or transported in California, whether they are sold here or not. Occupational exposure should be one of the criteria to be considered when prioritizing a chemical or consumer product. All exposure pathways must be examined if exposure analysis is needed. When DTSC posts public information, there needs to be a mechanism to distribute it to workplaces as well as provide it in languages accessible to workers.

For these and other reasons, we recommend the following amendments.

§69501(b)(2)
This section of the draft exempts products placed into the stream of commerce "solely for the manufacture" of a consumer product exempted from AB 1879. There is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes certain exempt products, not all chemicals used in their manufacture. This is an example where workers, who should be granted equal protection in the regulations, would be exposed to CoC's that others would not.

As such, the entire language of 69501(b)(2) should be stricken.

§69501(b)(3)
The provision states, "This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California."

Workers, and those living near and around manufacturing sites, will be exposed as products are manufactured, stored, and/or transported in the state, even if they are not sold here. Workers are members of the public who are entitled to equal protection from harmful substances. This provision has no basis in AB 1879 and subverts the statute's goal of promoting life cycle reviews, including hazards to workers and fenceline communities within the state.

The entire language of 69501(b)(3) should be stricken.

§69501.2(a)(5)
DTSC should specify that "public health" includes occupational health and is included in the definition so it reads: "Adverse public health impacts" means any of the toxicological effects on public or occupational health listed in the OEHHA draft regulation for SB 509 (articles 2 and 3 of chapter 54).

§69501.2(a)(21)
DTSC should ensure that the definition of "Consumer Product" makes clear that chemicals and products used in the workplace, including bulk purchases, are included.

§69501.2(a)(72)
Workers should be explicitly mentioned in the definition of sensitive subpopulations. There are many examples where they are at greater risk for adverse health effects when exposed to chemicals that exhibit certain hazard traits. Exposures to workers are often different from other members of the public. As GRSP member Julia Quint has stated in comments on an earlier draft, "In contrast to customers, clients and members of the public who may be exposed for short periods of time to low concentrations of consumer products when they are in workplaces on an infrequent basis, workers who use the products are typically exposed to much larger quantities, on a daily basis, for years."

§69501.2
Add a definition of "Public."
Define "public" to include workers. Specify that workers in an occupational setting during any stage of the life cycle are considered to be part of "the public."

§69501.2
Add a definition of "Public Health."
DTSC should specify that the health of workers in an occupational setting during any stage of the life cycle is included in the definition.

§69502.2(b)(1)(A)6
This should be amended to read: "The populations, including workers, and/or environmental receptors that are potentially adversely impacted."

§69502.2(b)(1)(B)1.
This should be amended to read: "Children, ***women of reproductive age,*** pregnant women, ***workers***, and other sensitive subpopulations."

§69502.2(b)(1)(B)3.
This should be amended to read "Widespread adverse, ***severe or chronic*** public health and/or environmental impacts.

§69503.2(a)(1)(A)2.a.
This should be amended to read: "Children, ***women of reproductive age,*** pregnant women, ***workers***, and other sensitive subpopulations."

§69503.2(b)
Workers clearly are affected by products that are widely distributed in commerce, assembled, formulated to be applied directly to the body, dispersed, and put on hard surfaces where they can volatilize. Given this, it makes sense to list workplace exposures in the list of Key Prioritization Criteria.

§69505.1(b)(2)
Exempting "bulk chemicals . . . not packaged for sale to . . . a retail customer" likewise has no basis in the statute and deprives DTSC of statutory authority; it would require new regulations before DTSC could ever consider a bulk product that is hazardous to workers and the environment. Workers should be afforded the same degree of protection from harmful CoC's and products as other members of the public.

The entire language of 69505.1(b)(2) should be stricken.

§69505.1(b)(2)
DTSC should specify that bulk chemicals "placed into the stream of commerce" include all that manufactured, imported, stored, sold, or used in California even if not packaged for sale to, or end use by, a retail consumer. Workers will handle these bulk chemicals and should be considered a member of the public afforded equal protection as all other Californians.

§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.

§69506.3(b)
Replace "formats" with "clear language" so it reads: "...by making the required information available to consumers, in easily seen, legible, understandable, and clear language..."

California has many people for whom English is not a first or well-understood language. Real protection comes by ensuring that as many people as possible can understand the information about products they buy and/or use.

§69508.1(a)(5)(A-N)
The list of skill sets listed in (A-N) should be expanded to include occupational health.

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6. The standard for DTSC to demonstrate causation is too high throughout the regulations and will prevent DTSC from taking action.

DTSC is imposing on itself a high burden of proof to show that chemicals and products cause harm to human health and the environment. This is not required by AB 1879. Ideally, DTSC should place the burden of proof on industry to demonstrate that consumer products are safe. At an absolute minimum, DTSC should reduce the burden of proof that it must carry on the issue of causation throughout the regulations.

The modern reality of the impact of toxic chemicals on the environment and human health is that often the best proof available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. A requirement for DTSC to have more information than that is essentially a deregulatory requirement – since the absence of required evidence means no regulation is possible.

Reducing the existing burdens of proof on government is one of the central goals of chemicals policy reform as articulated by the Green Chemistry Initiative and the national efforts to reform TSCA (Toxic Substances Control Act of 1976). The regulation should enable DTSC to act on the evidence that is reasonably available and to act on early warnings of harm. Indeed, the authoritative bodies being relied on by DTSC in this draft proposed regulation often employ a lower burden of proof than DTSC is imposing on itself in these regulations.

Accordingly, the regulations should enable DTSC to act on evidence that exposures to toxic chemicals create "threats of," or "may contribute to," adverse effects on human health and the environment. These recommendations should be employed throughout the document so consistency is maintained. Several examples of changes that we suggest are as follows:

§69502.2(a)
This should read: "Chemical of Concern if it **may** exhibit a hazard trait..."

§69501.2(a)(5)
This definition but no other definition of adverse impacts refers to "causation" and there is no logical need for such a reference in this section or others. The definition of "Adverse public health impacts" should read:
***"Adverse public health impacts" means any of the toxicological effects on public or occupational health listed in the OEHHA draft regulation for SB 509 (*articles 2 and 3 of chapter 54).**"*

§69502.2(a)(1)
This should read: "The chemical is identified as ***potentially*** exhibiting a hazard trait..."

§69502.2(b)
This should read: " . . . the Department may identify chemicals that ***potentially*** exhibit one or more hazard traits. . . ."

§69502.2(b)(1)(A)
This should read: "The potential for the chemical to ***contribute to*** adverse public health..."

§69502.2(b)(1)(B)
This should read: "... the chemical associated with ***or contributing to*** the adverse impact(s)..."

§69502.2(b)(2)
This should read: "...quantities that ***may contribute to*** adverse impacts..."

§69503.2(a)(1)
This should read: "The Department shall consider the potential ***of the Chemical of Concern in a product to contribute to adverse public health and environmental impacts*** due to potential exposures during the . . ."

§69503.2(a)(1)(A)1.
This should read: "...in a product to ***contribute to*** adverse public..."

§69503.2(a)(1)(B)
This should read: "quantities that ***may contribute to*** adverse impacts ***on human health and the environment***, considering:"

§69503.2(b)(1)
This should read: "The Chemical(s) of Concern in the product ***exhibit(s)*** a significant potential to ***contribute to*** adverse public health..."

§69503.2(b)(3)
This should read: "...in quantities that ***may contribute to*** adverse public health..."

§69503.2(b)(4)
This should read: "...in quantities that ***may contribute to*** adverse public health..."

§69503.4(b)(1)
This should read: "...that are a basis for the Priority Products listing and that ***may*** exhibit the same hazard trait..."

§69503.4(b)(2)
This should read: "...that are a basis for the Priority Products listing and that ***may*** exhibit the same hazard trait..."

§69503.4(c)(2)(A)
This should read: "there is the potential ***for exposures to the Chemical of Concern, or releases of the Chemical of Concern, to contribute to adverse impacts to human health and the environment***, due to one or more of the following:"

§69503.4(c)(2)(B)
This should read: " the Chemical of Concern ***may contribute to*** adverse ***impacts on human health and the environment*** in concentrations..."

§69503.5(b)
This should read: "and ***is unlikely to contribute to an*** adverse public health or environmental impact."

§69506.2(b)
This should read: *"**No regulatory response is necessary to limit potential exposures or reduce the level of potential adverse public health or environmental impacts posed by the selected alternative**."*
NOTE: this language is intended to track and impose the same test as in §69506.6(a) where DTSC's regulatory response power and obligation is articulated. Industry should not be able to establish that no regulatory response is warranted on a test that differs from DTSC's obligation and power to require such a response.

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7. Endpoints that protect the environment should receive greater weighting than is currently reflected in these regulations.

§69501.2(a)(2)
The definition for "adverse air quality impacts" should be expanded to read "adverse ***indoor and outdoor*** air quality impacts".

§69501.2(a)(16)
Without adding degradates, metabolites, and reaction products in the definition of chemicals, DTSC will need to make changes throughout the regulation to ensure that it adequately captures environmental impacts resulting from these types of substances. We suggest adding to the definition of "Chemical" language that ensures degradates, metabolites, and reaction products in the environment are captured in the definition.

§69503.2
Regarding Priority Products Prioritization, CHANGE recommends that the regulations require DTSC to consult with the State Water Resources Control Board, Department of Fish and Game, and other sister environmental agencies when establishing its lists of priority products and CoC combinations to capture emerging contaminants that cause water quality violations and other environmental problems. We further recommend that the department include at least one priority product that is proposed by the State and Regional Water Boards each time DTSC updates its list to protect water resources and prevent water quality violations in waste, storm, or drinking water.

§69503.2(a)
An additional Product Prioritization Criteria should be added, which is "breadth of use." This will ensure that DTSC captures chemical contaminants that, because of their broad use by the public or industry, enter the environment either in large quantities or on a regular basis and thus cause violations of air and/or water quality.

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8. The draft regulations include appropriate provisions to handle existing laws that regulate chemicals and/or products.

§69501(b)(4)(A)1.,2.
CHANGE supports how the draft regulations handle the impact of existing laws that regulate chemicals and products. That is, for a consumer product that is already under the purview of another regulatory agency, DTSC's Safer Consumer Product regulations would not apply only if the other agency addresses the same adverse public health and environmental impacts and exposure pathways; and it provides a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if regulated by DTSC.

These provisions are a dramatic improvement over those of previous drafts. They reflect the intent of AB 1879 and the groundbreaking substantive approach to regulation of chemicals that it is meant to produce. They should be retained.

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9. DTSC is breaking new ground in proposing a *de minimis* strategy, but more should be done to reflect current science.

§69503.4
CHANGE acknowledges that DTSC is breaking new ground in proposing a *de minimis* level that is 10 times more protective than any agency has proposed before for carcinogens, mutagens and reproductive toxins (CMRs), persistent bioaccumulative toxins (PBTs), and endocrine disruptors (EDs) - 0.01 % instead of 0.1%; and that DTSC will retain the authority to set a chemical-specific level if evidence warrants.

But DTSC should go further to restrict *de minimis* exemptions. CHANGE's position is that the regulations should adopt the strictest possible default *de minimis* standard of zero for all chemicals. We are learning more about chemicals that have impacts which were previously thought to be harmless. Each product examined could be assessed based on the hazard traits and toxicological endpoints in the chemicals of concern in the product.

De minimis exemptions in other chemicals laws function as a prioritization tool within laws that apply to very large numbers of products, such as REACH. But there are already so many prioritization steps in these draft regulations, particularly in the designation of Priority Products/CoC combinations, that it is hard to see why yet another prioritization tool is needed. One would presume that all Priority Product/CoC combinations are serious problems (unlike all products subject to REACH). DTSC should be mindful of the incentives created by the *de minimis* exemption: it will motivate product manufacturers to continue to use CoC's (and any other dangerous chemical) as long as they are below the *de minimis* thresholds, or to replace a CoC used at levels above the threshold with multiple CoC's each at levels below the threshold. These incentives (leading to reductions in the concentrations of CoC's in consumer products but not their actual use) undermine the intent and central goal of AB 1879, which is to prompt a search for safer alternatives.

Because DTSC is charting a new course in the arena of chemicals management, adopting a more protective standard would be a welcome contribution to other agencies, but more importantly, it would reflect current scientific understanding of what constitutes a "safe dose." Washington State is already moving beyond a "one size fits all" *de minimis* model.

DTSC should also consider requiring responsible entities to disclose chemicals of concern at any level that can be detected using an existing analytical method. This could be required regardless of what *de minimis* standard is ultimately finalized.

A zero *de minimis* standard would save DTSC scarce resources that could otherwise be directed to the task of setting chemical-specific *de minimis* levels and reviewing *de minimis* exemption notifications. While the burden of proof lies with the responsible entity to be accurate, it's hard to imagine DTSC will be able to provide sufficient quality control over the large number of *de minimis* exemption notifications that will come in the door.

At the least, chemicals that are carcinogens, mutagens, and reproductive toxicants (CMRs), persistent bioaccumulative toxins (PBTs), and endocrine disruptors (EDs) should have no *de minimis* exemption. These are known substances with adverse health effects, and increasingly seen at lower concentrations. For the endocrine disruptor bisphenol A, for example, effects can be observed in the parts-per-trillion range. A threshold of 0.01 percent would fail to be protective by several orders of magnitude. EDs in general will be under-recognized within this structure.

Even in cases where a *de minimis* level may be adequately protective as it relates to a chemical's use in a consumer product, it should be remembered that broad use of that product resulting in release to the environment (such as when the product rinses down the drain) can mean the aggregate environmental concentrations can be significant and the potential impacts quite significant.

If DTSC maintains the current two-tier *de minimis* structure as outlined in the draft regulations, it is imperative that DTSC actively exercise the authority to set a chemical-specific *de minimis* level where evidence warrants. We believe this would be much more likely to happen if the starting position were that there is to be no *de minimis* exemption, with DTSC establishing appropriate levels for a particular Priority Product/CoC combination where appropriate.

Meanwhile, concerning the "mode of action" language in the *de minimis* exemption:
The regulations provide that a *de minimis* exemption shall apply to a specified concentration applicable to all chemicals of concern that, among others, exhibit the same hazard trait or environmental or toxicological endpoint <u>and mode of action</u>**.** Applying the *de minimis* exemption to CoC's that exhibit the same endpoint is a solid approach to the problem of avoiding the *de minimis* exemption by incorporating more CoC's in smaller quantities but not reducing overall risk. But requiring the same "mode of action," is not appropriate. It bears no relation to the reason for this provision of the *de minimis* exemption in the first place. It is also very difficult analytically to establish, and the burden to do so would fall on DTSC, since it is unlikely industry will seek to establish that CoC's use the same mode of action (and therefore must be subject to a combined *de minimis* level). CHANGE therefore recommends that "mode of action" language be removed from the regulations.

Accordingly, we recommend the following amendments:

§69501.2(a)(25)(A)1.-9.
We are pleased to see a comprehensive listing of hazard traits/endpoints/effects in 1.-9. The list should also include "Neuro-Developmental Toxicity" which is an important hazard trait that OEHHA has specifically identified in its draft regulations to implement SB 509.

§69503.4(b)(1)
Eliminate the phrase, "and mode of action."

§69503.4(b)(2)
Eliminate the phrase, "and mode of action."

§69506.2(a)
Eliminate the phrase, "and mode of action."

§69503.4(b)(2)
Eliminate the phrase, "and mode of action."

§69503.4(c)(2)(A)4.
CHANGE recognizes that exposures will be considered in many places although we believe making decisions on hazard traits alone would generally be a more protective and forward-thinking approach. That said, CHANGE supports the language here that "the unintended presence of the Chemical of Concern in organs, tissues, or fluids" should be considered if a lower *de minimis* level is contemplated. Biomonitoring is an important tool that DTSC is wise to utilize.

§69506.2(a)
Eliminate the phrase, "and mode of action."

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10. Trade secret claims should be minimized.

DTSC is not providing any broad new leadership on transparency and trade secrets in the informal draft regulations, but instead relies on existing law in this area. CHANGE believes this will impair the program's ability to be fully trusted by all stakeholders. Nevertheless, DSTC does have the ability to take some steps to reduce the amount of trade secret claims that will be allowed under this program, and CHANGE urges it to do so.

Trade secrets should not be allowed for any health and safety or product ingredient information, nor for a chemical's identification in hazard trait submissions; nor for other kinds of information such as AA methodologies that AA assessors might choose. Transparency of this information is important for accountability, for public confidence in the program and for the ability of the program to affect the market. Simply put, consumers, workers and other downstream users of chemicals have a right to know about and avoid the hazards found in the chemicals and products they purchase. Recent tests by Women's Voices for the Earth found that popular cleaning brands had hidden ingredients linked to cancer, reproductive harm and allergies. Workers and employers have had similar experiences with inadequate and inaccurate Material Safety Data Sheets.

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.

We propose the following specific amendments to the regulations to implement these suggestions.

§69501.2(a)(75)
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).

§69505.2(b)
Regarding AA methodologies, as the draft regulations are written, trade secret provisions can apply to the process used to do the AA's where the assessor chooses a process that differs from that specified by DTSC. We understand that companies are developing AA methodologies for internal use and often consider them proprietary. If such processes are designated as trade secrets, not only will chemicals, alternatives, and specific products be redacted from public versions of AA reports, but the alternatives analysis process as well. This

would make the AA process less transparent, less accountable, and less able to influence the market. Therefore, the right to use an alternate AA process should be conditioned on full public disclosure of that process.

Accordingly 69505(b) should contain a new subsection that reads as follows:
"***§60505.2(5) If a responsible entity uses an alternate AA process under this section, that alternate process may not be claimed as a trade secret or as otherwise entitled to immunity from disclosure to the public, and must be made available for full and complete public disclosure in the Preliminary and Final AA Report."***

§69505.5
All finalized AA reports should be in the public domain, including those that don't follow DTSC's template.

§69505.5(b)(1)
DTSC should clearly specify that the Executive Summaries, which don't contain any information for which trade secrets are claimed, will be made publicly available by DTSC.

§69505.5(d),(e),(h)(2)
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). In fact, we recommend that this information be required earlier in the regulatory process to identify significant data gaps and enable the market to operate more efficiently.

This information will help the market operate more efficiently, and therefore it would be even better if DTSC required responsible entities to supply this information earlier in the regulatory process.

§69505.6(d)
All notices issued by the Department should also be posted on DTSC website.

§69506.3(a)(2)
While products meeting *de minimis* thresholds may not be subject to regulatory action that limits use of the chemical, the presence of such chemical(s) should not be exempted from rules on consumer product information. The public has the right to know that the chemical(s) are in the product, even at low levels.

§69508.3(e)
The language here reads: "An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach."

CHANGE supports the inclusion of this provision, while noting that the fact that it needs to be mentioned at all speaks volumes about the overly permissive allowances for trade secret claims.

§69510
Regarding the Assertion of a Claim of Trade Secret Protection, CHANGE appreciates the detail DTSC will require to ensure that trade secret claims are in fact valid and are not made frivolously.

§69510(c)(2)
CHANGE fully supports making a redacted copy of the documentation related to trade secret claims, excluding the information being submitted for trade secret protection, available to the public. This will allow the public, local agencies, and end-users to gauge the degree to which information is being kept confidential and allow them to make consumer, business, or regulatory decisions accordingly.

§69510(f)
This section provides that trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient. We support including this explicit language as it is derived directly from AB 1879, and reflects the importance of making this information publicly available.

However, the section should be amended to clarify that this exclusion includes the chemical identity of the chemical or chemical ingredient. Otherwise, as we've learned from TSCA, chemical identity will often be claimed as a trade secret, thus disconnecting the public disclosure of hazard trait information from any particular chemical and making it useless to the public and the market. Accordingly, §69510(f) should be amended to read:
"Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient**, or for *the chemical identity of the chemical or chemical ingredient***."

In addition, DTSC should inform the public when companies' trade secret claims have been approved so that the public knows it does not have complete information.

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11. DTSC actions will be hampered by a misplaced dependence on "available information."

There are many instances where DTSC's decisions and regulatory actions will be limited by the lack of available information. By 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 and not on the companies making the chemical or product containing the chemical.

DTSC should do everything within its authority under AB 1879 to obtain the information it needs to identify CoC's and safer alternatives and to fashion appropriate regulatory responses. Preferably, the burden of proof should be reversed so that in the face of uncertainty because of a lack of adequate data, the responsible entity must provide information that demonstrates with reasonable certainty that the chemical/product does not cause harm. DTSC should assert its data call-in authority to require the generation of new health and environmental impact data wherever it is unavailable, and DTSC should exercise this authority earlier in the program's implementation.

CHANGE continues to believe that chemicals for which there is little or no information demonstrating whether they are safe can reasonably be considered CoC's under AB 1879. This would give DTSC authority to request further information about them. At the very least, responsible entities must be required to identify data gaps earlier in the process.

We recommend the following specific amendments to the regulations.

At the very least, responsible entities must be required to identify data gaps earlier in the process.

§69501.5(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. The effort by DTSC to obtain

existing or new information is a good one, but the language should be strengthened so it's not simply an option for responsible entities, but a requirement. Throughout this section, "request" should be replaced with "require" as in 69501.3(a)(3); (69501.5(a)(4); (69501.5(b).

§69502.2(b)(3)
Here is an example where in considering additions to the CoC list, DTSC could, instead of merely considering "the availability of reliable information to substantiate the potential adverse impacts and exposures," require responsible entities to provide or produce the data that is needed. This would reverse the burden of proof and bring more information forward sooner.

§69503.2(a)
Here is another place where DTSC could compel responsible entities to provide or produce needed data as opposed to only considering factors "for which information is available."

§69503.2(a)(2)
Rather than rely on availability of information, DTSC should use this as an opportunity to require responsible entities to provide or produce information that is needed to make an informed decision.

§69505.4(a)(3)
The information listed in this section would be more useful if it was available earlier in the process; i.e. during prioritization.

§69506.1(a),(b)
CHANGE strongly supports the language in these two sections that gives DTSC authority to require the provision or development of needed additional information. This information would be even more useful earlier in the process.

§69506.3(a)
CHANGE supports the Product Information for Consumers labeling requirements outlined in this section.

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12. The definition of "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" will tie DTSC's hands and make the program less meaningful.

§69501.2(a)(67)
CHANGE strongly believes this definition will limit DTSC's ability to act in a meaningful way, and recommends the definition be deleted entirely. Much of what we are learning about potential harmful effects from chemical exposure is 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 this definition could be interpreted to require. DTSC has enough reliable information to act already in a way that is solidly legally defensible. If DTSC is required to meet this definition to consider data, a lot is going to fall through the cracks that the program should be looking at. Meanwhile, on the practical side, retaining this definition will create additional demands on staff time and resources (interpreting "environmental modeling" to name one example) which would be best avoided. The GRSP should be consulted if this definition is retained.

13. The regulations are silent about how to treat chemicals for which we have insufficient or no information.

CHANGE continues to believe that chemicals for which there is little or no information demonstrating whether they are safe can reasonably be considered CoC's under AB 1879. This would give DTSC authority to request further information in the form of minimum data sets.

In the absence of such a minimum data requirement, the regulations should at the very least create a mechanism to flag these chemicals – sort of a "yellow flag" that sends a message to the market and the public that they are under-studied and not necessarily safe.

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14. CHANGE is concerned about an over-reliance on exposure considerations.

We recognize that exposure data will be considered in some cases, but the innovative intent of AB 1879 is to base decisions on reducing hazard as the highest priority. That is, if a substance is dangerous, this is 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 an often-faulty plan of containing a chemical to prevent exposure. This approach unfortunately fails too often. This problem can be easily seen in the occupational setting where "containment" and limit standards are often inadequate and 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 the GCI. Decisions that result in merely containing a CoC should be considered an interim strategy to reduce danger to the public and environment.

§69501(a)
The regulations reflect the premise that any and all chemicals can be released into the environment and/or people may be exposed given the possibility of accidents and other failures to control chemicals. In the current draft, this section states the purpose of the regulations is to "to determine how best to limit potential exposures or the level of potential adverse impacts posed by the Chemical of Concern in the product." We would recommend that this phrase be changed to read the purpose is "to reduce the use of toxic chemicals."

§69501(a)
This section on the regulations' *Purpose and Applicability* "specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying potential alternatives for Priority Products to determine how best to limit potential exposures or the level of ***potential adverse impacts*** posed by the Chemical of Concern in the product." (emphasis added).

However the intent of the law, as noted in the Legislative Counsel's Digest of AB 1879 (1) is for chemicals of concern in products, and their potential alternatives, to be "evaluated to determine how best to limit exposure or to reduce the level of ***hazard*** posed by a chemical of concern." (emphasis added).

The phrase "potential adverse impacts" implies a risk assessment approach rather than "hazard assessment" which is consistent with the definition of green chemistry. We understand that DTSC will consider exposures as priority consumer product categories are identified, but it's important to remember that the intent of the law

is to use hazard characteristics as the basis for action.

§69501.2(a)(9)(D)
DTSC should specify that "any other change to the Priority Product" does not include simply "containing" the chemical within the product.

§69501.2(a)(70)
The phrase "and/or potential exposures" should be removed from the definition of "safer alternative."

§69503.4(c)(2)(A)2.
Is "inherent potency" another word for "hazard"? If yes, DTSC should simply use hazard. "Hazard" is consistent with the principles of green chemistry and intent of the law, as distinguished from "risk." If "inherent potency" is different from hazard, it needs to be defined in the Definitions section.

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15. Nanomaterials should be explicitly woven into and covered by the regulations.

First, the regulations should be altered to ensure that nanomaterials can be designated as Chemicals of Concern. The draft proposed regulations include a definition of "chemical" that apparently derives from TSCA and that may be interpreted so as not to permit adequate identification of nanomaterials as separate chemicals of concern that are distinct from their constituent chemicals. This is very important, because in some instances nanomaterials may be problematic where their constituent chemicals are not. The definitions of "chemical" and "chemical ingredient" should be amended to make clear that the properties of nanomaterials can form the basis for identifying substances as chemicals of concern.

Under the definition we propose below, while essentially all nanomaterials should be "chemicals" or "chemical ingredients," no regulatory implication whatsoever flows from that fact under these regulations. Only when DTSC designates a particular material as a chemical of concern would any requirements or other regulatory implications attach to that material.

Second, the process for designating materials as new CoC's should make it clear that the properties that make nanomaterials problematic can be the basis for identifying a new CoC.

Accordingly, we recommend the following amendments to the regulations.

§69501.2(a)(16)
Amend this section to read:
"Chemical" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, or any element, ***ion*** or uncombined radical. ***The term 'molecular identity' means the physical and chemical characteristics of the substance, including its chemical structure and composition, size and size distribution, shape and surface structure, reactivity, and any other properties that may be relevant to whether the substance is a potential chemical of concern."***

§69501.2(a)(17)
Amend this section to read: **"**Chemical ingredient" ***means a substance that comprises one or more chemicals."***

§69502.2(b)
This section should be amended to read:
"Additions to the Chemicals of Concern List. In addition to the chemicals ***and chemical ingredients*** identified as Chemicals of Concern pursuant to subsection (a), the Department may identify chemicals ***or chemical ingredients*** that ***potentially*** exhibit one or more hazard traits or environmental or toxicological endpoints as Chemicals of Concern by considering the following factors for which information is available:
(1) Potential Chemical or Chemical Ingredient Adverse Impacts.
(A) The potential for the chemical or chemical ingredient to cause adverse public health and/or environmental impacts, considering:
1. The chemical ***or chemical ingredient's*** hazard traits and environmental or toxicological endpoints, and modes of action;
2. The chemical ***or chemical ingredient****'s* aggregate effects;
3. The chemical ***or chemical ingredient****'s* cumulative effects with other Chemicals of Concern with similar modes of action;
4. The chemical ***or chemical ingredient****'s* physicochemical properties, ***including its chemical structure and composition, size, size distribution, shape, surface structure, reactivity and any other properties that may be relevant to whether it is a potential chemical of concern*****;**
5. The chemical ***or chemical ingredient****'s* environmental fate properties; and
6. The populations and/or environmental receptors that are potentially adversely impacted ***by the chemical or chemical ingredient***."

§69508.1(a)(5)(A-N)
Nanotechnology is listed as one of the skill sets in (L), but the draft regulations are mostly silent on how nanomaterials will be dealt with.

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16. Neuro-development toxicity should be explicitly included as a hazard endpoint.

Neuro-developmental toxicity is an important hazard trait that OEHHA has specifically identified in its draft regulations to implement SB 509.

§69501.2(a)(25)(A)1.-9.
We are pleased to see a comprehensive listing of hazard traits/endpoints/effects in 1.-9. "Neuro-developmental toxicity" should be added to the list.

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17. Add a definition of "Consumer"

§69501.2.
"Consumer" – a person or business who uses or buys a consumer product.

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18. Specify that nuclear materials are non-renewable resources.

§69501.2(a)(52)(C)
Add nuclear materials to the list under (C) which specifies non-renewable resources.

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19. The definition of "sensitive sub-populations" should be expanded to include women of reproductive age.

§69501.2(a)(72)
Women of child-bearing age should be 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. Many hazards to normal development actually threaten the fetus *in utero* early in pregnancy including before a woman may know she is 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. To protect the fetus, women of reproductive age must also be protected.

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20. Unnecessary and onerous burdens on DTSC will create huge bottlenecks

§69503.2(a)(1)(B)
This section as written will hamper DTSC's ability to act expeditiously in meaningful ways. There is far too much detail that will reduce the effectiveness of the regulations. CHANGE recommends a much simpler language to define the data needed to make prioritization decisions.

On the purely practical side, these sections will create huge workloads for DTSC. The specificity of the prioritization criteria will force DTSC on at least some wild goose chases while important data that should be considered will be off limits. This will detract from the program's "meaningfulness."

As GRSP member Kelly Moran has suggested, we recommend and agree with this improved and simpler language for (B):
"Potential Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts."

A clear articulation of a narrative approach should be included. The GRSP should be consulted to help craft these sections if more detail than this is contemplated. Here are additional recommendations for §69503.2(a)(1)(B) if the language is retained:

§69503.2(a)(1)(B)4.c.
We recommend amending the draft language so it reads: "Frequency and duration of exposure for each use scenario and end of life scenario, ***unless said Chemical(s) of Concern are deemed especially toxic or pose a serious hazard threat to human health and/or the environment."***

§69503.2(a)(1)(B)4.d.
We recommend deleting this language: "Containment of the Chemical(s) of Concern within the product, and engineering and administrative control" even as a prioritization factor. This is because there is no way to be sure such containment is viable and does not account for accidents and other occurrences that repeatedly demonstrate the flaws in such a strategy.

§69503.2(b)(4),(5)
These two "key prioritization criteria" inappropriately narrow what DTSC can consider and should be deleted. Many chemicals of concern, and products that contain them, would be missed entirely using these two criteria. Surely this is not DTSC's intention.

This is another section where the GRSP should be consulted to help craft language if these two criteria are to be retained.

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21. The Regulations should articulate an explicit legal standard for selection of alternatives and for regulatory responses.

§69506.6(a) of the regulations provides that DTSC will determine whether a regulatory response is "necessary to limit potential exposures." But this does not articulate a legal standard for what exposures are unacceptable and "necessary" to limit. The draft regulations as a whole lack any such standard.

AB 1879 provides limited explicit guidance on this critical question. §25253(a) directs DTSC to determine "how best to limit exposure or to reduce the level of hazard posed by a chemical of concern," but unfortunately does not articulate a clear legal standard for how conflicts between the interests in environmental health and economic factors are to be "best" balanced.

Inevitably, DTSC is going to have to confront this issue in deciding what regulatory responses to impose. Moreover, AA assessors will have to know how DTSC is going to approach this issue when they decide which alternative to choose because the consequent regulatory responses could affect that decision. Without an articulated standard, there is no hope of any either DTSC decisions or AA Report decisions being either transparent or consistent.

Accordingly, we urge DTSC to be forthright about this issue and articulate a transparent legal standard for its decision-making process that both the Department and AA assessors can apply consistently and to which the public can hold DTSC and industry accountable.

Fortunately, we believe that a solution to this problem is clear from the background and intent of AB 1879. It is emphatically clear that DTSC should not adopt the standard currently contained in the Toxic Substances Control Act. That statute places the burden of proof on the Administrator of U.S. EPA to make a number of showings before regulating a chemical, including demonstrating that the chemical presents an "unreasonable risk," as evaluated under a cost-benefit test. The difficulty EPA has had in carrying this burden of proof is the essential source of the "safety gap" that the Green Chemistry Initiative is intended to confront, as identified in the 2006 and 2008 Reports from UC Berkeley to the Legislature and DTSC, respectively.

We urge DTSC to adopt a standard that will implement the intent of the Green Chemistry Initiative to close the

safety gap. We recommend the standard set forth in the Safer Chemicals Act of 2011, a proposed law for reforming the Toxic Substances Control Act. Under S.847, the bill introduced in 2011 into the U.S. Senate, all chemicals in commerce, including both new chemicals and existing chemicals in order to remain in commerce, would be subjected to the requirement that the Administrator must find that "there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance." Safe Chemicals Act of 2011, S.847 (2011), at Section 6(b)(1)(C)(ii)(II)(bb), see p. 66. This "reasonable certainty of no harm" test was adopted by the US Congress in the Food Quality Protection Act (FQPA), which amended FIFRA, the federal pesticides law. In the FQPA, that test is interpreted to mean a one per million risk for cancer or 1000-fold less than a reference dose [often referred to as a "safe" dose] for other effects.

We urge that DTSC should ensure that this standard is adopted as the Department's goals for its Regulatory Responses and that AA assessors should ensure that any selected alternative meets this standard as well.

Implementing this standard will require carefully embedding it into several places in the regulation. We have not undertaken to do this, but will assist the Department in doing so.

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22. Enforcement must include significant penalties.

Enforcement needs to be strengthened so real penalties are imposed for failure to comply with the regulations. As the regulations are currently written, the only real consequence for ignoring the regulations is a notice of noncompliance on the DTSC website, and that only occurs if DTSC becomes aware of the noncompliance. Similarly, when a regulatory response is taken, DTSC should impose steep fines where appropriate. Low income and environmental justice communities have suffered economic and personal harm for years because enforcement of known polluters has been lax.

DTSC wants to retain flexibility, but this can work against the public interest if a non-responsive agency is running the show.

§69501.3(d)
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 responsible entities. Failure to comply needs to trigger more meaningful penalties, including fines, and other methods as appropriate.

§69501.3(d)
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.

Publicly listing those not in compliance with all or part of the regulations is one appropriate enforcement mechanism in that it also promotes the public's right to know. However, as we stated above, there should be more punitive repercussions, in the form of penalties or fines, to drive better compliance and to pay for DTSC's enforcement activities.

§69501.4.(a)
It's important that responsible entities take full responsibility for the work they perform under these regulations. We recommend the language here be amended to read that the individuals who sign on behalf of the responsible entity will be the responsible person(s) in charge of preparing or overseeing work for the responsible entity; or will be a ***high-level*** officer of the company.

Furthermore, CHANGE believes responsible entities should be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

§69501.5(c)
Fines should be part of the repercussions facing responsible entities that Fail to Respond within specified timeframes.

§69503.6(b)
Fines should be part of the repercussions facing responsible entities that Fail to Respond within specified time frames.

§69506.3
DTSC should ensure that phased-out products, with a consumer label or not, are not dumped into discount stores and low-income areas. An inventory recall mechanism to prevent this should be built into the regulations.

§69506.6(a)(2)(A)
This relates to "Other Regulatory Responses" DTSC may make. We strongly urge that the option to require "engineered safety measures to control access to or limit exposure…" be removed. Instead, we recommend adding to the end of the list of "other regulatory responses" language saying that the Department may require engineered safety measures to control access to or limit exposure to chemicals of concern as ***an interim action*** while the responsible entity acts to comply with the ultimate regulatory decision.

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23. There is great potential for unnecessary delays in program implementation.

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. We recommend 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.

CHANGE is also concerned that the dispute resolution process could be interpreted to extend to judicial review of disputes and not just the administrative process, which would lengthen potential delays even further.

CHANGE proposes the following amendments addressing these issues.

§69501.3(d)(2)
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.

§69503.3(d)
Posting the initial proposed list of Priority Products 180 days after the effective date of the regulations is too long, especially since we have heard several times from DTSC that there will only be 2-5 product categories in the first round. We think 90 days should be sufficient for the initial group of product categories to be identified and posted.

§69505.1
Regarding Preliminary and Final AA reports completed before 1/1/15, DTSC will be responsible for reviewing these before certified assessors come online. We note this is yet another activity that DTSC does not have resources for, lending weight to the need for the Legislature to act to provide fee authority to DTSC.

§69505.2(b)(3)
From the time a work plan for the AA Report is approved by DTSC, responsible entities will have up to 30 months to complete their work. Assuming that many responsible entities will ask for the maximum amount of time, and that there are no other delays caused by disputes, we believe 2.5 years is simply too long a period of time for the Final AA report to be generated. Reducing the deadline by at least one year, including requested extension time, will provide momentum for the program to work more quickly through a long backlog of potential priority products.

§69507(c)
The stay pending dispute resolution process needs clarification. Article 7 provides an administrative dispute resolution process. One of its provisions is that requirements pursuant this chapter shall be suspended "during the pendency of a dispute concerning the requirement." 69507(c). We understand DTSC's intent to be that requirements shall be suspended only during pendency of the administrative process, but that normal principles of administrative exhaustion of remedies and judicial review would apply if a petitioner were to seek judicial review of any requirements under this chapter, and that according to those principles a stay pending judicial review may or may not be appropriate. The current wording of 69507(c) is not clear on this point.

Accordingly, this section should be amended to read:
"...shall be stayed during pendency of ***the dispute resolution process under this article*** concerning the requirement."

§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. It is yet one more example of how the program will be slowed down by delays that are not necessary. A total of 90 days should be more than adequate for DTSC to act in this regard.

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24. Ensure that life cycle analysis must include all stages, including extraction.

§69503.2(a)(1)
Too often, extraction is left out of the considerations when talking about a life cycle analysis. The draft as written creates a permanent exclusion for adverse effects of CoC's that occur during the life cycle of the CoC that precedes the manufacture of the product it is incorporated into, including the manufacture and transport of the CoC itself. This limitation has no basis in AB 1879 and undermines its focus on the full life cycle of CoC's. This unwarranted limitation may also ultimately be incorporated into the AA process and perhaps the regulatory response process as well.

DTSC should amend the language to address this so it reads:
"The Department shall consider the potential of the Chemical of Concern in a product to contribute to adverse public health and environmental impacts due to potential exposures during its entire life cycle, including extraction of raw materials; during the manufacture and transport of the CoC itself; and during the manufacture, useful life, and end-of-life disposal or management of the product.

§69503.2(a)(1)(B)4.
Replace the word "useful" with "entire." Add the word "cycle" after "life." Amended language is:
"The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the ***entire*** life ***cycle*** of the product, considering the following factors:..."

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25. Minimize regrettable substitutions by prioritizing classes of chemicals.

The draft regulations may result in regrettable substitutions as companies switch out of chemicals of concern before their product is designated as a priority product. Past proposals for implementing regulations have included: (1) a no data, no market requirement for all or most chemicals in commerce; or (2) detailed, admittedly cumbersome reporting requirements anytime a CoC is altered in any product. The current regulations contain no provisions to address this, although the large number of CoC's may help somewhat with this problem.

Prioritizing classes or groups of chemicals or products rather than taking them up individually or relying on authoritative body listings would minimize regrettable substitutions and DTSC should consider building in a mechanism to do this when appropriate.

We suggest that at the very least, DTSC should try to collect information about the extent of this problem so as to inform the design of future elements of the GCI. In these regulations, DTSC could and should develop regulatory provisions to help accumulate information as to whether and how often companies switch out of CoC's prior to entering the formal AA process. For example, companies could be required to report to DTSC if they switch out or reduce the amount of a CoC in any product once the CoC list is finalized. A simple, non-burdensome program could provide information of great value to DTSC in the further development of the regulations.

26. The availability of alternatives should not limit decisions.

As written in the draft regulations, prioritization and other decisions are influenced by, and are in fact dependent on, the availability of safer alternatives. We believe this will send the wrong signal to the marketplace because it may deter innovation as well as run counter to the development of new alternatives which should be one of the goals of the program. DTSC should not unnecessarily limit their decisions based on the availability of a safer alternative, especially in the regulatory response phase.

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27. Responsible Entities have too much power to influence the outcome of AA Reports.

CHANGE is very concerned that responsible entities will be able to conduct their own alternative assessments. While the accreditation process builds in some accountability, the fact remains that a responsible entity will have a vested interest in a specific outcome of an alternatives assessment, and DTSC will not have the resources to adequately audit the many AA reports that will ultimately be generated. Moreover, the expected prevalence of trade secret claims is very likely to result in AA Reports that cannot be meaningfully evaluated by the public or other parties. Under these circumstances, the public is very unlikely to have a basis for confidence in the decisions made by the program. Some type of additional oversight mechanism must be developed. It would be far better for third party assessors to be responsible for undertaking the AA's after accreditation.

§69505.5(n)
Why is it necessary to ask responsible entities to propose regulatory responses? We don't know of other regulatory processes in California where a regulated entity is afforded the chance to recommend its own corrective action. DTSC is fully capable of imposing an appropriate regulatory response. We recommend this section be deleted.

§69506.2(b)
CHANGE recommends using this language for (b): *"**No regulatory response is necessary to limit potential exposures or reduce the level of potential adverse public health or environmental impacts posed by the selected alternative...**"*

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28. Better DTSC oversight of AA process is needed.

Rather than delegate authority to accreditation bodies to vet and approve certified alternative assessors, DTSC should strongly consider taking this responsibility on itself. It would be positive in several ways. First, the quality over the criteria for certification would be highly superior. DTSC will have to provide quality control in any case, so why not manage the process proactively? Second, it would build important expertise in the Department and in the community of alternative assessors generally as everyone would be operating from the same playbook. For the regulations to ultimately be meaningful, DTSC must have in-house experience so compliance with the regulations can be effectively assessed. And third, DTSC could reasonably charge fees for providing an important service. Since responsible entities will have to pay someone to receive accreditation, it would be strategic and appropriate for DTSC to fill this role.

§69508
Concerning the Qualification and Certification of Assessors, the plan that is outlined relinquishes greater oversight by DTSC, in large measure due to DTSC's lack of resources. However, what is proposed is too far removed from DTSC to ensure adequate quality control. This is one of many areas where fees could be put to good use so DTSC can assume responsibility over a key aspect of the overall program.

§609508 (a)(5)(A)
CHANGE supports the requirement for at least 20 hours of continuing education during each two-year accreditation period, including two hours each period in professional ethics.

§609508 (c)
CHANGE supports DTSC having the authority to rescind an assessor's certification and not completely delegate this authority to the accreditation body.

§69508.1(a)(5)(A-N)

The draft regulations say the accreditation body must have ability and experience teaching <u>one or more</u> of the following (A-N skill sets). It would be far better if the Department required more than simply one of these areas. As it's written, someone with experience as a risk assessor but nothing else on the list would be eligible. This would run counter to the intent of the legislation, which is to move away from risk assessment as the only tool with which to make decisions.

We recommend requiring one of these skill sets: pollution prevention, public health, or maternal and child health; plus requiring one or more of the other disciplines listed in (A)-(N), plus the addition of occupational health to the list of skill sets.

§69508.1(a)(6)
Requiring a lack of economic interest is essential, and there should be some binding mechanism that accreditation bodies agree to ensure this.

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29. CHANGE supports the draft language requiring a robust end-of-life management program.

§69506.4
Concerning the End-of-Life Management Requirements, CHANGE strongly supports the requirement for 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.

30. Copy Edits

§69503.2(c)(4)
COPY EDIT: Should be "Safer" not "Saver."

CHANGE appreciates the opportunity to make these comments. We will be happy to assist the Department in any way it would find helpful, including answering questions, elaborating our concerns and in developing more detailed proposals should the Department request us to do so.

We look forward to seeing a new proposal taking our concerns into accounts.

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Chemical Industry Council of California

April 19, 2013

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products – Proposed Regulations of April, 2013

Dear Ms. Buttle:

On behalf of the Chemical Industry Council of California[1] (CICC), we would like to once again express our appreciation for this final opportunity to comment on the Proposed Safer Consumer Products regulation. As we've previously noted, 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. We have a major stake in the practical implementation of these laws, and therefore have seriously attended to these regulatory proposals.

We noted in our comments of February 28, on the last draft set of regulations, that there were a number of major areas that we viewed as challenging practical implementation of these regulations. We are pleased to acknowledge that the current draft has a number of changes that are responsive to these concerns. Below we will highlight the areas where we find demonstrable progress toward more practical and implementable proposals.

However, we would be remiss if we did not clearly state that CICC remains seriously troubled about the overall impact of these regulations. As currently proposed, two key areas fail to capture the spirit and intent of the 2008 legislation: regulatory duplication, and protection of confidential business information and trade secrets. These threaten to undermine the integrity, if not the legal stability, of the overall effort. If left unchanged, they will face certain litigation and cannot be defended without inviting precedent-setting impacts far beyond the narrow interests of this regulation and this Department.

KEY REMAINING CONCERNS

Exemption - Conflict with Existing Regulations (69503.2, 69506.9): Once again we must note that the very narrow 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

[1] 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.

programs administered by other departments and agencies. 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 one of them: *"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."* Defending this standard may well put the State in the position of arguing that whole programs of workplace protection and other areas be subordinated to extraordinarily narrow rulings driven almost entirely by considerations of hazard, potentially without regard for relative risk and the efficacy of engineering and other risk-mitigation measures.

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 to the market (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 trade secrets, not patents. This option would be foreclosed under this proposal, seriously compromising its compatibility with genuine innovation in chemical development and application.

The State of California's remaining claim to economic greatness is very heavily invested in research and development and capitalizing on the State's extraordinary scientific and intellectual heritage. Ironically, this industry has absolutely no problem sharing the full range of confidential information with the State's regulatory authorities to enable them to exercise their responsibilities under the SCP regulations. But to dictate that that be systematically shared with the public and therefore the global market place is totally unnecessary and its precedent threatens serious damage to the core of California's economy.

KEY AREAS OF IMPROVEMENT IN THE CURRENT DRAFT

The following details those changes to the current draft that in our judgment are particularly significant with respect to practical implementation of these regulations, in light of the comments in our February submission. These are listed in order of their primary appearance in the draft.

Reliable Information (69501.1, pg 14): "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. The changes to the current definition would shift the criteria for evaluating such information to be somewhat more broadly applicable to any information considered in the Chemical-Product Prioritization, and additionally prescribe that such information is to be a "scientific study or other scientific information."

We regard these changes as positive, but they still short of calling for a full "weight of the evidence" determination in the application of such information. The standard of merely relying on "other scientific information" without being obligated to consider the weight of scientific evidence still leaves open the possibility of decisions being founded upon conclusions that would be undermined if a full consideration of available science were conducted. The decisions of prioritization and selection under these regulations will be very serious and could have major economic and other impacts upon Californians. The Department should ensure that the best scientific judgment of the State is brought to bear, and that

dictates consideration of the full range of available information. 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 current science, it will have effectively abdicated on that responsibility.

Candidate Chemicals (69502.2, pg 26): The Department's decision to recast the larger universe of chemicals under consideration for prioritization to designate them as "candidate chemicals" was a major step in the January draft toward a more rational approach to these laws. We take note of the changes to the process of adding additional "Candidate Chemicals" beyond the initial listing. In particular, we consider as positive the addition of a specific requirement to consider "Availability of Information" and the various considerations regarding the scientific rigor thereof. It is unfortunate, however, that that is not mandated for considering chemicals from the initial lists prescribed under these regulations. As noted in our February comments, we continue to question the inclusion of certain lists in this process, noting that some of the lists itemized do not seem to meet the criteria that would be applied to addition of subsequent "lists". It would therefore be appropriate to extend these criteria for scientific rigor to any chemical identified as a candidate chemical, regardless of its origin, including those selected from the initial "list of lists".

Product-Chemical Prioritization (69503.2, pg 28-29): We appreciate the Department's decision in this draft to explicitly frame this prioritization as applying to particular "product-chemical combinations." This reflects the practical implication of the changes made to the process in the January draft, which we support. As with the process for identifying Candidate Chemicals mentioned above, we view as positive the express inclusion of the considerations of scientific rigor in prioritizing Chemical-Product combinations under the regulations. We note some concern within the business community that these standards may be intended to negate inclusion of non-published information from industry. It is our expectation, however, that the State's scientists will be in a position to judge the scientific merit of such information per these regulations, pursuant to Item #1, in particular, recognizing that while industry often chooses to use its data very selectively, its scientists are of the highest caliber and can clearly contribute information germane to such evaluations.

Alternatives Analysis Threshold Exemption (69503.5, pg 32): The decision to authorize the Department to determine an alternatives analysis threshold different from the PQL for either an intentionally-added or a contaminant chemical of concern is far-and-away the most significant positive change made in this draft. We were very concerned about the Department's refusal to consider establishing reasonable *de minimis* standards, and the impact this would have in rendering the regulation far less predictable. It is our belief that it will often be the case that a threshold level exists above the level of detection. Enabling a stakeholder to make the scientific case for such recognizes that the State's scientists are able to make judgments based upon the scientific merit, and is fully consistent with the spirit of the 2008 laws. This will not propagate predictability to the extent a more general *de minimis* standard would, but it at least has the potential render the process far more rational and manageable.

One issue that is already raising questions in this regard may merit refinement of this section. That is the question of how the Department will deal with different manufacturers of the same chemical, which may submit information documenting differing thresholds. This situation is likely to arise, given that this consideration will be evolving around the limits of detection and therefore at our technological and scientific understanding. The Department must find ways of avoiding the appearance of arbitrary decisions under these laws, and would therefore be well-advised to address specifically its intent in such circumstances.

Public Comment on Alternatives Analysis (AA) (969505.1, pg 38 and 69505.8, pg 56): This is another very significant and positive change in the current proposal. The January draft introduced the notion of public comment on various stages of the alternatives analysis, and placed the onus on the

Responsible Entities to respond to each comment. We could foresee such a process evolving much as the California Environmental Quality Act (CEQA) has, leading to complex, costly and obstructive civil litigation that would have the potential to mire the entire process, while contributing little to the rigor of the end result. Complicating this further would be the difficulties arising from the extraordinarily narrow protections of confidential business information (CBI) afforded by these proposed regulations. To invite the public into the conduct of the AA process would greatly complicate the challenge of protecting confidential business information, including that which may not ultimately prove relevant to the final AA decisions.

The current draft provides a more rational process, in restricting those comments to the Final AA and in dictating the DTSC serve as an intermediary to determine which of those comments warrant response in an Addendum to the AA. This, again, places the State's scientists and regulators in a more appropriately responsible role in implementing this regulation. It also insulates the AA process from potential legal harassment and better-enables protection of confidential information during the development of the AA.

CONCLUSION

CICC maintains an overriding concern with the proposed regulation's treatment of conflicts versus existing regulatory programs and its treatment of confidential business information. In both regards, we view the current proposal as inconsistent with the letter and spirit of 2008 laws, and fear that pushing these to their logical end risks undermining the entire program. Notwithstanding these very important issues upon which the Department and the regulated community appear resolute in advocating opposing views, the changes in the current draft are positive and will prove important to rendering the regulation more workable. We therefore very much appreciate the Department's willingness to consider and respond to these aspects of our previous comments.

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. 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

Ms. Buttle,

We are a refurbisher in Colorado and we completely agree with the statements put forth by Willie Cade of PCRR concerning Proposed Regulation on Safer Consumer Products.

-Rich

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+----------
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April 25, 2013

VIA EMAIL AND OVERNIGHT MAIL

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

Re: Comments of the Complex Durable Goods Coalition on the April 2013 Revised Proposed Safer Consumer Products Regulations

Dear Ms. Raphael:

I am pleased to submit the comments of the Complex Durable Goods Coalition (the "Coalition")[1] on the revised proposed Safer Consumer Products ("SCP") Regulations (sometimes referred to as the "Proposed Regulations") released by the Department of Toxic Substances Control ("DTSC") on April 10, 2013 for public comment.

The Coalition acknowledges DTSC's attempts to render the SCP Regulations more practicable, including revising the scope of the Alternatives Analysis Threshold Exemption to encompass intentionally added ingredients. However, too many aspects of the Proposed

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[1] 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 Alliance of Automobile Manufacturers, the Association of Global Automakers, the Automotive Aftermarket Industry Association and the Motor and Equipment Manufacturers Association.

Regulations remain uncertain and confusing and, overall, the Proposed Regulations remain unworkable.

DTSC's proposed program is the first of its kind in the United States, with the ambitious goals of promoting "benign by design" approaches to consumer product design and manufacture, and of creating a new green economy in California. The program's implementation will be scrutinized closely by the public and executive level agencies in this and other jurisdictions. The Coalition is perplexed that four years into this regulatory process the SCP Regulations remain an unwieldy muddle. If DTSC does not revise, improve and incorporate real-world guidance from numerous industry experts charged with complying with the Proposed Regulations, its program is destined to very publicly fail.

The Coalition has five key concerns:[2]

- The failure of the SCP Regulations to address replacement parts and the inappropriate inclusion of repair/refurbishment/maintenance activities in the definition of "assemble";
- The failure of the SCP Regulations to address appropriately the importation of components and assembled complex durable goods;
- The continued lack of clarity about the Alternatives Analysis Threshold Exemption, including the absence of any criteria by which DTSC will develop an Alternative Analysis Threshold, and the continued use of the Practical Quantitation Limit as a cap on the maximum level of a chemical of concern ("COC") as a contaminant in a Priority Product;
- The continued deficiencies in the proposed public comment process for Final and Abridged Alternatives Analysis ("AA") Reports; and
- The confusing revisions to the definition of "Replacement Candidate Chemical" and "replacement chemical."

The Coalition discusses its five concerns in greater detail below.

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[2] The Coalition attaches and hereby incorporates by reference its prior comments on earlier versions of the Proposed Regulations, submitted on October 10, 2012 and February 28, 2013.

I. THE SCP REGULATIONS STILL FAIL TO ADDRESS REPLACEMENT PARTS AND INAPPROPRIATELY INCLUDE PERSONS WHO REPAIR, REFURBISH AND/OR MAINTAIN CONSUMER PRODUCTS WITHIN THE SCOPE OF RESPONSIBLE ENTITIES

In each of its prior comments to the iterations of the Proposed Regulations, the Coalition has pointed out the critical need to allow the continued manufacture of replacement parts for complex durable goods, and the critical need to ensure that persons undertaking repair, refurbishment and maintenance activities are not deemed "responsible entities." Those persons have no involvement in developing products and merely come in contact with those already in existence – at a point where chemical composition control is long past. Rather than ensuring such persons will not bear the burdens of DTSC's proposed program, the Proposed Regulations do precisely the opposite, thereby threatening California's economy, environment and consumer choice.

Ensuring that replacement parts remain available for complex durable goods is critical. Numerous unique factors interact to make the supply of replacement parts a challenge in any scenario, and the constraints to be imposed by the SCP Regulations promise to make those challenges insurmountable. Some of these unique factors are described below:

- 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 must remain available for years, even for products that are no longer being manufactured.

- Frequently, replacement parts must meet specific legal requirements and/or regulatory approvals or certifications. In these circumstances, it is not possible to simply substitute newly designed parts – not without substantial investment of time and resources, and certainly not in the short time frames contemplated by the SCP Regulations. As evidenced by multiple global COC-type regulations, replacement parts are designed and manufactured to the relevant regulatory requirements in effect at the time in which the product originally was sold. These other regulatory programs recognize that there is no feasible scenario in which resources could be adequately allocated to the re-engineering and re-development of parts associated with legacy products no longer being manufactured. Further, such efforts would drain resources from other efforts to "green" current and future products currently or imminently entering commerce – contrary to DTSC's stated goal.

- The lead-time necessary for product design, development and validation of complex durable goods is on the order of years, not months or weeks. At a minimum, this means that design changes to replacement parts also require substantial lead-time. And, for complex durable goods no longer being manufactured, there may be little

incentive to invest the resources for re-design of replacement parts to comply with the SCP Regulations. While DTSC's intentions may be noble, no evidence exists that DTSC understands the timing, design, sourcing, manufacturing or sale of complex durable goods, nor the inherent regulatory and timing roadblocks in the Proposed Regulations, which virtually assure failure. This apparent lack of understanding is made even more perplexing because multiple industries and associations have spent nearly five years working with DTSC to explain the unique issues surrounding the assembly of durable goods and to provide workable solutions toward a successful program. DTSC, to this day, either ignores or skews those solutions.

- With the multi-tiered, multi-faceted global supply chain inherent in the assembly of complex durable goods, replacement parts may be available only from overseas manufacturers. Such manufacturers may not provide re-designed replacement parts to fulfill demand for a single market, i.e., California, within the constraints of the SCP Regulations. In such circumstances, severe supply chain disruptions will result, with the ultimate victims being California's consumers and economy.

If implementation of the Proposed Regulations results in the unavailability of replacement parts meeting all applicable requirements, the net and ironic result could very well be detrimental impacts on the environment and sustainability. Greater waste will be generated as consumers discard broken and (now) unrepairable complex durable goods and buy new ones (also unnecessarily draining their financial resources); those broken goods will end up in landfills. With the repair of goods being discouraged by DTSC's proposed program, more virgin material will be used to manufacture goods to meet supply needs and comply with the program. These consequences will be exponentially exacerbated by the Proposed Regulations' inclusion of contaminants as triggers for the new program's burdensome regulatory requirements. The Coalition does not believe that DTSC intends the SCP Regulations to result in such environmentally detrimental consequences.

Nor does the Coalition believe that DTSC intends to encompass, within the hierarchy of responsible entities, persons who are ill-equipped to take leading roles in the sophisticated and costly AAs required by the SCP Regulations. Yet that is precisely the consequence of including repair, refurbishment and maintenance activities in the definition of "assemble." With this new definition, businesses that merely offer repair and maintenance services will be captured as assemblers within the hierarchy of responsible entities.

Aside from the fact that such businesses do not even sell or lease ***consumer products*** within the meaning of the authorizing statute, but merely offer ***services***, these entities are primarily small business owners that lack the expertise and financial resources to undertake AAs. The Coalition fails to see the logic in causing such damage to businesses, many of them part of a multi-billion dollar industry in California, whose only actions, at worst, would be to replace an existing part with a similar one. These businesses' only recourse may be to stop purchasing parts

– which will put them out of business. This will have an enormous economic impact and will create an uneven playing field vis-à-vis non-California businesses. DTSC has undertaken no economic analysis that would demonstrate otherwise and again has demonstrated a lack of understanding of industry and business needs within its own state.

The Coalition acknowledges that DTSC may have intended the new definition of "assemble" to clarify that persons providing repair, refurbish and maintenance services are not "manufacturers." The Coalition agrees that such persons should not be in the highest tier of responsible entities. Indeed, because such entities sell services rather than consumer products, it is far from clear that DTSC has ***any*** authority to regulate such persons under AB 1879. Aside from that threshold issue, DTSC's proposed approach would impose on a family-owned repair shop the same resource-intensive regulatory burdens as are imposed on national and global corporations. DTSC's approach has created a new problem that must be fixed by clearly removing from the responsible entity hierarchy altogether those persons offering such services.

The Coalition urges DTSC to make all of the following revisions (additions in underline; deletions in strikethrough):

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)(15)*:

   "Assemble" means to fit, join, put or otherwise bring together components to create~~, repair, refurbish, maintain or make non-material alterations to~~ a consumer product. "Assemble" does not include activities to repair, refurbish, maintain or make non-material alterations to a consumer product.

3. *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.

II. THE SCP REGULATIONS MUST APPROPRIATELY ADDRESS ASSEMBLERS OF COMPLEX DURABLE GOODS

The Coalition previously has described to DTSC the challenges arising from the global nature of supply chains for complex durable goods, and acknowledges DTSC's effort to appropriately assign the regulatory obligations of assemblers to a lower tier in the responsible entity hierarchy. Nevertheless, the SCP Regulations miss the mark regarding the importation of assembled complex durable goods and their components.

Assemblers of complex durable goods sometimes may import the components that they assemble and/or in some cases may 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. Yet, if such assemblers are considered "importers," they will be more likely to be called upon to conduct the sophisticated and resource-intensive alternatives analyses for the assembled products or components that they import. It is unrealistic to assume that these entities can acquire and maintain the level of chemical ingredient knowledge which DTSC apparently believes is readily available.

If the goal of the responsible entity hierarchy is to ensure that the most knowledgeable entity conducts the AA, then the SCP Regulations in their current form fail to achieve it. The Coalition therefore urges DTSC to adopt all of the following revisions (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 current proposed 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.

III. THE SCP REGULATIONS MUST CLARIFY THE ALTERNATIVE ANALYSIS THRESHOLD EXEMPTION

The Coalition acknowledges the changes to DTSC's treatment of the "Alternatives Analysis Threshold" ("AAT") Exemption, e.g., including intentionally added ingredients within its scope. However, many uncertainties remain and DTSC must clarify its approach to this component of the SCP Regulations.

At the outset, the Coalition makes one more attempt to urge DTSC to adopt a clear numerical value to the AAT, such as 0.1%. A "hard" number approach has been successfully used in the global regulations from which DTSC itself has drawn inspiration. A "hard" number provides clarity and certainty to the regulated community and vastly improves supply chain communications regarding product and ingredient specifications. Such clarity and certainty are key factors to the success of DTSC's program.

In addition, the continued inclusion of contaminants as a category of chemicals targeted under the overall SCP Regulations is the wrong approach for achieving the goals of DTSC's proposed program. Targeting contaminants results in confused priorities for eliminating "chemicals of concern" in California commerce. In a program as broadly scoped as this one, it is a better investment of resources to target intentionally added ingredients. Targeting contaminants in any manner also threatens the viability of recycling efforts and undermines other legitimate approaches to protecting the environment and promoting sustainability. Had sound, science-based reasoning been the primary driver for an effective regulatory solution, this proposition would be self-evident. Otherwise, the SCP Regulations may the first regulatory program in history that discourages reuse, recycling and recoverability. The Coalition cannot discern any rationale justifying such a result.

Beyond that, the Coalition is very concerned that the Proposed Regulations specify no criteria at all by which DTSC will develop AATs. No member of the public has any understanding of how DTSC will implement this aspect of its program. This is far from the transparent process that DTSC has aimed to create in the SCP Regulations and that is mandated by statute under Health & Safety Code section 25253(c). ***DTSC must identify objective, science-based criteria for developing AATs, and must allow the public another chance to provide input on those criteria via another round of public comments.***

Finally, the Coalition remains concerned about the viability of using the Practical Quantitation Limit ("PQL") as an AAT alternative for contaminants. PQLs are a moving target. They depend on the analytical method, the instrumentation, and even the laboratory in which a PQL is developed. PQLs rely primarily on the substrate being tested. Reliance on PQLs as AATs will cause inconsistent regulatory outcomes affecting responsible entities manufacturing, importing, assembling and/or selling the same Priority Products. Relying on a PQL based on the capability of a testing methodology, rather than the reality of testing a sample's unique

properties, continues to highlight that a science-based understanding and approach to the SCP Regulations is lacking. If PQLs are to be used at all as a component of AATs, they should set a widely accepted, science-based floor, rather than the cap, for the level of contaminants in Priority Products.

IV. THE PROPOSED PUBLIC COMMENT PROCEDURE FOR AA REPORTS STILL IS DEFICIENT

The Coalition understands that, through the public comment process set out in proposed Section 69505.8, DTSC seeks to establish a transparent quality assurance procedure for Final and Abridged AA Reports that shifts some burdens away from the agency. The Coalition also acknowledges DTSC's revisions to the public comment process for AA Reports, so that DTSC takes the lead role in collecting and reviewing public comments, rather than the private responsible entity. This lead role is the correct and appropriate one for any regulatory agency. However, the revisions to Section 69505.8 do not go far enough because the responsible entity, rather than DTSC, must respond to public comments via an Addendum.

The Coalition cannot find any precedent for a California public comment process in which a regulated private entity, rather than the regulatory agency, directly responds to public comments in a regulatory proceeding like the one being proposed. This procedure is not a lawful one under the Administrative Procedures Act and is contrary to Health & Safety Code section 25253(c) (requiring that tools for evaluating chemicals of concern be "in a form that allows ease of use and transparency of application"). DTSC must revise Section 69505.8 so that DTSC, and not the responsible entity, responds to public comments.

Proposed Section 69505.8 also fails to establish any criteria by which DTSC will filter what public comments warrant a response. It falls short of the statutory mandate that the tools for evaluating chemicals of concern be "in a form that allows…transparency of application." *See* Health & Safety Code section 25253(c). ***DTSC must identify objective, science-based criteria for reviewing and responding to public comments on Final and Abridged AA Reports, and must allow the public another chance to provide input on those criteria via another round of public comments.*** In this regard, DTSC must provide more than 15 days for comments on a proposal that will have such an extensive potential impact on the AA process. Indeed, this current 15-day comment period was insufficient to fully digest this new approach.

Finally, the Coalition remains concerned that this public comment procedure establishes an AA process with no finality discernible at the front end of the AA exercise. AAs already will be resource-intensive and time-consuming to prepare. The proposed public comment proceeding at the back end of the AA process will add more uncertainty and will increase the resources and time to necessary to finalize AAs – with as-yet-unknown benefits, if any.

V. THE REVISED DEFINITION OF "REPLACEMENT CANDIDATE CHEMICAL" AND "REPLACEMENT CHEMICAL" MUST BE CLARIFIED

Proposed Section 69501.1(a)(59) is incomprehensible. That section now defines "Replacement Candidate Chemical" and "replacement chemical" completely opposite to its original meaning. In light of the significant impact of this definition on implementing the Proposed Regulations and, particularly, the AA process to be undertaken by responsible entities, DTSC must revise the definition to make its meaning clear and must provide the public with a further opportunity to comment on the revised definition. If DTSC keeps the definition as is, DTSC must explain its rationale in detail and provide illustrations of its application in DTSC's final statement of reasons. This is critical for regulated entities to properly understand and implement the program's requirements.

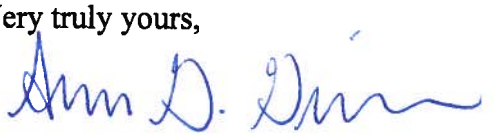
VI. OTHER ISSUES

Beyond what is described above, the Coalition remains concerned that the implementation of the AA process is still unclear. Among other things, DTSC has not clarified whether the AA guidance materials it posts will be mandatory requirements, whether they will establish some sort of baseline level for AAs, or whether they are merely recommendations. *See* Section 69505. And there is little confidence that the AA process will be a disciplined, science-based one that still contains sufficient flexibility to appropriately encompass the vast spectrum of products it will address. The AA process apparently will be an iterative one, with each round revealing its strengths and weaknesses. As implementation of the SCP Regulations proceed, the Coalition strongly urges DTSC to heed the voices of those actually in the trenches and undertaking these AAs.

Finally, once again the Coalition expresses its disappointment in the piecemeal approach of this entire regulatory process. The fragmented process has made it difficult for members of the public, and members of the regulated community in particular, to provide meaningful input.

Thank you for this opportunity to comment on the Proposed Regulations.

Very truly yours,



Ann G. Grimaldi

AGG

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Cliff Rechtschaffen, Senior Advisor to Governor Brown (via first class mail)
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February 28, 2013

VIA E-MAIL (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.[1] 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.

[1] *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. 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) 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.[2] 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~~.

[2] 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 ± 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 copyt 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.[3] 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.

[3] 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.

1 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.

Thank you again for this opportunity for the Coalition to comment on the Revised SCP Regulations.

Very truly yours,

Ann G. Grimaldi

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October 10, 2012

VIA E-MAIL (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 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;

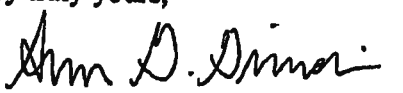
c. The amount of time that the Chemical(s) of Concern in the product is/are in contact with the body of the intended user during reasonably foreseeable use of the product; and

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.

Thank you again for this opportunity for the Coalition to comment on the Regulations.

Very truly yours,



Ann G. Grimaldi

Attachments

cc: Matthew Rodriquez, Cal/EPA Secretary (w/ attachments, via first class mail and email: 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)
Jeff Wong, Chief Scientist (with attachments, via email: jwong@dtsc.ca.gov)
Krysia von Burg, Regulations Coordinator (with attachments, via first class mail and email: gcregs@dtsc.ca.gov)

Madriago, Odette@DTSC

From: Pat Furr <pfurr@chicousd.org>
Sent: Wednesday, April 24, 2013 12:58 PM
To: GCRegs@DTSC
Subject: Response to April 2013 proposed regulations for Safer Consumer Products (R-2011-02,April 20130
Attachments: letter to Jackie Buttle, DTSC 4-13.docx

Jackie,

I am very interested in this proposed change. I am located in Chico, just 90 miles north of Sacramento. We are the largest non-profit in California that receives state donations for reuse. We currently have thousands of computer systems at use in schools and with low-income families.

I received notice of the DTSC meeting held monthly in Sacramento. What would be the best way of having our voice heard? Should I attend one of the meetings or meet with a staff person working on the wording? If you can guide me to the right direction, I would appreciate it. It is certainly worth my time to come to Sacramento to explain the implications to refurbishers by the choice of wording.

Pat Furr, President
Computers for Classrooms, Inc.
www.ComputersForClassrooms.org

530-521-9782

Microsoft REGISTERED Refurbisher

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Microsoft REGISTERED Refurbisher

COMPUTERS FOR CLASSROOMS, INC.

R2 is Responsible Recycling R2 3rd Party Certified: r2certification.info

R-2 Certified

April 24, 2013

DTSC

Attention: Jackie Buttle.

Computers for Classrooms, Inc. in a California based non-profit that has refurbished thousands of computers since its beginning in 1991 as a volunteer program through Chico Unified School District.

At a recent hearing in Sacramento Computers for Classrooms was described as the model non-profit in the state in working with school districts to reuse state surplus. We were the first non-profit in the world to become R-2 Certified and adhere to the highest standards of refurbishing, data security and recycling.

I am very concerned about the wording in the proposed regulation in Safer Consumer Products (R-2011-02, April 2013). In Section 69501.1 Definitions, "End-of-Life" number 30 (page 12 line 25 of the April 2013 text) is defined as "the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs **first".** This would indicate that all used goods would be subject to Section 69506.7 End-of-Life Requirements.

We are able to furnish thousands of refurbished computer systems to schools and low-income families each year. By extending the life of the computer systems we alleviate the need to build new systems. During the initial manufacturing process the greatest environmental harm results to air quality, water, mining, etc.

The EPA mantra is: Reduce, Reuse, then Recycle. Please do not generate language that would keep us from Reusing donated systems since the original owner decided to donate them for reuse.

Pat Furr, President/ CEO
Computers for Classrooms, Inc.
www.ComputersForClassrooms.org
530-521-9782 cell

Upon being notified that CFC was the first non-profit to become R-2 Certified, Jeff Hunts wrote:

As a founding participant in California's great e-waste experiment, CfC has demonstrated that reuse and recycling can co-exist and be both operationally successful and environmentally responsible.

Congratulations on such a noteworthy accomplishment!

Jeff Hunts, Manager

Electronic Waste Recycling Program

Department of Resources Recycling and Recovery (CalRecycle)

Ms Buttle,

Regarding the Safer Consumer Product Regulations, DTSC Reference Number: R-2011-02

The wording in In section 69501.1 Definitions, “End-of-Life” number 30 (page 12 line 25 of the April 2013 text): "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first”

Should be changed to: "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs last”

This will help to insure that reusable equipment can be reclaimed for it's highest and best use.

--
Ozzie Serrano
Computers for Classrooms
Warehouse Manager
530-566-6480 (Cell)
530-895-4175 (Office)
ozziecfc@gmail.com
R-2 Certified Recyclers
computersforclassrooms.org
http://www.turninggreentv.com/CFC.html

As a founding participant in California’s great e-waste experiment, CfC has demonstrated that reuse and recycling can co-exist and be both operationally successful and environmentally responsible.

Congratulations on such a noteworthy accomplishment!

Jeff Hunts, Manager

Electronic Waste Recycling Program

Department of Resources Recycling and Recovery (CalRecycle)

Representing Household & Institutional Products

Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

April 25, 2013

Via E-Mail: GCRegs@dtsc.ca.gov

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Revised Safer Consumer Products Regulation (Z-2012-0717-04)
Additional Post-Hearing Changes

Dear Ms. Buttle:

The Consumer Specialty Products Association (CSPA)[1] appreciates the opportunity to review and provide comments on the revised Safer Consumer Products Regulation. CSPA and our member companies have participated throughout the years-long regulatory development process through with submission of written comments, and participation in public hearings and workshops/seminars.

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.

We appreciate the efforts of the Department of Toxic Substances Control (DTSC) to review the vast public comments on the previous draft and efforts to address concerns identified, particularly:

[1] 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®, 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.

- Explicit indication that the Alternatives Analysis Threshold (AAT) can be above the Practical Quantitation Level (PQL);
- Improvement of public review process of Alternatives Analysis Reports; and
- Improved measure of reliability of information received by including a specified standard before being "accepted."

However, as this proposed rulemaking approaches conclusion, we remain disappointed that a number of provisions, many of which have been raised regarding each successive iteration, have not been addressed. We incorporate by reference our comments submitted on previous drafts, and specifically draw to your attention the following points which are either critical in terms of implementation or are significant changes from the previous draft:

- Explicit articulation that DTSC will follow the Administrative Procedures Act (APA) process on future Priority Products lists without administrative exemptions;
- Lack of an internationally harmonized *de minimis* threshold;
- Lack of guidelines or criteria for consideration for raising the Alternatives Analysis Threshold;
- Continued concerns with exemption and regulatory overlap; and
- Fundamental misunderstanding by DTSC of confidential business information and trade secret protection and the critical necessity of protecting such.

CSPA offers the following comments on the revised proposed Safer Consumer Products Regulation and respectfully requests DTSC address the concerns raised regarding this draft as well as comments on previous drafts to provide a regulatory process that is workable for the regulated community.

Concerns Associated with the California Administrative Procedures Act.
Throughout the SCP development, DTSC has indicated that the regulation specifies a "process" and correspondingly relied on this basis for exemptions to CEQA[2], Economic Analysis[3], and multimedia analysis[4]. In addition, in apparent response to comments DTSC has indicated that the Priority Products process will follow the APA process, implying that the exempted analyses of the APA process will be completed. CSPA requests that DTSC explicitly indicate the CEQA Analysis, Economic Analysis and multimedia analysis and preclude reliance upon the exemptions granted during the regulation development.

CSPA is concerned that the piecemeal APA process undertaken by DTSC will have a chilling effect on judicial review of agency decisions. The current proposed process could have the unintended and atypical consequence of obviating judicial review. If the Initial Priority Products

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[2] Notice of Exemption published July 26, 2012. http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-CEQA-NOE-7-26-12.pdf
[3] See Economic and Fiscal Impact Statement and associated attachments, http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-399-7-17-2012.pdf
[4] Exempted via Environmental Policy Council resolution, Feb 28, 2013. http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/CEPC-Signed-Resolution-2-28-13.pdf

selected are no longer in commerce, are products with minimal interest to those with the standing to challenge the outcomes, or are not representative of the larger class of potential priority products—with their diverse chemical, toxicological, and environmental fate characteristics-then stakeholders who could appropriately raise concerns and judicial challenges may not see a need to do so. This would result in subsequent stakeholders who have interests in products selected later in the process being left without a meaningful opportunity to raise concerns. CSPA has grave concerns regarding such an outcome.

Purpose and Applicability (Article 1, § 69501).
CSPA remains 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 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.

Definitions (§ 69501.1).
(57) – Reliable Information - CSPA is pleased with the updated definition of "Reliable Information" but remains concerned that the provision in §69501.1.(57).(A).1 of "Published in a scientifically peer reviewed report or other literature" is excessively broad and undefined. CSPA recommends that this provision's scope be improved to ensure confidence in the underlying science and avoid the appearance of arbitrary decisions.

(59) Replacement Candidate Chemical – CSPA is concerned about the provision in §69501.1.(59).(B) of "A chemical that is or would be present in the alternative at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than the Chemical(s) of Concern." CSPA recommends that this provision's scope be improved to consider risk-based determinations which would more accurately account for multiple chemicals being required to replace the function of a single chemical or potential increased exposure of a 'less toxic' replacement.

Chemical and Product Information (§ 69501.4).
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.

Availability of Information on the Department's Website (§ 69501.5).
CSPA is concerned about the inclusion of the website posting of exemption determinations and rescission of exemptions determinations. CSPA is unclear about the benefit of posting this information and recommends removal of these provisions.

Candidate Lists (Article 2, § 69502).
CSPA remains concerned that 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 described indicates that the mere presence on a list warrants inclusion. This situation is further compounded by the changes in the regulation that only contaminants may be exempted from consideration, provided they are below the PQL.

CSPA remains 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* public comment by their inclusion in the Initial Statement of Reasons (ISOR). Each other list has been evaluated publicly 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 reiterates the recommendation to remove this list.

CSPA remains 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 environment. In addition, the other lists under consideration have undergone rigorous scientific justification and substantiation *via* public comment by their inclusion in the Initial Statement of Reasons. Each other list has been evaluated publicly 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 reiterates the recommendation to remove this list.

Process for Identifying and Prioritizing Product-Chemical Combinations (Article 3 § 69503).
CSPA remains concerned that undue emphasis is placed on "potential" rather than "actual" exposures and reiterates the recommendation that DTSC consider risk-based approaches and to utilize scientifically recognized methodologies by which to evaluate product/chemical combinations.

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.*

(C) Availability of Information
CSPA is pleased with additional criteria and detail that the Department will evaluate to "substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects."

(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). 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. There remains significant concern that a responsible entity could be in full compliance with existing regulatory authority and that DTSC could exercise its discretion and imbue additional burden that appears to be in contrivance with the authorizing statute.

(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.

Alternatives Analysis Threshold (§ 69503.5).
CSPA appreciates the explicit indication that the Alternatives Analysis Threshold (AAT) may be specified via the Priority Product listing at a level above the PQL. If the proposed priority listing does not include an AAT, CSPA assumes that DTSC may consider public comments regarding the need for an AAT, and establish one in the final list, subject to at least an additional 15-day comment period. While this change to allow the option of DTSC specifying an AAT is a significant improvement, CSPA requests that DTSC determine the AAT based upon

scientifically valid risk-based determinations and utilize the underlying list(s) forming the basis for the Priority Product listing where the list establishes a *de minimis*. This approach would provide certainty and consistency with the current product development process.

Alternatively, it would allow for greater consistency and certainty if DTSC used the PQL concept promulgated by Washington State and Maine in their similar regulatory programs. The PQL should only be used as an AAT for intentionally added chemicals, with a more explicit *de minimis* established for contaminants (e.g., Washington State's and Maine's 100 ppm). Given the similar regulatory programs in other states, consistency is absolutely necessary to prevent undue burdens on manufacturers, given these state-to-state differences lead to minimal or no increase in public health and environmental benefit. CSPA requests DTSC adopt one of the two options detailed above.

In addition, CSPA is concerned with how the Department will appropriately manage multiple submissions regarding the same chemical by different manufacturers which suggest differing thresholds. While there would most likely be technical capability variations between manufacturers or their suppliers, it is also possible for potential disclosure of confidential business information or trade secret information about methods or suppliers that would need careful consideration. CSPA recommends the Department clearly articulate the scientific and technical basis for the AAT during the APA process.

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 with 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.

Related to this exercise, there is no guidance regarding how public comments should be evaluated. Should the opinion of a public commenter be 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. We request clarity on the criteria DTSC will use to determine which public comments require a response and to what degree the Responsible Entity will be required to respond.

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 regulation. As such, as DTSC goes through the process of identifying chemical/product combinations, DTSC is 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." Properly monetizing 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 responsibly 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 (§ 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 measureable 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, publicly 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 publicly 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.

Public Comments on AA Reports (§ 69505.8).
CSPA is encouraged by the inclusion of the Public Comments on AA Reports section. CSPA requests additional detail about the criteria by DTSC will use to identify whether a public comment should be addressed by in the Final AA Report or Abridged AA Report.

In addition, CSPA is concerned that the possibility the comments could create conflict with other regulatory authority or potential trade secret or Confidential Business Information concerns.

Trade Secret Protection (Article 9).
CSPA is extremely concerned about the effects of numerous portions of proposed Article 9 on its members and other companies in California and throughout the United States. We find that these

portions of Article 9 are not legally defensible, exceed statutory authority, and are inconsistent with California law.

Before turning to CSPA's concerns, we note that we are not aware that DTSC has any protocols in place for the protection of information claimed as trade secret under this regulatory program. Thus, as a threshold matter, CSPA requests that DTSC provide written assurances that it has, or will have, protocols in place to protect trade secret information against unauthorized disclosure.

Now turning to CSPA's specific concerns, the substantiation and documentation requirements of proposed Section 69509(a)-(c) exceed what California law requires to establish the existence of a trade secret. Instead of these burdensome and unnecessary requirements, DTSC should require only that the submitting entity provide a signed certification stating that the information being claimed as trade secret meets the requirements for protection under relevant law. DTSC should defer a request of substantiation information until such time the agency actually receives a request for disclosure of information claimed as trade secret, rather than when the claim is first made in a submission.

Proposed Section 69509(f) is overbroad and unnecessarily increases the risk that hazard trait submissions will be used in an anti-competitive manner. DTSC must revise this regulation so that the interests of public access to important information, on the one hand, and of the business need to prevent competitive gamesmanship, on the other, are balanced properly.

Proposed Section 69509(g) conflates two very different types of intellectual property protection to create an indefensible limitation on trade secret protection. This section purports to protect limited types of information, and then only if patent protection is sought for the chemical and only for the time period until the patent is issued or denied. This proposed regulation is in direct conflict with California trade secret law and therefore violates the California APA. Gov't Code § 11342.2. DTSC must eliminate proposed Section 69509(g).

Overall, DTSC appears to be operating under several misunderstandings regarding the nature and scope of trade secret and patent protection. With these apparent misunderstandings, DTSC has fashioned a regulatory proposal in this Article that is unworkable and that fails to balance properly the interests of the public and of owners of intellectual property.

The Nature of Trade Secret and Patent Protection

As a foundation for CSPA's discussion of its specific concerns with Article 9 of the Revised SCP Regulations that follows, we set forth below the legal background of trade secret and patent protection.

The Uniform Trade Secrets Act ("UTSA") is the main civil vehicle for protecting trade secrets in the United States. It has been adopted in varying forms by the majority of states, including California at Civil Code sections 3426 *et seq.* The California Uniform Trade Secret Act ("CUTSA") defines a trade secret as follows:

> '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, and not being readily ascertainable by proper means by, 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.

California Civil Code § 3426.1(d); *see also* UTSA § 1(4).

Recent developments in trade secret law show that this body of common law is dynamic and growing. The importance of trade secrets in our commercial lives has increased greatly in the last several decades for a multitude of reasons including: (1) the applicability and validity of other forms of legal protection for intellectual property in many of the emerging technologies have been fraught with uncertainty; and (2) trade secrets have gained importance because, in many fields, the technology is changing so rapidly that it is outstripping the existing laws intended to encourage and protect inventions and innovations.

Another factor enhancing the value of trade secrets is the relative ease of creating and controlling trade secret rights. There are not any bureaucratic delays or multiyear waits for government grants, such as those for patents. Trade secrets rights, in contrast, can be established by the explicit conduct or agreement of the interested parties. Trade secret rights have immediacy and controllability. A trade secret right arises upon creation of the idea in some concrete form, and continues without any time limitations as long as secrecy is maintained.

While the benefits of trade secret protection are often discussed in relation to encouraging innovation in the marketplace, another key purpose for the protection of business secrets is to enhance commercial morality and good faith dealings in business. As far back as the early 1800's, English common law began to consider protection for trade secrets, and the public policy of enhancing commercial morality by granting protection of trade secrets quickly spread to the United States. *Vickey v. Welch*, 36 Mass. 523 (1837). Since the beginning, the focus of United States trade secret cases has been on penalizing a breach of confidence and trust by misappropriation. *Peabody v. Norfolk*, 98 Mass. 452 (1868).

The concern for business morality has been a constant theme as the common law of trade secrets developed in the United States over the last century, and was emphasized by the U.S. Supreme Court in its landmark case of *Kewanee Oil Co. v. Bicron Corp*. After reviewing the public

policies underlying United States patent laws and state laws governing trade secrets, the Court held that trade secret law was not preempted by federal patent law and, in support of trade secrets, the Court noted:

> The maintenance of standards of commercial ethics and encouragement of invention are the broadly stated policies behind trade secret law. The necessity of good faith and fair dealing is the very life and spirit of the commercial world.

Kewanee Oil Co. v. Bicron Corp. (1974) 416 U.S. 470, 481-82.

A main policy goal of United States trade secret law is thus to foster and preserve a wholesome and fair-minded commercial ethic. Encouragement of honest and good faith business dealings is even more important in modern society, where extremely valuable ideas are often embodied in compact and easily transportable form, and espionage techniques are highly sophisticated worldwide.

Thus, trade secrets play a major role in protecting innovations and establishing rights to use new technology, and in maintaining high standards of commercial ethics. Nevertheless, this protection of intellectual property has shortfalls. They are a volatile form of property, and they terminate when secrecy is lost. They require vigilance to protect them from either intentional or inadvertent destructive disclosure. In this regard, secrecy is a particular challenge when addressing cyber security issues.

A. Patents, Policy and Nature of Protection

Patent protection arises from authority different than that for trade secret protection, is in many ways more limited than trade secret protection, and serves different public policy goals. Under the authority of the United States Constitution, Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for a limited Time to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8. This constitutional right is provided by the patent system, which grants to patentees the right to exclude others from making, using, offering for sale and selling a patented invention in the United States or importing the invention into the United States. 35 U.S.C. §154(a)(1). In exchange for the right granted by a patent to exclude other from these activities, a patent holder must disclose the invention to the public. This *quid pro quo* principle is rationalized to promote the progress of science by encouraging public dissemination of scientific knowledge and advances and encouraging research to design around patented inventions.

U.S. patent laws are set forth in Title 35 of the United States Code. Procedurally, patent applications are filed before the United States Patent and Trademark Office ("USPTO") where they are examined for compliance with the statutory requirements for patentability, including

novelty and nonobviousness.[5] As a threshold, only subject matter that is a process, machine, manufacture or composition of matter is eligible for patent protection, while a law of nature, physical phenomena or abstract idea is not patent eligible. *Diamond v. Chakrabarty* (1980) 447 U.S. 303, 309. Filing a patent application does not *per se* entitle the applicant to a patent unless the claimed subject matter meets the patentability requirements.

If subject matter is deemed to be patentable, the patent application is issued into a patent. For patent applications filed on or after June 8, 1995, issued patents are entitled to a right of patent exclusivity of 20 years from the earliest claimed priority date.[6] 35 U.S.C. §154(a)(2). When the patent expires, the subject matter is no longer granted any intellectual property protection.

Until this century, pending applications were not published unless and until they were granted as a patent. The American Inventors Protection Act of 1999 ("AIPA") amended Title 35 to provide that applications filed on or after November 29, 2000, with a few exceptions, would be published 18 months from the earliest filing date or earlier if requested by an applicant. P.L.106-113; *see also* 35 U.S.C. § 122.[7] Of course, any trade secret rights attaching to the subject matter of the patent are extinguished as soon as the patent application is published.

The average pendency of a patent application before it issues is approximately 32 months.[8] Therefore, a patent application can be published and available to the public for up to 2-3 years or more before it ever issues into a patent granting any rights – if, indeed, it ever does. In some cases, the publication date can be as much as 5-7 years or more before the patent application is "finally" denied, after exhaustion of all rights of appeal of that denial, including appeal to the U.S. Supreme Court. As a practical matter, as soon as an entity submits a patent application, it must be ready to surrender its trade secret rights in the intellectual property for which it seeks a patent, with the knowledge that for a substantial amount of time after the application is published and before a patent is issued (if it ever is), its trade secret is in the public domain and subject to use by any other person.

In sum, due to the requirement that patents, and in most cases pending patent applications, are published and not secret, the patent system is an intellectual property alternative to trade secret

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[5] The USPTO applies the statutory requirements of eligibility, utility, novelty, unobviousness, enablement and written description to each patent claim. 35 U.S.C. §101-103, and §112.

[6] The patent term can be extended by Patent Term Adjustment. 35 U.S.C. §154(b). The patent term can be reduced by filing of a terminal disclaimer. 37 C.F.R. §1.321.

[7] A patent application is not published prior to issuance as a patent under certain circumstances, including if it is no longer pending, is subject to a secrecy order under 35 U.S.C. §181, or is not or will not be the subject of an application filed in a foreign jurisdiction that requires publication of an application 18 months after filing and such non-publication is requested. 35 U.S.C. §122(b)(2). Empirical studies have shown that only about 7.5% of U.S. patent applications employ any of these provisions to keep their inventions secret before grant. Graham, Stuart J.H. and Hegde, Deepak, *Do Inventors Value Secrecy in Patenting? Evidence from the American Inventor's Protection Act of 1999* (November 2, 2012). Available at SSRN: http://ssrn.com/abstract=2170555 or http://dx.doi.org/10.2139/ssrn.2170555.

[8] United States Patent & Trademark Office, USPTO Performance and Accountability Report Fiscal Year 2012 at p.3, http://www.uspto.gov/about/stratplan/.

protection. Unlike trade secret protection, a patent confers a right to exclude others from practicing the invention. This right, however, is a limited right. It is granted for a defined time, is only granted for certain types of subject matter, and requires that the subject matter patented is novel and nonobvious. Also, the expenses involved in patent protection are high, including costs for preparing a patent application and separate fees for patent filing, prosecution, issuance and maintenance for the life of the patent. For these reasons, in certain instances, trade secret protection can be more advantageous than patent protection.

In essence, the policy behind patent protection stands in stark contrast, and is counter to, trade secret protection that is based in *not* publicly disclosing the intellectual property. The two are mutually exclusive. In *Kewanee Oil Co. v. Bircron Corp*., the U.S. Supreme Court affirmed that patents and trade secrets are independent forms of intellectual property by holding that federal patent law does not preempt state trade secret law even if the subject matter could be patented. 416 U.S. 470 (1974). As stated by the Supreme Court:

> Trade secret law and patent law have coexisted in this country for over one hundred years. Each has its particular role to play, and the operation of one does not take away from the need for the other. Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor by contracting with a company large enough to develop and exploit it. Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.

Id. at 493.

Many companies rely on a combination of trade secret and patent protection in order to protect their discoveries and inventions. 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. For example, trade secret protection is the only intellectual property form available for subject matter that is not or may not be patentable, such as a formula, recording or other compilation of information used in a business. In other cases, where the trade secret is not readily discernible from the product, electing trade secret protection can be the preferred intellectual property protection scheme, and a patent application is never filed. There are well known instances in which companies have relied on trade secret protection to protect their intellectual property. These include Colonel Sander's "secret" chicken recipe and Coca-Cola Company's "secret" formula for COKE. The

choice of which intellectual property form to pursue is a fundamental business decision that should not be dictated or mandated by any agency.

Specific Comments Regarding Article 9: Trade Secret Protection

Apparent Absence of DTSC Protocols to Protect Against Disclosure. Cyberspace is a notoriously porous medium, subject to breaches if strong measures are not undertaken to protect against them. Especially with electronic transmission as the favored means of submitting the necessary documents and reports under the Act, DTSC must provide the regulated community with assurances, in the form of specific descriptions, of the protocols it will implement to protect against disclosure of information claimed as trade secrets.

CSPA's concerns are not baseless. The White House recently has acknowledged the escalation of industrial espionage and the role of cyber intrusions:

> Emerging trends indicate that the pace of economic espionage and trade secret theft against U.S. corporations is accelerating. There appears to be multiple vectors of attack for persons and governments seeking to steal trade secrets. Foreign competitors of U.S. corporations, some with ties to foreign governments, have increased their efforts to steal trade secret information through the recruitment of current or former employees. ***Additionally, there are indications that U.S. companies, law firms, academia, and financial institutions are experiencing cyber intrusion activity against electronic repositories containing trade secret information***. Trade secret theft threatens American businesses, undermines national security, and places the security of the U.S. economy in jeopardy. These acts also diminish U.S. export prospects around the globe and put American jobs at risk.

Administration Strategy on Mitigating the Theft of U.S. Trade Secrets, February 2013 (http://www.whitehouse.gov//sites/default/files/omb/IPEC/admin_strategy_on_mitigating_the_theft_of_u.s._trade_secrets.pdf) (hereinafter "Trade Secret Administration Strategy") at p. 1 (emphasis added). The Obama Administration has called on private businesses to share information regarding best practices to protect trade secrets, including practices relating to information security policies. *Id.* at p. 6.

Recent and well-publicized cyber intrusions have affected government agencies as well. In 2012, hackers stole 3.6 million Social Security Numbers and other sensitive financial information from the South Carolina government. "Hacking of Tax Records Has Put States on Guard," *The New York Times* (November 5, 2012), http://www.nytimes.com/2012/11/06/us/south-carolina-tax-hacking-puts-other-states-on-alert.html?_r=0. In California, hackers breached the San Francisco Bay Area Rapid Transit ("BART") website and stole personal information of about 2000 individuals. "BART Website Hacked, Customer Info Leaked," *San Francisco Chronicle* (August 15, 2011),

http://www.sfgate.com/bayarea/article/BART-website-hacked-customer-info-leaked-2335175.php.

The federal administration has acknowledged ongoing and escalating breaches of government agencies' electronic information repositories:

> Cyber tools have enhanced the economic espionage threat, and the Intelligence Community (IC) judges the use of such tools is already a larger threat than more traditional espionage methods.
>
> * * *
>
> The trend in both commercial and government organizations toward the pooling of information processing and storage will present even greater challenges to preserving the security and integrity of sensitive information.
>
> * * *
>
> The trend of foreign economic collection and industrial espionage activities and U.S. Government agencies is accelerating.

"Foreign Spies Stealing US Economic Secrets in Cyberspace," *Office of the National Counterintelligence Executive Report to Congress on Foreign Economic Collection and Industrial Espionage, 2009-2001* (October 2011), attached as Annex C to Trade Secret Administration Strategy, p. i and 1.

Public agencies must assure entities submitting trade secret information that those agencies have protocols in place to protect against cyber intrusions and other breaches to protect such information against unauthorized disclosure. Just as significantly, such protocols are necessary for a submitting entity to ensure that it is taking reasonably necessary steps to protect against unauthorized disclosures, for otherwise the information submission itself could be deemed a waiver of its trade secret rights. The only way that entities may disclose trade secrets without losing their economically valuable protection and the economic advantage derived from the trade secret, is by making the disclosure under a written obligation of confidentiality and non-disclosure of the trade secret by the receiving party. Absent written protocols establishing protection of submitted trade secrets from disclosure, DTSC's regulatory program 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 that ultimately would place those trade secrets in the hands of the public, including foreign competitors.

Substantiation/Documentation Requirements (Section 69509(a)-(c)).
The substantiation and documentation requirements set forth in proposed §69509(a)-(c), which are intended to support DTSC's determination of whether certain information constitutes a trade secret as claimed by a submitter, far exceed the test for a trade secret under CUTSA. Therefore, in addition to creating an undue burden on parties asserting trade secret protection, the proposed rule impermissibly conflicts with existing law in violation of Government Code section 11342.2.

CUTSA provides a simple two-part test to identify a trade secret: the information derives independent economic value, actual or potential, from not being generally known or ascertainable by proper means, and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Civil Code § 3426.1(d). However, proposed Section 65909(a)-(c) makes numerous additional requirements to support an assertion of trade secrets. These many additional substantiation requirements far exceed the scope of a determination of trade secrets under CUTSA and create an unnecessary burden on companies, which will ultimately increase costs for consumers. Further, this substantiating information itself may be trade secret.

Substantiation of the nature described in this proposed regulation may arise in the context of litigation regarding disclosure of trade secrets. Similarly, substantiation often is required in the context of responding to a request for disclosure under the California Public Records Act, Government Code section 6254 *et seq.* Substantiation of trade secrets under Section 5194 of Title 8 of the California Code of Regulations is required only when the entity claiming trade secret refuses to provide chemical information to a health care provider. In all of those circumstances, the context informs the process and justifies the burden of establishing the various elements for substantiating a trade secret. Here, however, DTSC demands a particularly burdensome upfront substantiation of trade secret claims in the total absence of any demand or any other context informing the agency's review of the substantiating information. Indeed, a request for disclosure may never even be made. There appears to be no reason to use limited agency resources to review trade secret substantiation in a contextual vacuum. Nothing in Health & Safety Code section 25257(a) requires substantiation in this manner.

The proposed requirements set forth in proposed Section 69509(a)-(c) are therefore inconsistent with California law, and should be modified to balance the interests of the public and of members of the business community. If DTSC believes it must demand such information, it should:

> with a submission in which a trade secret claim is asserted, require only a signed certification from the submitting entity stating that the information meets the requirements of the "trade secret" definition under relevant law. In this regard, trade secrets and other confidential business information 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 Regulations; and make the request, if any, for substantiation after first receiving a request for disclosure.

In this way, DTSC receives preliminary assurance that the submitting entity is making a genuine claim. Then, if a disclosure request is ever made, those specific circumstances will help inform the substantiation process, assisting DTSC's review of a trade secret claim while reducing the burden to submitting parties.

Hazard Trait Submissions (Section 69509(f)).
Notwithstanding the apparent statutory authority under Health and Safety Code section 25257(f), this proposed regulation is overbroad and does not adequately protect owners of trade secrets. First, the regulation purport to exclude chemical identity information and therefore impermissibly narrows the application of CUTSA; nothing in Health and Safety Code section 25257(f) establishes that authority.

Second, the regulation offers no protection against disclosure to competitors. The intent of the law and this regulation is to ensure that the public has access to important information about chemicals. Such an intent should not be undermined to also expand the potential for anti-competitive behavior. Finally, forcing Californian and American companies to reveal their trade secrets has an indirect impact on the companies' abilities to retain talent and create high-paying jobs.

In the context of pesticide regulation, both federal and state laws acknowledge this problem and have developed a solution. Although health and safety studies are not deemed "trade secrets" under these respective programs, 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). DTSC must include a provision and process similar to that under Government Code section 6254(g).

Chemical Identity Masking When a Patent Is Pending (Section 69509(g)).
The DTSC revisions to §69509(g) appear to create a temporary right to obtain trade secret protection for a replacement chemical only if patent protection is sought for the chemical and only for the time period until the patent is issued or denied. This proposed regulation is in direct conflict with California trade secret law in three respects: it purports to limit the type of information that may be deemed trade secret, it purports to limit the time that a trade secret may enjoy its secret status, and it purports to predicate that protection on the application of a patent. Thus, proposed Section 69509(g) violates the APA. Gov't Code § 11342.2. DTSC must eliminate this provision. If DTSC wishes to provide in these regulations any guidance regarding the nature and scope of trade secret protection, it should refer to existing California law on the subject.

As has been discussed at length, CUTSA specifies two requirements for information to be trade secret: the information derives independent economic value, actual or potential, from not being generally known or ascertainable by proper means, and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Proposed Section 69509(g) purports to limit the universe of information categories that may enjoy trade secret status. Thus, this proposed regulation contradicts the CUTSA and is invalid.

California law does not limit the time of trade secret protection. As long as the holder of the trade secret takes measures to prevent its disclosure, the trade secret remains protected. *Vacco Indus., Inc. v. Van Den Berg* (1992) 5 Cal.App.4th 34, 50. Yet, proposed Section 69509(g) purports to limit the time of trade secret protection. Nothing in the Act confers authority on DTSC to restrict existing law. Proposed Section 69509(g) therefore is invalid for this reason as well.

Finally, proposed Section 69509(g) improperly requires a patent application to be submitted to obtain even the limited trade secret protection the regulation offers. Most patent applications are published. If the *sine qua non* of a trade secret is its very secrecy, then a patent application is a sure path to its obliteration.

Proposed Section 69509(g) conflates two distinct forms of intellectual property protection, while eroding the rights each form confers. Trade secret protection and patent protection are distinct and alternative forms of intellectual property. To take advantage of the rights under each, an entity will never, and simply cannot, choose to pursue both patent protection and trade secret protection because these protections are based on opposing principles and, ultimately, are mutually exclusive. Trade secret protection requires protecting intellectual property as a secret, while patent protection mandates public disclosure of discoveries. Linking the two in the manner as required under proposed Section 69509(g) is counter to the very principles and policies that have established these rights in this country. It is also counter to the U.S. Supreme Court's determination in *Kewanee Oil Co. v. Bicron Corp*. that federal patent law does not preempt state trade secret law.

There is no public policy or legal reason to support DTSC's requirement that trade secret protection only can be afforded if patent protection is sought. This requirement seriously erodes existing statutory and common law property rights currently guaranteed to owners of trade secrets under federal and state laws that permit protection of a trade secret for an unlimited time. 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. Moreover, the requirement also erodes the constitutional right to choose whether to secure for a limited the rights in a discovery afforded by the patent system.

The DTSC draft proposal thus errs in making several critical assumptions about how entities conduct business:

1. 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, trade secret protection and patent protection are distinct and alternative forms of intellectual property that do not overlap. In many instances, trade secret protection may be the only form of intellectual property protection available, or is otherwise the most advantageous form of intellectual property. For example, certain types of intellectual property may not be eligible for patent protection, including aspects related to certain diagnostic methods and certain business methods or other subject matter, or because of the rigorous statutory requirements of novelty and nonobviousness. In addition, where the discovery or invention is a product formulation that cannot readily be analyzed or which is not discernible by inspection, an entity often chooses trade secret protection to take advantage of the unlimited time frame of protection, as opposed to the limited 20 year exclusive right derived from filing a patent, assuming the patent ever issues.
2. 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, which is statutorily required approximately 18 months after the earliest priority date. A published patent application is not confidential, nor does it impose an affirmative obligation on the receiving party (i.e. the public) not to disclose the received trade secret to any third party. Publication of a patent application thus automatically triggers the loss of trade secret protection. Further, once an entity files a patent application and it is published, the subject matter of the patent application will not be a trade secret in any country. Thus the patentee will need to file patent applications in countless countries in which such protection is desired – which is costly.
3. Third, the DTSC proposal errs in assuming that it has a proper legal basis to require entities to either waive their property rights to trade secrets, or only temporarily grant those rights until a patent application publishes or a patent issues. To the contrary, such a requirement could be challenged in court as an unconstitutional "taking" of property. Trade secrets under state law are a property right protected by the Taking Clause of the Fifth Amendment. *Ruckelshaus v. Monsanto Co*. (1984) 467 U.S. 986. DTSC's proposed requirement also could be challenged under state trade secret law, since federal patent laws do not preempt state law. An entity cannot be forced to pursue patent protection over obtaining trade secret protection, even where the subject matter sought to be protected may be patentable.

Summary Regarding Article 9.

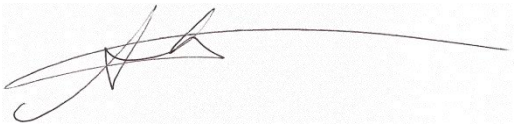
CSPA does not believe that the latest DTSC draft properly addresses the substantial unintended economic effects of requiring mandatory disclosure of trade secrets. For all of the foregoing reasons, the proposed regulations in Article 9 must be modified (proposed Section 69509(a)-(c), (f)) or eliminated (proposed Section 69509(g)).

Summary and Conclusion

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.
Senior Director, Scientific Affairs & Sustainability

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
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CSPA State Government Affairs Advisory Committee
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April 25, 2013

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

VIA EMAIL: gcregs@dtsc.ca.gov

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

Dear Ms. Buttle:

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

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

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

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

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

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

For purposes of the direct selling industry, this would require direct selling companies manufacturing products to report the name, home address, electronic address and phone number of each individual distributor to whom the companies sold their products. DSA has serious concerns related to the privacy issues associated with disclosing this information in an AA Report that could then be posted on the DTSC website for public comment pursuant to § 69505.8.

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

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

Sincerely,

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

Electronics Industry Comments on Proposed Regulation on
Safer Consumer Products (R-2011-02, April 2013)

The Information Technology Industry Council (ITI), TechAmerica, the Consumer Electronics Association (CEA) and the Semiconductor Industry Association (SIA), are pleased to provide these comments on behalf of the information technology, consumer electronics, and semiconductor industries on the Proposed Regulation for Safer Consumer Products (Proposed Regulation). Our industries have been longstanding stakeholders in the California Department of Toxic Substance's rulemaking to develop regulations for safer consumer products, and we continue to appreciate the opportunities that the Department of Toxic Substance Control (DTSC) has provided stakeholders to provide input on these regulations as they have progressed through the drafting process.

While the current draft of the proposed regulations contains significant improvements from the previous draft, ITI, TechAmerica, CEA and SIA are united in our belief that the proposed regulations remain unnecessarily onerous and that significant additional changes are necessary for these regulations to be workable. For example, the changes that have been made to the Alternative Analysis threshold are largely inadequate and additional improvements, as referenced in our comments to the January 2013 and October 2012 drafts of the proposed regulations, are needed in order for the DTSC to achieve its stated goal of making these regulations practical, legally-defensible and meaningful.

Because of the significance of these regulations and the precedent that they will set, the undersigned organizations urge the DTSC to conduct a formal, public review of the implementation of these regulations commencing nine months after their effective date. Within that time period, DTSC should have designated the first Priority Products, the producers of those products should have submitted their preliminary alternatives assessment report, and DTSC should have completed its review of those reports. A formal, public review of the implementation of the rules at that point should enable DTSC and the

public to determine whether the rules are likely to achieve their intended benefits at a cost commensurate to those benefits.

Specific Comments by Section:

Section 69501.1 Definitions

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

(13) –" Alternative Analysis Threshold" or "AAT" is defined as "the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant."

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

Worldwide, chemicals management programs and regulations such as the Global Harmonized System (GHS) for chemical reporting on Material Safety Data Sheets (MSDS), the EU REACH Directive for reporting of chemicals in articles, and the Consumer Product Safety Improvement Act all incorporate a *de minimis* regulatory threshold below which no action is required. In addition, for the electronics industry, the EU RoHS Directive and the Electronics Product Management Methods in China (China "RoHS") both apply *de minimis* regulatory thresholds for the 6 chemicals that are restricted in electronic products. While Washington State's Children's Safe Products Act implementing regulations and Maine's revised Toxic Chemicals in Children's Products Law use the PQL as a regulatory threshold, this threshold <u>only</u> applies for intentionally-added chemicals; contaminants are regulated at 100 ppm. The Electronics Industry again suggests that the Department develop a process to establish a reasonable threshold other than PQL that would trigger regulatory action, and we are willing to work with the DTSC to develop such a process. Absent such a threshold, the rule's regulatory requirements would be triggered by a chemical's presence at the analytical detection limit, which has no connection with public health or environmental risk and which raises significant enforcement concerns due to uncertainty regarding the presence of

contaminants and background concentrations of the regulated chemical in manufacturing materials.

Additionally, the PQL for any given chemical will vary based on the matrix in which the chemical is contained as well as the specific test being used. Therefore, there will be the potential for the same chemical to be regulated at different levels for different manufacturers. Furthermore, as analytical testing methods and detection limits improve over time, the threshold level for a specific chemical, if set at the PQL level, will also change over time. These advances in laboratory detection methods and analytical chemistry have absolutely no correlation with public or environmental hazard or risk. Therefore, establishing the alternative assessment threshold for contaminants at the PQL level will create testing uncertainty and compliance difficulties, and will require manufacturers of products that pose no environmental or public health risk to undertake expensive and unnecessary alternatives analyses.

The Electronics Industry appreciates that the DTSC may establish chemical-specific AATs above the PQL. However, any AATs that are set at "Zero", "Not Detectable," or the PQL level are not practical and unworkable and will give rise to compliance uncertainty. However, if DTSC does use the PQL concept, it should harmonize with the approaches taken by the states of Washington and Maine.

(15) "Assemble" is defined as "to fit, join, put, or otherwise bring together components to create, repair, refurbish, maintain, or make non-material alterations to a consumer product."

This definition adds "repair and refurbishment" to the scope of "assembler." While this definition will expand the scope of potentially responsible entities, we are concerned that covering the repair and refurbishment of products that were potentially not in scope when they were manufactured would be environmentally counterproductive. Rather than extending a product's useful life and deriving benefit from the remaining functions that the product can achieve, this definition will likely cause the early disposal of products that would have remaining useful life through reuse or repair, thereby, wasting these valuable resources and producing an overall negative impact on the environment. Even recycling of these products will have a greater adverse impact than extending their useful life. The Electronics Industry recommends removing the terms "repair" and "refurbish" from the definition of "assemble."

(57) – "Reliable Information"

We appreciate that the Department has taken efforts to address weight-of-evidence in determining reliable information in conjunction with new language in Sections 69502.2 and 69503.2. However, we remain concerned that the current requirement for peer-reviewed studies will disallow any well designed and implemented studies that have not been published in peer-reviewed literature. For example, studies that do not show an association between a chemical and an adverse effect often are rejected by journals because such studies are not considered newsworthy.

Additionally, as stated in our previous comments, we have identified the limitations to the peer-review process, and believe that simply because a study is in a "peer-reviewed" journal does not automatically provide a level of sufficient credibility or scientific rigor to deem it reliable. Similarly, studies "conducted, submitted, prepared for, or reviewed and accepted by" an international, federal, state or local agency "that implement laws governing chemicals" are not necessarily reliable merely by virtue of the agency conducting those activities. The definition of "reliable information" should be modified to encompass any study that meets the objective criteria of reliability (e.g., the criteria listed in section 69503.2(b)(1)(C)). In addition, the public should be given the opportunity to challenge the reliability of any study upon which DTSC relies for its regulatory decisions.

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

Section 69503.2. Product-Chemical Identification and Prioritization Factors

We believe that the new language in this section that adds the requirements of reproducibility and independent review of information are positive changes. However, without a requirement of a method that would show general acceptance by the scientific community, these new requirements are not as meaningful as they could be. For example, a single study (peer-reviewed or otherwise) may be useful if it fills in gaps in existing knowledge and fits into generally accepted fact patterns and error rates. However, a study that contains results that are counter to prevailing scientific thought may need to be

evaluated against several key factors to determine whether its results are of sufficient reliability to be considered new evidence. For example, more information or study may be needed before the results are generally accepted, or a method should be identified to demonstrate why such a study is, or is not, up to accepted levels of rigor. This is critical to ensure that DTSC's decisions to require a safer substitute or impose restrictions on use of chemical of concern are based on a sound scientific foundation, which is, in fact, reliable.

Section 69503.5. Priority Products List

As we mentioned in our comments regarding the "Alternative Analysis Threshold," the Electronics Industry believes that the regulations should establish a reasonable and standardized *de minimis* level for all chemicals, with the ability for the Department to set a lower threshold for a specific chemical if there is a sound justification for doing so. Setting a threshold for a chemical based on evidence specific to that chemical is more defensible than defaulting to the PQL as a threshold. As we explained above and in previous comments, the PQL is dependent on many factors, including the testing method and the matrix in which the chemical of concern is contained. Therefore, the PQL is not useful as a regulatory threshold. ITI, TechAmerica, CEA and SIA have suggested alternative approaches in our previous comments, and are willing to continue a dialogue with the Department to develop a practical, workable and effective regulatory threshold that will provide regulated entities with sufficient compliance certainty.

Article 5. Alternatives Analysis

Section 69505.5. Alternatives Analysis: First Stage
Section 69505.6. Alternatives Analysis: Second Stage

The Electronics Industry appreciates the changes made in the Alternatives Analysis sections. As mentioned in our previous comments, allowing a responsible entity that is performing the AA to determine the impact of factors in an analysis will significantly simplify the process and allow more effort to be placed on the analysis of factors that are most relevant. It is particularly important when allowing for the re-evaluation of factors (as is now done in the

second stage), since it is likely that not all factors will be found to have an appreciable effect during the first stage analysis.

Section 69505.8. Public Comments on AA Reports

The Electronics Industry continues to believe that the allowance for public comment on AA reports are not likely to provide significant improvement to the AA process since the majority of the public will not be familiar with the manufacturing processes, design demands, legal requirements and market pressures that go into the development and design of a product. However, the process put forth in this section is a significant improvement over the process described in the January proposed regulation.

Article 10. Trade Secret Protection

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

The minor change to section 69509, which severed the connection between the release of information to a patent application being granted or denied, does not respond to the concerns of the electronics industry regarding confidential business information (CBI) protections.

The Electronics Industry has serious concerns with the proposal, which would only allow a replacement chemical that is the subject of a hazard trait submission to be masked if a patent application is pending for the chemical or its contemplated use in the product. In the new draft, it appears that the DTSC has taken the position that if a trade secrecy claim is asserted over the identity of a chemical that is the subject of a hazard trait submission, that chemical must be an alternative that is being considered or proposed in an Alternatives Analysis, and further, that the entity seeking trade secret protection must file a patent application that is published in order to temporarily withhold the identity of the chemical. Our previous comments clearly identified why this is improper. In many cases, the chemical component may not itself be patentable, even though its presence in the product formulation (i.e., the chemical's identity) will in fact be legitimately protectable as a trade secret. In essence, DSTC is imposing a patentability requirement on a trade secrecy

claim, which is at odds with both state and federal trade secrecy laws and U.S. patent law. The current language in Article 9 improperly limits trade secrecy claims for chemical identity to those chemicals which meet the utility, novelty and nonobviousness requirements of the Patent Act (35 U.S.C. Section 101 et seq.), even though California common law and the model federal Uniform Trade Secrets Act does not so limit trade secrecy claims. The Electronics Industry recommends that subsections (f) and (g) be removed, and that the rule's trade secret protections be revised to be consistent with existing California and Federal trade secret protections.

Conclusions

ITI, TechAmerica, CEA and SIA wish to thank the Department for its ongoing work on the Proposed Safer Consumer Product regulation, including its continued outreach and request for public input on the draft regulations, and we appreciate the positive changes made in this draft of the proposed regulations. However, the Electronics Industry continues to believe that significant changes are necessary to meet the Department's stated goals of a practical, effective and workable regulation.

The proposed regulation contains several sections that require significant revision, but were not changed in this draft. We wish to refer the Department to our submitted comments on previous drafts. In particular, the section on product information for customers remains unworkable. It is not clear how attaching a booklet or manual to a device will provide any health or environmental benefit, and given the lack of options presented by the Department, we are left with this lone option.

The proposed regulation continues to present a burdensome regulatory regime that is predicated on significant paperwork requirements; an expansive alternatives analysis requirement that is difficult to implement; a vague and difficult to enforce regulatory threshold, and a general overreliance on testing that, especially for manufactured products (e.g., articles), will be difficult and expensive to implement while providing few, if any, health or environmental benefits. Issues such as the lack of a uniform regulatory response, the significant burden on responsible entities throughout the supply chain, and lack of trade secret protections are likely to inhibit the introduction of new and innovative products into California.

We hope that the Department remains open to suggestions for improvements. We are committed to continuing to work with the Department to secure a final regulation that will ensure human health and environmental protection, without inhibiting innovation. If you have any questions, please do not hesitate to contact Chris Cleet at (202) 626-5759 or ccleet@itic.org, Robert Callahan at (916) 443-9088 or robert.callahan@techamerica.org, Allison Schumacher at (703) 907-7631 or aschumacher@ce.org, or David Isaacs at (202) 446-1709 or DIsaacs@sia-online.org.

Sincerely,

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About ITI

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

About TechAmerica

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

About CEA

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

About SIA

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

Dear TBT-Enquiry-Point,

The EU-TBT-Enquiry-Point would like to thank the US authorities for the phone conference of 4 April 2013 and for the communication of 16 April 2013 confirming that the Department of Toxic Substances Control (DTSC) has provided a comment period on the latest version of the Draft Regulation of the Californian Department of Toxic Substances Control on "Safer Consumer Products", ending on 25 April 2013.

Following the discussion during the phone conference of 4 April 2013, the EU-TBT-Enquiry-Point welcomes that there are some improvements in the latest notified draft since the last comments of the EU of 28 February 2013 (in particular on some references to EU legislation). However, the EU-TBT-Enquiry-Point would like to underline that the majority of the EU comments expressed previously, such as the potential of the draft for unequal treatment of economic operators, the complexity of the proposed alternative assessment procedure and high administrative burdens related to its implementation and many of the more specific comments are still valid (in particular also the deviation from the definition of chemical substance from the international standard set in the UN GHS).

Best regards,
(on behalf of L. Kojnok, legal officer)

Bettina LICHDI
Administrative Assistant

European Commission
EU-WTO-TBT Enquiry Point
DG Enterprise and Industry
Unit C3 – Prevention of Technical Barriers

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April 25, 2013

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Via Electronic and Regular Mail

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Acting Regulations Coordinator
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gcregs@dtsc.ca.gov

Re: Comments on the Revised Regulations for Safer Consumer Products

Dear Ms. Buttle:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the revised regulations for Safer Consumer Products (SCP) issued on April 10, 2013, to implement Article 14 of chapter 6.5 of division 20 of the California Health and Safety Code (hereinafter, "the Green Chemistry Initiative" or "GCI"). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry.[1] Members of this Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, transporting and serving food products. The comments provided herein reiterate the Coalition's position that food contact materials and substances used as components of food contact materials should be excluded from the scope of GCI regulations. We hereby incorporate by reference comments from the Coalition's submissions on the draft SCP regulations dated November 1, 2010; December 3, 2010; December 30, 2011; October 11, 2012; and February 28,

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

2013; and on the revised Initial Statement of Reasons dated January 22, 2013; copies of which are enclosed.

The Food Packaging Coalition (hereinafter, "the Coalition") appreciates DTSC's efforts to continue the open stakeholder process during the development of implementing regulations for the GCI, a process in which the Coalition has participated since 2009. The Coalition commends DTSC's responsiveness to concerns raised by Coalition partners with the previous draft of the SCP regulations, in particular by extending the Alternatives Analysis Threshold to intentionally added components of Priority Products and by including a provision whereby the Department may specify an Alternatives Analysis Threshold concentration that is higher than the applicable Practical Quantitation Limit (PQL) for contaminants.

The Coalition is concerned, however, that the April 10 draft of the SCP regulations fails to specify a clear scientific process whereby the Department will determine the Alternatives Analysis Threshold concentration for intentionally added ingredients and unintentional contaminants in Priority Products. The Coalition is also concerned that the expensive, administratively difficult, and overly burdensome PQL approach is retained in the latest draft of the SCP regulations. The PQL essentially establishes a threshold of "non-detectable" for analytically determining when an Alternatives Analysis is required. The PQL approach should be reconsidered because it is: (1) resource-intensive, as companies are forced to conduct testing in the low parts per billion or parts per trillion range; (2) administratively difficult, if not impossible within a reasonable timeframe, as DTSC will have to undertake significant scientific research to establish a PQL for each substance; and (3) overly burdensome without providing additional protection of human health, because for food packaging materials the PQL is likely to be substantially lower than any safe level of exposure. DTSC should consider a more pragmatic and viable approach for establishing a *de minimis* threshold for intentionally added substances, as well as unintentional contaminants, and make this approach clear to the regulated community.

The Coalition applauds DTSC's incorporation of study design, level of rigor, independent review, corroboration and replication of information into its evaluation of the quality of information available to substantiate the existence or absence of potential adverse impacts, potential exposures and potential adverse waste and end-of-life impacts. However, the Coalition respectfully submits that DTSC should remove "disinterested" from the criteria of a peer reviewer's independence and trustworthiness, and simply look to the education and experience of the reviewer.

The Coalition remains concerned with DTSC's failure to address our request made repeatedly in comments for clear language excluding from the proposed SCP regulations food contact materials, which are already subject to a comprehensive federal regulatory program that ensures their safety for the public health and environment. In all of the Coalition's previous submissions enclosed with this letter, we have stated our position and provided information to

support the fact that food contact materials are already fully and effectively regulated throughout the life cycle by the U.S. Food and Drug Administration (FDA) and California governmental agencies to protect public health and the environment. Our analysis demonstrates that further regulation of these materials by DTSC under the GCI would be duplicative and in direct conflict with the existing federal regulatory scheme.[2]

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

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

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

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

******

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

Sincerely,

Devon Wm. Hill

Enclosure

Food Packaging Coalition

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February 28, 2013

Via Electronic and Regular Mail

Ms. Krysia Von Burg
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Re: Comments on the Revised Regulations for Safer Consumer Products

Dear Ms. Von Burg:

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

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

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

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

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

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

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

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

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

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

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

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[4] Defined in Sec. 69501.2(a)(52) as "the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures."

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

Sincerely,

Devon Wm. Hill

Enclosures

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October 11, 2012

Via Electronic and Regular Mail

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Re: Comments on the Safer Consumer Product Alternatives Proposed Regulation, Dept. Ref. No. R-2011-02, Office of Administrative Law Notice File No. Z-2012-7017

Dear Ms. Von Burg:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the *Safer Consumer Product Alternatives* (SCPA) proposed regulations published on July 27, 2012. The proposed regulations are intended to implement Article 14 of chapter 6.5, division 20, of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States, as well as trade associations that represent the food industry. This group has a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.[1]

We respectfully submit that DTSC should exclude food contact materials from the SCPA because these materials are already subject to a comprehensive federal regulatory scheme that ensures their safety for the public health and the environment. The GCI prohibits DTSC from adopting regulations that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI. The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Food and Drug Administration (FDA) fully regulates food

[1] Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, and the Recycled Paperboard Technical Association.

contact materials through a comprehensive, science-based regulatory framework, rendering DTSC's further regulation of these materials under the GCI redundant and unnecessary. This additional layer of state regulation will, at the least, only duplicate the extensive and costly federal reviews already undertaken for these materials, resulting in higher costs for manufacturers as well as the inhibition of the technological innovation that develops safer and more environmentally friendly food packaging materials. More likely, the application of the SCPA to food contact materials will result in product deselection that could even force safe products out of the California market. For these reasons, DTSC should exempt food contact materials from the SCPA.

I. Introduction

Food packaging is an essential component in ensuring the safety and quality of food. Food contact materials are carefully designed to prevent the transfer of their components to food and to ensure that they do not affect the purity of the contacted food. These materials are selected to have technical properties that preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products. They are subject to a comprehensive, science-based federal regulatory program that protects the public health and environment from any adverse impacts that could potentially occur from their use in food packaging. Moreover, this program provides FDA the legal tools and authority to evaluate food contact materials prior to their arrival on the market, as well as the ability to remove these products from the market should a safety concern arise.

Food packaging materials are evaluated using a rigorous risk assessment approach, by scientists with extensive knowledge and training in complex scientific areas such as chemistry and toxicology, based on extensive scientific data. Yet the flexibility of the regulatory framework permits manufacturers to develop new, safer, and more environmentally friendly materials in response to market demand. The inclusion of food contact materials within California's SCPA regulation would subject these products to duplicative and potentially conflicting regulatory programs, without providing consumers any added safety benefit, and when the existing federal regulatory framework already addresses the purposes of the GCI. Moreover, DTSC's regulation would undermine the goals of the FFDCA, and potentially be directly contrary to FDA requirements. Therefore, DTSC should revise the SCPA to exclude food contact materials from the scope of the regulation, avoid regulatory duplication and focus limited public resources on the regulation of products that are not currently subject to thorough regulation and safety evaluations.

II. The Existing Federal Regulations of Food Contact Materials are Consistent With the Purposes of the GCI

The purpose of the Green Chemistry Initiative is to develop a comprehensive approach to chemicals policy, with the goal of creating a systematic, science-based process to evaluate

Chemicals of Concern, and identify safer alternatives to ensure product safety.[2] The GCI seeks to address what DTSC calls "structural weaknesses" in the federal Toxic Substances Control Act (TSCA),[3] by compelling manufacturers to provide DTSC, and by extension, the public, information about the health and environmental effects of many chemicals used in consumer products. It certainly is the goal of our members to provide food contact materials (FCMs) that are safe, and FDA's existing regulations ensure that this goal is met. The FFDCA establishes a legal framework prohibiting the use of unsafe materials in contact with food, and FDA implements this legal mandate through its review process. This framework grants FDA the authority to conduct premarket evaluations, as well as to remove unsafe products from the market. The flexibility of this framework also permits manufacturers to continue the research and development efforts that result in ever-safer and innovative food packaging material. Thus, FDA's framework fully regulates the safety of every alternative substance used in contact with food and achieves the purposes of the GCI.

A. FCMs Are Regulated Through a Systematic, Science-Based Framework

Food contact materials already are the subject of a systemic, science-based review process that evaluates the chemicals used in the manufacture of these products, assesses the potential exposures, and ensures that any exposures are safe for the public health and environment. Indeed, FDA has assigned an entire office, the Division of Food Contact Notifications, which employs over 30 chemists, toxicologists, and other scientific staff, for the sole purpose of evaluating the safety and environmental impact of chemicals in FCMs. The collective decades of experience of the personnel in the Division all work to ensure that the packaging materials contacting food meet FDA's safety standards.

DTSC's Initial Statement of Reasons (ISOR) describes the structural weaknesses of TSCA that lead to the development of the GCI, particularly the fact that the burden of information collection under TSCA is placed on the Environmental Protection Agency (EPA) rather than on the chemical manufacturer, which has resulted in an alleged absence of data and information on the substances being regulated. Further, in the 45-Day Public Notice announcing the publication of the SCPA, DTSC reviews one of the reports that helped the development of the policy underlying the GCI: *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation.*[4] This report identified three information gaps in federal

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[2] *See* Initial Statement of Reasons (ISOR), page 8.

[3] Title 15, U.S.C. § 2601 *et seq.*

[4] 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.

chemical policy: (1) a data gap, based on a lack of information on which chemicals are safe and what products they are in; (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. The report then connected those gaps to health and environmental damage occurring in California. Without addressing the merit of these conclusions, the simple fact is that these weaknesses and information gaps do not apply to FCMs.

As noted above, FCMs are regulated pursuant to the FFDCA, which establishes a thorough legal framework for the safety of substances used in contact with food. The mandate of the FFDCA is to ensure that the use of FCMs is safe throughout the country because most packaged food products are marketed nationwide, and many globally. Manufacturers must ensure the safety of their products for the public health and environment *before* placing the product in the marketplace. This premarket evaluation must be undertaken in accordance with extensive FDA regulations and guidance on how to determine whether a product is safe. Moreover, this premarket evaluation ensures that the gaps—data, safety, and technology—identified in the *Green Chemistry* report are not applicable to FCMs.

The rigorous premarket evaluation ensures that substantial amounts of data are available on FCMs and their potential exposures to the public and the environment. Any potential exposures must be evaluated to ensure there is no safety concern. The vast majority of materials used in the manufacture of FCMs are the subject of regulatory approvals in FDA's Indirect Food Additive Regulations or through other FDA programs,[5] while the remainder are rigorously evaluated to ensure that there is no reasonable possibility of them becoming part of the food at unsafe levels. FDA is fully aware of the potential uses for 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.

Finally, the technology gap does not exist for FCMs because industry is highly active in producing materials that are "green." The recycling of FCMs has long been of interest for materials such as paper and plastic; indeed, FDA reviews recycling processes to ensure that any substances that may be present in the source material of a recycling stream do not contaminate the finished product or make it unsafe for use. New products are in development that are

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[5] FDA regulates FCMs through several programs in addition to the Indirect Additive Regulations. For example, FDA evaluates new food contact materials through its Food Contact Notification (FCN) program (see 21 C.F.R. § 170.100 *et seq.*). FDA can also determine that a substance is exempt from the need for premarket approval because the potential exposure from its intended use is so low that it cannot adversely impact the public health or environment, pursuant to a request for a Threshold of Regulation exemption (see 21. C.F.R. § 170.39).

biodegradable, compostable, or are manufactured using renewable and sustainable raw materials. Of course, the fast development of these products is tempered by the need to ensure that these new materials are safe for their use, a need met by the existing regulatory framework.

Among consumer products covered by the GCI, food packaging is unique. Other consumer products 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. By contrast, substances used in food contact materials are often trapped within a matrix (*e.g.*, a polymer, coating or paper) that prevents their migration and limits exposure to very low levels. In fact, modern packaging is designed to be inert and to not transfer its components or have an effect on food. This designed safety complements FDA's thorough regulation of these materials. Thus, including FCMs within the SCPA would subject food contact materials to duplicative schemes, when FDA's regulation already is consistent with the purposes of the GCI.

B. The Existing Regulatory Framework Ensures the Safety of FCMs for the Public Health and the Environment

As noted above, the Food and Drug Administration, using the legislative authority granted by the Federal Food, Drug, and Cosmetic Act, has established a comprehensive regulatory scheme to ensure the safety of food contact materials from both a public health and environmental perspective. This regulatory scheme is wholly consistent with the goals and purposes of the GCI, and duplication of this regulatory scheme by the SCPA is prohibited by the GCI and is unnecessary. Specifically, the FFDCA establishes a premarket approval requirement for components of food packaging materials that may become significant components of food. In addition to the health and safety concerns with the use of the product, FDA also considers the potential environmental impact that may result from the use of a new food packaging material. Section 25257.1(c) of the California Health and Safety Code restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other agencies that are consistent with the purposes of the GCI.[6] Moreover, the SCPA itself requires DTSC to consider the scope of existing laws that protect the safety of the public health and environment, through the relevant exposure pathways. For FCMs, the relevant exposure pathway is oral exposure, which is already fully addressed under the FFDCA. Thus, due to the existing whole chain regulation of FCMs, further regulation under the SCPA would represent regulatory duplication that is prohibited by the GCI and the proposed rules.

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[6] 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."

1. FFDCA Legal Framework

The regulation of food contact materials was established by Congress as part of the 1958 Food Additives Amendments.[7] These amendments require FDA to regulate food contact materials in the same manner as substances intentionally added to food as ingredients (to the extent that there is any migration or exposure to the components of the packaging). More specifically, Section 201(f) of the FFDCA defines food to mean "articles used for food or drink for man or other animals," including "articles used for components of any such article" (*i.e.*, food additives). The FFDCA further defines a "food additive," in Section 201(s), as a substance that is reasonably expected to become a component of food under the intended conditions of use, with certain statutory exceptions.[8] Thus, to the extent that there is any migration, FDA regulates a food contact material in the same manner as any substance that is directly and intentionally added to food. Food additives, including food contact materials, are subject to premarket authorization by FDA before they can be marketed, unless the use of the substance qualifies for one of the limited exceptions provided under the FFDCA. Accordingly, unless an exemption applies, a person intending to market a new food contact material must first seek clearance from the FDA.

Like substances directly added to food, one of the ways that FDA regulates components of food packaging materials is by the promulgation of food additives regulations, which set forth the conditions under which a particular substance may be used. FDA's food additive regulations may be found in Title 21 of the Code of Federal Regulations, Parts 170-189. For each of the clearances in these regulations for a food contact substance FDA has conducted a detailed review of the substance's safety. In addition, as part of its promulgation of a new food additive regulation, FDA (as required by the National Environmental Policy Act[9]) conducts an environmental assessment of the proposed applications to determine if there would be any environmental impact from the manufacture and use of a new substance or whether the use and disposal of the new product would adversely affect the recycling of post-consumer materials.[10,11]

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[7] Pub. L. No. 85-929, 72 Stat. 1784 (1958).

[8] As detailed below, examples of substances that are exempt from the definition of food additive include substances that are generally recognized as safe (GRAS) or prior-sanctioned for their intended use by FDA before January 1, 1958.

[9] 42 U.S.C. §§ 4321 *et seq.*

[10] FDA has published guidance documents discussing the information and data that must be included for its environmental review. *See* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at

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Congress provided FDA with authorization to use a new regulatory procedure for the review of new food contact substances and new uses of food contact substances when it enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).[12] FDAMA added Section 409(h) to the FFFDCA authorizing the Food Contact Notification (FCN) program. The FCN program has been operational at FDA since 2000, and now FDA reviews the overwhelming majority of food contact substances under this program. Under the FCN program, manufacturers must submit information on the identity and use of the food contact substance, along with information supporting the conclusion that the substance is safe for the intended use. While the system does not result in the promulgation of a new food additive regulation, the safety and environmental evaluation standards are the same as for the food additive petition process. (Arguably, FDA's evaluation of food contact substances under the FCN program is even stricter than it was before the FCN program was available, as the Agency added additional chemistry and toxicity data requirements when it established guidelines for the new program.) If FDA does not object to a manufacturer's FCN, the proposed substance, along with the terms and conditions under which it may be used, is published on FDA's website along with the identity of the notifier.[13] FCNs are proprietary to the notifier and may only be relied upon by the notifier and its customers. Manufacturers who produce the same material must submit their own notification to FDA.[14]

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http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm *and* "Environmental Assessment Technical Assistance Handbook" at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm084224.htm.

[11] An article describing FDA's food additive approval process and safety evaluation was recently published by the former director of FDA's Center for Food Safety and Applied Nutrition and the former Director of the Office of Food Additive Safety. While the article focuses on food ingredients, *per se*, FDA regulates the safety of food contact materials in a similar manner, thus, the article is instructive of the Agency's safety assessment. *See* "FDA's food ingredient approval process – Safety assurance based on scientific assessment" A.M. Rulis and J.A. Levitt, *Regulatory Toxicology and Pharmacology* 53 (2009) 20-31.

[12] Public Law No. 105-115, 105th Congress (Nov. 21, 1997).

[13] Effective notifications are published on FDA's website at http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm.

[14] Additional information on the FCN process and FDA's regulation of food contact materials can be found in a recent chapter in a book published by the Food and Drug Law

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Once a material is cleared by FDA, the Agency continues to monitor public information and safety that may question whether the use of the material continues to be safe. Under the FCN, notifiers are required to submit to FDA any new toxicological data or other information that may come to their attention that could affect FDA's decision that the use of the substance is safe.

2. Data Required for FDA's Review

To evaluate the safety and environmental aspects of the use of a new food contact substance, FDA requires a manufacturer to submit extensive data to the Agency. FDA has published guidance documents regarding its requirements for the data and information that must be included in a food additive petition or FCN.[15] These data include:

1. a full chemical description of the food contact substance, its impurity profile, and details regarding its manufacture;

2. information on the technical properties of the substance for its intended use;

3. data demonstrating the amount of the substance that may migrate from the article to food;

4. calculations of the estimated dietary exposure to the substance and its impurities based on its anticipated use;[16]

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Institute. *See* D.W. Hill and R.A. Bond, "Chapter 4: Food and Drug Packaging," in the Food and Drug Law Institute's *Food and Drug Law and Regulation* (2011).

[15] FDA, "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" (Sept. 1999, updated Apr. 2002), at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm and "Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations" (Apr. 2002, updated Dec. 2007) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm.

[16] The dietary exposure is calculated by multiplying the amount of a component expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing the additive. This fraction is known as a "consumption factor." These calculations invariably represent a conservative estimate of the dietary exposure of the additive because they
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5. all available toxicological data that the notifier has in its possession or that is publicly available must be provided for the substance and its impurities;

6. certain minimum toxicological data, the volume of which depends on the estimated dietary exposure from the proposed use; FDA's tiered requirements for toxicological data for substances with a potential dietary exposure between 0.5 parts per billion (ppb) and 50 ppb mandate two *in vitro* genotoxicity studies demonstrating that the substance is not mutagenic or genotoxic; for substances with dietary exposures above 50 ppb, FDA requires a third genotoxicity study in the form of an *in vivo* chromosomal aberration study, and two subchronic feeding studies, generally one in a rodent species and one in a non-rodent species. For substances with exposures above one part per million in the diet, FDA requires a full panoply of toxicological data, including the data identified above as well as from a chronic two-year bioassay, a one-year feeding study in a non-rodent species, and multigenerational reproductive and developmental toxicity studies. Of course, if any of these studies indicate a hazard trait or toxicological endpoint of concern, FDA may require additional studies to demonstrate that the proposed use will be safe;[17]

7. data that allow FDA to consider the potential environmental impact that may result from the clearance of a new food contact material;[18] unless the proposed use of the food- contact substance qualifies for an exemption, petitioners and notifiers must submit information that the proposed manufacture of the food

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are based on the assumption that the component will always migrate at maximum levels, and that all food contact materials of a given type will be made using the subject substance.

[17] *Id.* To put these toxicity thresholds into perspective, 1 ppm is equivalent to one drop of water diluted into 50 liters (roughly the fuel tank capacity of a compact car), 1 ppb is equivalent to one drop of water diluted into 250 chemical drums (50 m^3), and 1 part per trillion (ppt) is equivalent to one drop of water diluted into 20 Olympic-size swimming pools (50,000 m^3).

[18] FDA's categorical exclusions are set forth at 21 C.F.R. §§ 25.30-34. The Agency set forth its rationale for why certain applications are exempt from the need for an environmental assessment in the Federal Register notice promulgating this rule. *See* 62 Fed. Reg. 40569-40600 (July 29, 1997). *See also* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm

> contact substance will not affect compliance with any federal and state environmental laws related to any discharge to the environment, such as air and water emissions.

So, as you can see, the information required for FDA's review is comprehensive, addressing a product's identity, intended use, potential exposure, and safety.

a. Specific Toxicological Information

As discussed above, FCMs are designed to be inert and to not release their components to food or have an effect on the food. The potential transfer of substances from FCMs is, therefore, only likely at very low levels, resulting in negligible exposures. As stated above, this is in contrast to other consumer products for which there are direct exposures at substantially higher levels. Thus, while FDA requires the submission of acute toxicity data when available, the Agency is more concerned with potential carcinogenicity effects or other endpoints from repeated-dose studies. The end points of interest strongly correlate with the hazard traits and toxicological endpoints identified in the SCPA. Section 69502.2 of the SCPA establishes the initial list of Chemicals of Concern based on lists from authoritative organizations, considering seven hazard traits: carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity. As discussed in more detail below, FDA considers all of these toxicological endpoints when evaluating the safety of a food contact substance.

(1) Carcinogenicity

The FFDCA prohibits the use of carcinogenic food additives, including substances used in food contact materials that become components of food. Specifically, Section 409(c)(3)(A) of the Act (also known as the "Delaney Clause") states that no food additive shall be deemed by FDA to be safe if the additive is found "to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of safety of [the additive], to induce cancer in man or animal."[19] Thus, it is not possible to use a substance considered to be a carcinogen that would be a food additive when used in food contact materials.

The Agency has established standards for the presence of any carcinogenic impurities that may be present in food contact materials. The standard that FDA has established for these materials is known as the "constituents policy."[20] FDA sets an extremely strict standard for

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[19] FFDCA § 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A).

[20] 47 Fed. Reg. 14,464 (Apr. 2, 1982). Although this Advanced Notice of a Proposed Rulemaking was withdrawn by the agency in a November 26, 2004 Federal Register notice (69 Fed. Reg. 68,831, 68,831), the impetus of the withdrawal was administrative only, and FDA

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carcinogenic impurities. The Agency uses data from animal carcinogenicity studies, together with extrapolation procedures, to calculate the potential risk from the estimated daily exposure to the carcinogenic impurities as a result of the particular use. In order to determine that there is a reasonable certainty of no harm, FDA requires that the dietary exposure to a carcinogenic impurity must not exceed the calculated upper-bound lifetime risk from all sources of exposure and be lower than a risk of 1 in 1 million.[21]

(2) Reproductive and Developmental Toxicity

FDA requires that reproductive and developmental toxicity data be submitted for substances when the dietary exposure may be significant for these toxicological endpoints. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for reproductive or developmental toxicity, the Agency may request additional data. As with genotoxicity data, any GRAS determination must consider these toxicological endpoints as well. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.[22]

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has since made clear that the constituents policy remains a valid means by which it evaluates minor carcinogenic impurities of food additives.

[21] *Id.* at 14,468.

[22] In a 1999 paper, Dr. Ian Munro and colleagues established a safety evaluation procedure for use by the Joint Food and Agricultural Organization/World Health Organization of the United Nations (FAO/WHO) for flavoring substances implementing a threshold of toxicological concern approach involving a number of toxicological endpoints. The study authors concluded that "toxicity endpoints, such as developmental toxicity, neurotoxicity, and immunotoxicity demonstrate considerably higher human exposure thresholds than the threshold value [established using carcinogenicity data], making it highly unlikely that these non-cancer endpoints are a relevant concern in applying the threshold concept." *See also*, Kroes, R., Galli, C., Munro, I., Schiltwe, B., Tran, L.-A., Walker, R., and Würtzen, G. (2000) "Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A Practical Tool for Assessing the Need for Toxicity Testing," *Food and Chem Toxicol*; 38: 255-312. The Kroes study reviewed an expanded databases to establish if additional toxicological endpoints were more sensitive than the carcinogenic endpoints of a variety of chemical substances. The report indicates that none of the specific non-cancer endpoints (*i.e.*, developmental toxicity, developmental neurotoxicity, and immunotoxicity) was more sensitive than cancer endpoints for the same substances. The results of a more recent analysis were published by Kroes and colleagues in 2004. The authors conclude that, based on their examination of metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific toxicological
(continued ...)

(3) Genetic Toxicity and Mutagenicity

FDA requires genetic toxicity and mutagenicity testing for any chemical substance with a potential dietary exposure above 0.5 ppb. In addition, if structural alerts suggest that a substance may have genetic or mutagenic attributes, FDA may request that additional data be provided. Any GRAS determination must consider these toxicological endpoints, as well. In the case of materials that do not migrate, there would be no exposure, although the level of analytical sensitivity needed to determine whether the "no migration" threshold would be lower than 50 ppb also is based on these genotoxicity concerns.[23] In our experience, if a substance is determined to be mutagenic or genotoxic in screening tests, FDA will require (a) data demonstrating whether these affects are likely to be observed *in vivo*, (b) a cancer bioassay to resolve whether the material is a carcinogen, or (c) proof that potential dietary exposure will be insignificant even if the material is later determined to be a carcinogen; generally, this would be at a level that would not exceed 50 parts per trillion, 0.05 ppb, in the diet.

(4) Endocrine Disruption

The proper assessment of the endocrine disrupting potential of a particular chemical is a topic of much current discussion. Whether the *in vitro* endocrine disrupting effect exhibited by a chemical at the extremely low doses of oral exposure associated with food packaging actually translates to an adverse physiological effect is in our opinion, at best, very controversial. Moreover, the health effects of chemicals acting through an endocrine mode of action should generally be captured by traditional toxicological tests, which are designed to detect adverse health effects acting through any means, including interaction with the endocrine system.

FDA and other bodies around the world that regulate food contact materials are monitoring current scientific information on this subject. At this time, however, no regulatory body in the world that is responsible for food safety has established separate endocrine disruption

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(...continued)
endpoints, including neurotoxicity, teratogenicity, developmental toxicity, and immunotoxicity, carcinogencicity is the most sensitive toxicological endpoint. *See* Kroes, R., Renwick, A.G., Cheeseman, M., Kleiner, J., Mangelsdorf, I., Piersma, A., Schilter, B., Schlatter, J., van Schothorst, F., Vos, J.G., and Würtzen, G. (2004) "Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet," *Food and Chem Toxicol*; 42: 65-83.

[23] The use of 50 ppb in this context is a concentration that could migrate from the package, not a level of dietary exposure. The resultant level of dietary exposure from food is determined by the consumption factor and would be at least an order of magnitude less, or even more in some cases.

data requirements for food contact materials. Instead these regulatory bodies rely on information from reproductive, developmental and other well established, validated toxicology studies to understand the potential health effects of chemicals, regardless of their mode of action. Moreover, there is no one test that can clearly demonstrate whether a substance is an endocrine disruptor; instead, there must be a case by case determination. FDA already addresses this concern as part of its evaluation. Thus, while industry and government continue to monitor this issue, it is our opinion that there is not sufficient scientific information or agreement on the data at the present time to establish endocrine disruption as a regulatory criterion.

(5) Neurotoxicity

FDA can require that neurotoxicity data be submitted for substances when indicated by the subchronic oral toxicity data for a substance and when the dietary exposure may be significant for this toxicological endpoint. If a substance is identified as a potential neurotoxicant, FDA may require additional special neurotoxicity testing designed to confirm and characterize the scope of nervous system involvement and to determine dose-response characteristics. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for neurotoxicity, the Agency may request additional data. Any GRAS determination must consider this toxicological endpoints as part of the GRAS evaluation. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.

(6) Bioaccumulation

FDA considers the biopersistence and bioaccumulation of a proposed food contact substance as part of its evaluation of food additive petitions and FCNs. If a substance is suspected of being bioaccumulative, the Agency requires further data on its absorption, distribution, metabolism and elimination to determine the potential bioaccumulation in the body. Any GRAS evaluation of a substance would also take this outcome into account. With regard to the other materials that may not be subject to FDA's review, the Agency considers that a daily exposure of 0.5 ppb in the diet is an insignificant addition to the diet from a cumulative exposure standpoint (except for carcinogens). If a substance is present at levels below 0.5 ppb, its bioaccumulation potential is considered to be insignificant.

b. Specific Environmental Information

The National Environmental Policy Act of 1969 (NEPA) requires FDA to assess the environmental impacts of its decisions regarding the safe use of FCMs. Under FDA regulations, all submissions must be accompanied by either a claim of categorical exclusion or an adequate environmental assessment (EA) to permit FDA to determine whether a clearance for a food contact material may significantly affect the quality of the human environment. As part of its safety evaluation, FDA requires that a food contact substance not have an adverse environmental

impact during its manufacture, use, and disposal. Any environmental impact that may result from manufacture, use, or disposal, such as aquatic toxicity or toxicity to terrestrial organisms, must be addressed.

Most importantly, because of their inert design there is not likely to be any chemical exposure from a food contact material that could have an adverse effect on the environment at any level of concern. Substances used in food contact materials are trapped within a matrix (*e.g.*, a polymer, coating or paper) and are designed to not leach from the product, thus preventing migration and limiting exposure to low levels. Unlike other substances that are designed to directly come into contact with consumers or their environment, the potential for direct exposure to a substance from a packaging material is very small. The possible levels of migration of a substance from a food contact article are very low, generally in the part per million range or lower. Indeed, FDA has determined that a significant number of submissions for FCMs are categorically excluded from the need for an EA because they do not, individually or cumulatively, have a significant effect on the environment. For other substances, an EA is required.

The EA focuses particularly on the introduction of substances into the environment as a result of the use and disposal of FCMs, the fate of those substances, and the resulting environmental impacts. The evaluation should address not only the food contact material, itself, but also its degradation products, and any other substance resulting from its use and disposal. With regard to the use and disposal of the food contact material, the EA addresses the market penetration, how much will enter the waste stream, the mode and frequency of the disposal, as well as the expected concentration of the potential chemical substances introduced into the environment as a result of the disposal. Information must be submitted that evaluates the potential environmental impact of the disposal, including bioaccumulation, for methods such as landfill leachate and incineration. The extent of the potential environmental impact is determined with reference to the physico-chemical properties and environmental depletion mechanisms for each substance. Finally, any environmental impacts are assessed in relation to their toxicity to laboratory animals, to satisfy human safety requirements, and to organisms that may be exposed in the environment, such as vertebrates, invertebrates, plants, fungi, and bacteria. If adverse environmental impacts are demonstrated, mitigation measures and alternatives must be discussed.

In addition, FDA pays particular concern to any impacts that the proposed use of the substance may have on the ability to recycle post-consumer packaging materials. If there is a concern that the new substance may create problems with the recycling processes currently being used, FDA will require further data and information or limitations to ensure that the proposed use will not create an adverse economical or technical impact on the ability to recycle food packaging materials.

FDA's environmental review for FCMs is thorough, and addresses all of the concerns raised in the GCI. Therefore, requiring FCMs to undergo an environmental review under the SCPA would be duplicative and unnecessary.

3. Exceptions from Premarket Review

As noted above, there are limited exceptions to the need to obtain a food additive regulation or an effective FCN for the proposed use of a new food contact substance. First, FDA may exempt a material from the need for a regulation of FCN under its Threshold of Regulation exemption procedure. FDA's Threshold of Regulation procedure, which is codified at 21 C.F.R. § 170.39, allows the Agency to exempt a substance from the need for a regulation or FCN if the proposed use of the substance meets certain criteria:

1. the substance must not be a carcinogen and may not contain any carcinogenic impurities with a TD_{50} (*i.e.*, median toxic dose) value less than 6.25 mg/kg body weight per day;[24]

2. the proposed use of the substance must not result in a dietary exposure exceeding 0.5 ppb or, if the substance is currently regulated for direct use in food, the proposed increase in the dietary exposure must be less than one percent of the established acceptable dietary intake (ADI) for the substance;

3. the substance has no technical effect in the food; and

4. the proposed use of the substance may not have a significant impact on the environment.

FDA adopted the Threshold of Regulation procedure after reviewing a large number of published studies indicating that there was little toxicological concern from the exposure to noncarcinogenic substances at levels below 0.5 ppb in the diet.[25] FDA reserves the right to determine if substances qualify for the exemption and provides response to companies submitting such a request.

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[24] The TD_{50} is the chronic dose level that would induce tumors in half the test animals at the end of a standard lifetime for the species.

[25] 60 *Fed. Reg.* 36595, July 17, 1995. A full report and all of the individual papers written as part of a study examining this issue were published in the August 1990 issue of *Regulatory Toxicology and Pharmacology*. *See* Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).

The FFDCA also provides certain exceptions to the definition of a food additive that also apply to food contact materials. Specifically, the Act exempts those materials that are considered to be generally recognized as safe (GRAS) or that were sanctioned by either FDA or the United States Department of Agriculture (USDA) prior to the adoption of the Food Additives Amendment in 1958. Food additives, as well as food contact materials that qualify under these exemptions, are not technically subject to premarket review by FDA, although in many cases companies request FDA's review.

The FFDCA exception for GRAS substances as provided in Section 201(s) states that such a determination requires a general recognition "among experts qualified by scientific training and experience to evaluate [the additive's] safety, as having been adequately shown through scientific procedures…to be safe under the conditions of its intended use." FDA has promulgated regulations setting forth the criteria that the Agency regards as necessary to establish that the use of substance is GRAS. These eligibility requirements provide that a general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."[26] Moreover, FDA has clarified that "scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation."[27] The main toxicological data and other information that support a GRAS determination must be published, generally in peer-reviewed scientific journals.

FDA has a procedure to review and sanction GRAS determinations through a GRAS Notification process.[28] In addition, the Agency has listed or affirmed some materials as GRAS in Parts 182, 184, and 186 of the food additive regulations. A determination may be made without FDA's review that a substance is GRAS provided that sufficient published toxicological data exist to establish the general scientific recognition that a substance's use is GRAS. The standards for such a self-determined GRAS assessment are robust. As stated by two former FDA officials, Drs. Alan Rulis and Joseph Levitt, "many people mistakenly associate GRAS with a sort of "second" tier of safety protection based on a less-than rigorous standard compared to

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[26] 21 C.F.R. § 170.30(a)(2).

[27] 21 C.F.R. § 170.30(b).

[28] *See* FDA, GRAS Notification Program, at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm.

petitioned food additives. This is not true. In fact, the safety standard applicable to GRAS food ingredients is the *same* as for food additives; namely reasonable certainty of no harm."[29] The former directors went on to say that "[i]n fact, the GRAS criteria are in some ways more difficult to satisfy than the food additive criteria because of the additional requirement of public availability of the data and general recognition and acceptance of a safety conclusion based on those data."

The FFDCA also expressly exempts those materials that were sanctioned by USDA or FDA in letters issued by these Agencies before the passage of the Food Additive Amendments in 1958. In the experience of our members, the substances covered by prior sanctions and still used in commerce are limited, and many of the substances were subsequently petitioned or notified to the FDA. FDA very strictly interprets previously issued prior sanction letters, and limits the scope of the exclusion by construing prior sanctions as narrowly as possible.[30]

Substances also may be used without express premarket approval from FDA if they can additionally be shown to not migrate from the food contact article. The standard for this assumption is strictly interpreted by both the Agency and industry. In general, a showing of no migration must be based on an analytical sensitivity demonstrating that there would be no migration at a level equivalent to 50 ppb and often lower in some situations.[31] The basis of the exclusion from premarket clearance is that, given the very low migration of the substance to food, the resulting dietary exposure among consumers will be negligible.

In sum, the exemptions from premarket approval for food contact materials are strictly limited by the FFDCA. Only those materials that are subject to published toxicological data and generally accepted by the scientific community as safe may be considered to be GRAS and used without FDA review. Those substances covered by prior sanctions are limited, and the substances used in food contact materials that do not migrate to food result in no exposure to consumers. In addition, these substances when used in food contact articles are still subject to FDA regulation under Section 402 of the FFDCA.[32] Under no circumstances may any substance cause a health or safety concern when used as intended and may not affect the taste or odor of the food. Thus, it is our opinion that the substances that qualify for these limited exceptions do

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[29] *See* A.M. Rulis and J. Levitt, p. 26.

[30] *See* 456 F. Supp. 207, 209 (d. Neb. 1978), *aff'd sub nom. United States v. Nielsen* (8th Cir. 1979), cert. denied 444 U.S. 832 (1979). *See also*, 21 C.F.R. § 170.38(d).

[31] The resulting dietary exposure for most food contact substances, even if there were some migration below the level of detection, would be less than 0.5 ppb, a level below FDA's threshold of toxicological concern.

[32] 21 U.S.C. § 342(a)

not result in exposures of concern and, therefore, subjecting them to the scope of the GCI would not promote the purposes of the statute. Including such materials within the scope of the GCI will duplicate the existing regulatory scheme which Congress and FDA have established.

C. Summary

FDA has in place a comprehensive and robust system of regulation for food contact materials that establishes a large margin of safety. The regulations proposed by DTSC to implement the GCI would duplicate this system, yet FDA's regulatory scheme is consistent with the purposes of the GCI. Thus, the inclusion of these products in the SCPA 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.

III. Potential Consequences of Including FCMs in the SCPA

It is difficult to see any benefit that could come from DTSC's additional regulation of FCMs. Such regulatory duplication would likely result in product deselection rather than an extensive analysis of chemical alternatives because consumers do not have the knowledge to understand the complex scientific analysis that goes into a safety evaluation for a food contact material. Duplication also imposes unnecessary additional administrative and financial costs on both industry and DTSC, and potentially inhibits the development of safer materials. In some cases, this may force the use of packaging that is less proven to be effective in reducing the risk from dangerous food spoilage bacteria. Ultimately, duplication could result in the withdrawal of safe food packaging products from the California market to the detriment of both industry and consumers.

A. Use of a Chemical of Concern is Likely to Result in Product Deselection

The stated goal for the GCI is to enable businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products. This goal implicitly assumes that the implementing regulations will ensure a thorough analysis of the chemical in question, how it is used, whether there is the potential for consumer or environmental exposure, and whether there is an alternative chemical to use that would work in the same technical manner, without drastically increasing costs and resulting in a safer product. Practically, however, once a chemical has been identified as a Chemical of Concern many manufacturers will require reformulation or will simply drop the substance because of the likelihood that consumers will no longer buy products containing that chemical. For food packaging, reformulation often is much more complex from a technical or cost perspective and can result in significant trade-offs in the efficacy of a product. FCMs specifically are designed 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. Moreover, recent experience has shown that even a rumored chemical safety concern starts a strong consumer

movement toward deselection of products containing that chemical. It is reasonable to expect, therefore, that once the list of Chemicals of Concern is published, deselection of these products will occur, rather than a reasoned discussion of the safety or the merits of chemical alternatives or the chemical, itself.

The GCI seeks to provide information to consumers to permit informed choices regarding the products they purchase, but the scientific complexity of a safety assessment for FCMs makes it extremely difficult for consumers to evaluate the safety concerns for a packaging material that contains a Chemical of Concern, should they seek to do so. As described above, the evaluation of FCMs requires a substantial amount of information regarding a product's identity, intended use, the potential exposures to the product and any of its components and impurities, and a rigorous safety analysis of those exposures. This evaluation is undertaken by scientists with years of training and experience in chemistry, toxicology, biology, and environmental assessments. Yet the use of a Chemical of Concern in an individual food packaging product may be extremely small, without any reasonable possibility for the substance to become part of food or be exposed to consumers or the environment. Thus, many FCMs, the safety of which has already been established under the existing FDA framework, could be irrationally deselected by consumers on the basis of the presence of one Chemical of Concern. This result is clearly not to the benefit of either industry or California consumers.

B. Including FCM is Administratively and Financially Inefficient

The SCPA establishes substantial burdens on those products that are designated as "Priority Products," including a broad range of evaluation and reporting requirements. We are concerned that the scope of the regulations as proposed will create such an immense administrative and scientific burden on DTSC that it will not be feasible for the Agency to implement. The regulation contains an abundance of new responsibilities for DTSC, many of which require time-consuming and difficult scientific evaluations. We believe that DTSC is not equipped, with financial support or personnel, to administer these responsibilities. As discussed above, the safety evaluation for FCMs is scientifically complex and requires technical knowledge and experience. FDA and industry has invested in countless personnel and resources to ensure that FCMs are safe to bring to market. The GCI product mandate is broad, addressing almost all consumer products on the market. Thus, considering the scientific and technical complexity of evaluating FCMs, DTSC should defer to the reasoned and scientific judgment of FDA, otherwise there will likely be long delays and regulatory uncertainty that is detrimental to industry and consumers. As noted in a recent letter signed by sixteen California legislators and provided to Governor Jerry Brown, ". . . DTSC has the authority to impose a range of unclear regulatory actions from doing nothing to completely banning a particular chemical or product from being sold in the state . . . it is critical that businesses be provided with certainty of future conditions, so as to not discourage job creation in California."

DTSC also should consider that the financial and administrative burden of the alternative analysis process will inhibit technological innovation and the development of safer and more environmentally friendly food packaging materials, as companies divert their resources to California compliance activities rather than research and development of new, safer products. If DTSC implements the SCPA as is, the practical result is likely to be the withdrawal of a substantial number of products from the California market as companies choose to withdraw from the market rather than undertake the costly alternatives analysis requirements when these products have already been subject to review by FDA.

The existing regulatory framework for FCMs is more than sufficient to provide safe products for consumer use. DTSC's duplication of this scheme will almost certainly delay the arrival of safe materials on the market and, ultimately, the extra regulatory compliance costs could even force industry and safe consumer products out of the California market. In this competitive global marketplace, the goals of the GCI should be achieved in the most efficient and least burdensome means possible—in this case, by deferring to the existing, comprehensive, science-based legal and regulatory framework established by the FFDCA and implemented by FDA.

IV. The SCPA is Preempted by Federal Law

Regulating food contact materials under the SCPA is not only barred by the duplication provision of Section 25257.1(c), but also preempted under Federal law. Applying the SCPA to food contact materials would conflict with the FFDCA not only by undermining the goals set by Congress when it enacted the Food Additives Amendment of 1958 ("Amendment"),[33] but also by imposing, on a substance-by-substance basis, regulatory responses like use restrictions that could be directly contrary to FDA requirements. As such, the SCPA, to the extent that food contact materials are not exempted, would be subject to challenge on multiple fronts, both the statute as a whole and as applied to specific substances.

Preemption analysis begins with the Supremacy Clause of the U.S. Constitution, which declares that the "Constitution and the Laws of the United States . . . shall be the supreme Law of the Land."[34] As the Supreme Court has stated, "it has been settled that state law that conflicts with federal law is without effect."[35] The same holds true of state law that conflicts with federal regulation.[36] Courts look specifically to the intent expressed by Congress when adopting a

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[33] 21 U.S.C. § 348, *et seq.*

[34] *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617 (1992).

[35] *Id.*

statute as the "ultimate touchstone" of preemption analysis.[37] Such intent may be explicitly stated or implicitly contained in the statute's structure and purpose.[38]

While there are various types of preemption, at least one is relevant here – conflict preemption. Specifically, Federal law nullifies conflicting state law in at least two instances. The first type is where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" ("obstacle preemption").[39] The second type is where it is "impossible" for a private party to comply with both state and Federal law" ("impossibility preemption").[40] As discussed below, both forms of conflict preemption would apply in this case absent an exemption for food contact materials.

A. The SCPA Stands As An Obstacle To Reaching FFDCA's Goals

Under obstacle preemption, courts look specifically to the goals underlying a given regulatory scheme and ask whether the state law would frustrate the Federal agency's efforts to reach those goals. For example, the U.S. Supreme Court in *Geier* held that an injured motorist's design defect claim, which sought to hold a car manufacturer liable for failing to install a driver's side airbag, was preempted. The Court noted that Federal regulations at the time required manufacturers to install passive restraints in "some but not all" of their vehicles and provided a "range of choices among different passive restraint devices" to be "introduced gradually over time."[41] Citing to comments made by the Department of Transportation ("DoT") when issuing the regulation, the Court noted that its purpose was to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance – all of which would promote [the regulation's] safety objectives."[42] In other words, DoT adopted a compromise between gradually forcing technological development and addressing immediate safety needs. The Court, not surprisingly, found that a state tort law which would require airbags in all vehicles "presented an obstacle to the variety and mix of devices that the federal regulation

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36 *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes").

37 *Cipollone*, 112 S.Ct. at 2617.

38 *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

39 *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

40 *Cipollone*, 112 S.Ct. at 2617.

41 *Geier* 529 U.S. at 864, 874-75.

42 *Id.* at 875.

sought" and to the "gradual passive restraint phase-in that the federal regulation deliberately imposed."[43]

The same conflict exists between the FFDCA and SCPA. It is clear from the Amendment's legislative history that Congress pursued a carefully considered approach that struck a balance between insuring food safety and encouraging the advancement of food technology. Prior to the Amendment, Congress had become increasingly concerned that Federal law at the time "entirely prohibit[ed] the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies."[44] As the Senate Report noted:

> The second flaw in existing law which has proved detrimental to consumers, to processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the [FDA] that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the [FDA] as safe.[45]

Indeed, the House Report stated that the "purpose of the legislation is twofold: (1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels."[46] This "dual purpose,"

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[43] *Id.* at 881. *See also In re Bextra*, 2006 WL 2374742, at *9 (N.D. Cal. Aug. 16, 2006) (finding failure to warn tort claims involving an anti-inflammatory drug preempted under the FFDCA where class action plaintiffs argued for warnings that would have upset the policy choice made by FDA to require the disclosure of known risks, but prohibit "defensive" labeling warning of unsubstantiated risks); *Blue Circle Cement, Inc. v. Bd. of County Comm'rs*, 917 F. Supp. 1514, 1519-20 (N.D. Okla. 1995) (holding local ordinance effectively prohibiting the burning of hazardous waste for energy was preempted by the Resource Conservation and Recovery Act's goal of "replac[ing] land disposal with advanced treatment, recycling, and incineration").

[44] H. Rep. No. 2284, at 2 (1958).

[45] S. Rep. No. 2422, at 2 (1958).

[46] H. Rep. No. 2284, at 1.

therefore, demonstrates that Congress clearly intended to forge a middle ground, similar to the regulatory approach adopted by the DoT in *Geier*, between emerging technology and an immediate need for food safety.[47]

The SCPA and the proposed regulations if adopted, however, pose a substantial obstacle to achieving and maintaining this compromise between food safety and technology. To begin, the primary purpose of the SCPA – to reduce or completely remove chemicals of concern from consumer products – is antithetical to a Federal scheme that permits the safe use of such substances. Merely listing a food contact material as a chemical of concern, and thus subjecting it to further regulation under the SCPA program, would taint any FDA decision authorizing those in the food industry to use the substance. FDA cannot effectively provide consumer confidence about the safe use of substances and ensure that their benefits are fully realized if, at a minimum, a cloud of future state regulation or an outright ban hangs over certain food contact materials.

Simply being targeted as a chemical of concern under the SCPA, moreover, could lead to a *de facto* ban on the substance. Even where FDA has approved a food contact material as safe for use, regulatory burdens and market pressure resulting from being listed or associated with a priority product could, in effect, result in the removal of a substance from the stream of commerce. For instance, in recent testimony before the DTSC, the National Products Association stated that retailers would likely pull priority products off the shelves rather than incur the expense of compliance.[48] This is precisely the outcome that Congress intended to avoid when it amended the FFDCA in 1958—stifling further development of food technology when the substance is otherwise safe to use.

Finally, in the event that DTSC places use restrictions on a specific food contact material, obstacle preemption could be implicated on a substance-by-substance basis, particularly where the state's requirements are more stringent than FDA's. For example, the proposed regulations permit the DTSC to impose "[r]estrictions on the amount or concentration of the Chemical(s) of Concern permitted in a product" and "[a]ny other use restriction that reduces the amount of any Chemical(s) of Concern in the product, or reduces the ability of the product to contribute to or

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[47] *See also* S. Rep. No. 2422, at 3 (The Amendment "would make possible the use of additives discovered by our scientists which, having been adjudged safe for humans and animals when used in or within certain quantitative limits, could materially advance our ability to make more wholesome foods available to more people at all seasons and, perhaps, we hope, to assure to ourselves and others the ability to stockpile supplies of healthful and appetizing foods over such long periods of time as emergencies might make either desirable or essential.").

[48] DTSC, Hearing Transcript, at 53 (Sept. 10, 2012), available at http://www.dtsc.ca.gov/SCPRegulations.cfm.

cause an exposure to the Chemical(s) of Concern in the product."[49] Similarly, the FDA is authorized under the Amendment to set the maximum quantity of a food contact material that may be used.[50] However, if DTSC sets a use level more stringent than that deemed safe by FDA, the objectives set forth by Congress, for all practical purposes, will be defeated.[51]

B. Regulation Under The SCPA Could Directly Conflict With The FFDCA

Regulation of FCMs under the SCPA could also put manufacturers in a precarious position where it is impossible to comply with both Federal and state law because DTSC's regulations are not just an obstacle to FDA's safety determinations, but in fact directly conflict. Under such circumstances, Federal law would prevail.[52] For instance, FDA regulations limit the types of uses permitted for certain types of food contact materials (for example, see 21 C.F.R. § 176.170 (limiting uses for paper and paperboard that come into contact with aqueous and fatty foods)). Likewise, the proposed regulations allow DTSC to "impose restrictions on the use of one or more Chemicals of Concern . . . in a Priority Product . . . or restrictions on the use of the product itself."[53] This includes the form in which a product is sold and who may purchase or use the product. It is possible, therefore, that FDA and DTSC could limit a substance to entirely different uses. In this instance, if a manufacturer complies with the Federal standard, it would necessarily violate the state limitation, and vice versa. As such, the state regulation would be preempted. Given the extensive authority proposed for DTSC in terms of regulatory responses, including labeling requirements, use restrictions, and outright bans, it would be no surprise if DTSC's regulatory responses lead to numerous instances of impossibility preemption.

C. Summary

Without an exemption for food contact materials, the SCPA and the regulations, if adopted, would be subject to preemption challenges on a number of levels. Not only would the entire statute and state regulatory scheme be placed into question as they clearly frustrate and undermine the purposes for which Congress adopted the Federal program, DTSC may also face

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[49] SCPA § 69506.5.

[50] 21 U.S.C. § 348(c)(1)(A).

[51] *See, e.g.*, *Frith v. BIC Corp.*, 863 So. 2d 960, 967 (Miss. 2004) (finding objective preemption where plaintiffs' design defect claim would have imposed safety requirements for cigarette lighters that were stricter than the federal standard, thus upsetting the balance struck by Federal regulators of "sanctioning child-resistant lighters not too difficult for adult operation").

[52] *Cipollone*, 112 S.Ct. at 2617.

[53] SCPA § 69506.5.

constant lawsuits seeking to bar regulatory action on individual substances as the agency pushes for restrictive regulatory responses that conflict with FDA requirements. While this would ultimately be a matter for a court to decide, DTSC should be mindful of these considerations when determining its future regulatory actions and not risk the state's resources in litigation that may not be successful.

V. Other Concerns

A. Alternatives Analysis Threshold Exemption

The SCPA includes an exemption from the requirement for a Priority Product to conduct an Alternatives Analysis. For each Chemical of Concern that is the basis for the product being listed as a Priority Product, DTSC must specify an "alternatives analysis threshold;" if that Chemical of Concern is present in the Priority Product at a concentration lower than the established threshold then an alternatives analysis is not required for that product.[54] For FCMs, the appropriate threshold for safety has already been established by FDA based on a stringent evaluation and FDA's experience. It is difficult to see how and why DTSC would substitute its judgment for FDA's, when the Agency has decades of experience with these types of chemicals and products. Moreover, FDA coordinates with other federal agencies to harmonize the development of safe levels of potential exposure, and to benefit from collective knowledge of many scientists. DTSC does not have the resources and experience to duplicate this system.

All FCMs are evaluated to ensure that they are safe when used as intended. As part of the evaluation, limits may be set on the use of the material, including a limit on the concentration of a chemical. The levels set by FDA are determined based on its thorough scientific review and risk assessments. FDA has over fifty years of experience reviewing and evaluating food contact materials, and employs over thirty people for the specific purpose of evaluating their safety. DTSC has very little experience with evaluating the safety of FCMs, and will not have a staff dedicated solely to these materials. Instead, DTSC will be responsible for scientifically evaluating thousands of chemicals, in hundreds of products from all areas of the market. Thus, as a legal, scientific, and practical matter, DTSC should not be establishing threshold levels for a substance used in a food packaging material; instead, it should defer to FDA.

B. DTSC Should Remove Certain Sources from its "List of Lists"

Several of the primary sources for the "list of lists" from which DTSC will prepare the list of Chemicals of Concern should not be relied upon because they are either based on incomplete scientific evidence or are overinclusive. The SCPA regulations establish an immediate list of Chemicals of Concern based on existing lists of substances with identified

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[54] SCPA § 69503.5.

hazards. Specifically, Section 69502.2(a) lists the twenty-two existing lists that either: (i) list chemicals on the basis of exhibiting at least one of seven hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity); or (ii) list chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. Three of these lists—(1) the International Agency for Research on Cancer (IARC) Group 2B substances, (2) the Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, and (3) the National Toxicology Program's (NTP) Monographs on the Potential 16 Human Reproductive and Developmental Effects—should not be relied upon to develop the Chemicals of Concern list. The IARC Group 2B and Category 1 endocrine disruptor sources are lists based on incomplete scientific evidence and are, thus, insufficient as a resource for substances that should be classified as a chemical of concern, while the NTP list is overinclusive because it also lists substances that have been determined to be safe. These three lists were not developed to be lists of hazardous substances and are not an appropriate resource for developing such a list.

1. IARC Group 2B Substances

The IARC Monographs identify environmental factors that can increase the risk of human cancer. The Group 2B substances are those defined as possibly carcinogenic to humans, because there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals or when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. As per IARC guidance, there are a number of issues when evaluating chemicals with "limited evidence of carcinogenicity," thus, this group should not be used as a list to identify cancer hazards.

For Group 2B substances, a definitive evaluation of cancer hazards cannot be made because (a) the evidence of carcinogenicity is restricted to a single experiment, (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies, (c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential, or (d) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

By comparison, the IARC list for Group 1 and 2A carcinogens are more reliable and, thus better able to identify substances as hazardous. For inclusion in Group 1, the substance is determined to be carcinogenic to humans and must show "sufficient evidence of carcinogenicity." To be included in Group 2A, the substance is "probably carcinogenic to humans" and must demonstrate that "a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more

independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence. A single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites." The standards for listing in Groups 1 and 2A are significantly more stringent than for 2B.

DTSC could potentially be relying on poor science if it includes the Group 2B list. As outlined above, there can be many concerns with the evidence used to classify the substances. More specifically, these concerns include the following:

- High dose animal studies are not relevant to consumer exposure – there is a wide margin of safety between those substances exhibiting a threshold response and the levels to which consumers might be exposed. As discussed above, substances in food contact materials are trapped within the polymer matrix, and migration is expected to occur only at very low levels;
- Tumor type may be isolated to only limited number of target tissues at an incidence that is not considered to be statistically or biologically significant;
- Tumor type may be rodent specific and not relevant to humans as the mode of action may not be plausible or possible in humans;
- Tumor type may be limited to only one sex or in one species (or strain) and be of questionable biological significance;
- Many cancer bioassays are designed to identify hazardous substances that are used in the workplace where direct and repeated exposures are typical Consumer exposure in the marketplace is many orders of magnitude lower than in the workplace and may only occur sporadically. The chemicals (272 to date) that appear on the IARC 2B list have occupational exposure limits, which are designed to provide an estimate of acceptable daily workplace exposure;
- The route of exposure used in many of the cancer bioassays, such as inhalation (e.g., lung overload as in the case for carbon black and titanium dioxide which are both 2B carcinogens) may not be applicable to the potential exposure in the consumer product; thereby considerably overestimating hazard potential;
- Some chemicals were designated as 2B based on non-standard studies such as non-guideline, very old, and/or do not meet currently acceptable protocols or testing methodology;
- Study results may not be robust or reproducible or consistent with results available for analogues or structurally similar substances;

- For 2B chemicals, there may be some evidence in animal models, but stronger evidence against carcinogenicity from available human epidemiology studies, nonetheless the classification was assigned as 'possibly' carcinogenic;
- Data interpretation may vary by investigator (e.g., pathologists may have differing opinion on the tumor incidence, severity, or biological significance); and
- Some studies are not conducted properly such as with using non-concurrent control groups or inappropriate survival rates in control or treatment groups.

For these many reasons, the rationale for including a substance on IARC Group 2B is not a scientifically reliable basis for inclusion on DTSC's list of Chemicals of Concerns, and this group should be removed from the "list of lists."

2. Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*

The Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption* should not be included in the "list of lists" because these substances were identified only on a preliminary basis, and have not been subjected to the rigorous testing necessary to determine whether they truly are Chemicals of Concern. This report was prepared by a consultant for the European Commission, and explicitly states that the report was intended as "a first step towards the establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption" (emphasis added).[55] Indeed, the "working list" of 564 chemicals proposed in the report has been substantially pared down over time, with many substances removed due to insufficient scientific evidence or because they should not have been included in the first place.

This report clearly has been superseded by subsequent chemical evaluations, and should not be included as a scientifically reliable source for Chemicals of Concern. For this reason, we urge DTSC to remove this report from the "list of lists."

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[55] BKH Consulting Engineers, in association with TNO Nutrition and Food Research, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, November 10, 2000.

3. NTP Monographs on the Potential 16 Human Reproductive and Developmental Effects

The NTP's monographs on reproductive or developmental toxicants should not be included as a source of Chemicals of Concern because this list includes substances that have been evaluated as having no evidence of adverse effects. The monographs are produced by the NTP's Office of Health Assessment and Translation (OHAT), which is the successor to the Center for the Evaluation of Risks to Human Reproduction (CERHR). CERHR/OHAT monographs classify chemicals based on: (1) the weight of scientific evidence on adverse effects, expressed on a seven-part scale ranging from "clear evidence of adverse effects" to "clear evidence of no adverse effects;" and (2) the agency's level of concern that a chemical is associated with various reproductive and developmental effects, expressed on a five-part scale ranging from "serious concern for adverse effects" to "negligible concern for adverse effects." In the second analysis, the agency may also find that "insufficient hazard and/or exposure data" exists.

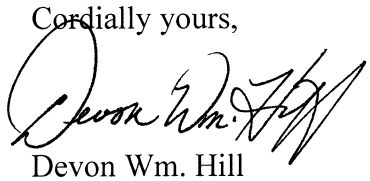
A CERHR monograph can therefore determine that a particular chemical presents "clear evidence of no adverse effects" and express "negligible concern for adverse effects," yet the chemical is not removed from the monographs. Thus, a chemical could be qualified as a Chemical of Concern because it was "identified" in a CERHR/OHAT monograph but not present any sort of hazard. We respectfully recommend that these monographs be removed from the potential sources of Chemicals of Concern, or alternatively, that DTSC make clear that only CERHR/OHAT monographs indicating high levels of evidence and concern regarding adverse endocrine effects are considered as the basis for addition to the Chemicals of Concern list.

VI. Conclusion

Food packaging is important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products to reduce food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI. In the opinion of our members, a separate duplicative regulate scheme would inhibit technological innovation and development that is important to ensure the safety of food and provide consumers with even safer and more environmentally friendly food packaging materials. Thus, the further regulation of food contact materials under the GCI is prohibited by Section 25257.1(c) of the Health and Safety Code.

For the reasons set forth above, we respectfully request that the DTSC exclude food-contact materials and substances used as components of food-contact materials from the scope of any regulations promulgated to implement the GCI.

Cordially yours,



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December 30, 2011

Via Electronic Mail and Regular Mail

Ms. Heather Jones
Safer Consumer Product Regulations, MS-22A
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806

Re: Comments on the Informal Draft Regulations for Safer Consumer Products

Dear Ms. Jones:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the informal draft regulations for Safer Consumer Products (SCP) issued on October 31, 2011, to implement Article 14 of chapter 6.5 of division 20 of the California Health and Safety Code (hereinafter, "the Green Chemistry Initiative" or "GCI"). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry. Members of this Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, transporting and serving food products. The comments provided herein reiterate the Coalition's position that food contact materials and substances used as components of food contact materials should be excluded from the scope of GCI regulations. We hereby incorporate by reference comments from the Coalition's submissions dated November 1, 2010, and December 3, 2010, on the draft *Safer Consumer Product Alternatives* regulation, copies of which are enclosed.

The Food Packaging Coalition (hereinafter, "the Coalition") appreciates your efforts to continue the open stakeholder process that DTSC has conducted relative to the development of the Green Chemistry Initiative (GCI), a process in which the Coalition has participated since 2009. The Coalition commends DTSC's responsiveness to concerns raised by Coalition partners with previous iterations of the GCI regulations. In particular, the Coalition appreciates that DTSC has incorporated more flexibility into the Alternatives Assessment (AA) process and has included provisions in the SCP informal draft regulations whereby a responsible entity may rely on an alternate process to prepare an AA Report, provided that the alternate process substantially meets the requirements of section 69505.5 and uses the same factors, associated exposure pathways, and life cycle segments as those specified in sections 69505.3 and 69505.4 of the SCP informal draft regulations. This allows companies to rely on and enhance existing approaches to

product development and improvement without costly implementation of a new and rigid evaluation approach that would yield no further improvement in the safety of product alternatives identified through the process. The Coalition also supports DTSC's plan to issue an initial list of two to five Priority Products to facilitate a learning process.

The Coalition remains concerned, however, with the absence of clear exemption language in the SCP informal draft regulations for food contact materials that are clearly regulated at the federal and state level. In the Coalition's November 1, 2010 and December 3, 2010 submissions, we provided support for the fact that food contact materials are already fully and effectively regulated throughout their life cycle by the U.S. Food and Drug Administration (FDA) and California governmental agencies for the protection of public health and the environment. Our analysis demonstrates that further regulation of these materials by DTSC under the GCI would be duplicative and in conflict with the existing federal regulatory scheme.[1] Furthermore, this duplicative regulation would divert DTSC's finite resources from those substances that present a real risk to public health and environment.

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

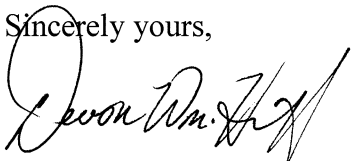
For the reasons set forth above and in comments previously submitted by the Coalition, we respectfully request that DTSC exclude food contact materials and substances used as components of food contact materials from the scope of any regulations promulgated to implement the GCI.

* * *

[1] 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."

We thank you for your efforts and consideration of our views, and we look forward to further collaboration as this process moves forward. If we can provide you with additional information or clarification, please contact Devon Hill at (202) 434 4279 or hill@khlaw.com.

Sincerely yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

Enclosures

Members of The Food Packaging Coalition

American Chemistry Council - Plastics Foodservice Packaging Group
American Forest & Paper Association
Can Manufacturers Institute
Flexible Packaging Association
Foodservice Packaging Institute
Grocery Manufacturers Association
North American Metal Packaging Alliance, Inc.
Paperboard Packaging Council
Recycled Paperboard Technical Association
Retail Industry Leaders Association
SPI – The Plastics Industry Trade Association

cc: The Honorable Matthew Rodriguez, Secretary, Cal-EPA
Miriam Ingenito, Deputy Secretary, Cal-EPA
The Honorable Debbie Raphael, Director, DTSC
Odette Madriago, Acting Deputy Director, DTSC
Jeff Wong, Office of the Chief Scientist, DTSC
Cliff Rechtschaffen, Office of the Governor

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December 3, 2010

Via Electronic Mail and Regular Mail

Mr. Jeff Woled, Regulations Coordinator
Office of Legislation & Regulatory Policy
Department of Toxic Substances Control
California Environmental Protection Agency
1001 I Street
P.O. Box 806
Sacramento, California 95812-0806

Re: Comments on the Revised *Safer Consumer Product Alternatives* Draft Regulation

Dear Mr. Woled:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the revised *Safer Consumer Product Alternatives* (SCPA) draft regulation (hereinafter SCPA 2) issued on November 16, 2010 to implement Article 14 of chapter 6.5 of division 20 of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI). These comments are being submitted on behalf of the Food Packaging Coalition ("the Coalition"), a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States, as well as trade associations that represent the food industry. The members of the Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.[1]

The comments provided herein follow up on the Coalition's comments submitted November 1, 2010, on the first draft of the proposed *Safer Consumer Product Alternatives* regulations (hereinafter "SCPA 1"). Our comments in this letter focus solely on the changes made to the draft regulation published on November 16, 2010.[2] Nonetheless, we hereby reiterate and incorporate by reference the comments from the Coalition's November 1, 2010 submission, a copy of which is enclosed.

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[1] Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, the Recycled Paperboard Technical Association, the American Chemistry Council Plastics Foodservice Packaging Group, and the Flexible Packaging Association.

[2] All section references are to SCPA 2.

As a general matter, we appreciate DTSC's efforts to streamline and clarify the regulations. SCPA 2 is easier to read and understand, and is a substantial improvement over SCPA 1. There are, however, some areas for which the Coalition believes that DTSC has not fully considered the potential implications of SCPA 2 on food packaging materials. We provide comments on these areas, below.

I. Regulatory Nonduplication

In the Coalition's November 1 submission, we stated our position and provided information to support the fact that food-contact materials already are fully regulated, by the U.S. Food and Drug Administration (FDA), to protect the safety of the public health and environment. Therefore, the regulation of these materials is not legally permitted under SCPA 2 because section 25257.1(c) of the California Health and Safety Code prohibits regulatory duplication.[3] We further discussed the regulatory nonduplication exemption set forth in various sections of SCPA 1.[4]

The Coalition considers several of the changes made in SCPA 2 with regard to the regulatory nonduplication exemption to be improvements. To start, the nonduplication exemption has been significantly simplified by the fact that it is now positioned at the beginning of the regulation (*see* § 69301(b)(5)), as opposed to being scattered throughout the implementing regulation. In addition, the nonduplication exemption has been clarified so that the analysis of whether the SCPA would comprise duplicative regulation for a given Chemical of Concern is determined by whether the hazard trait that otherwise would cause the chemical to be listed as a Chemical of Concern is already regulated by another federal or California regulatory program.

While we appreciate these changes, the Coalition would like to reiterate its position that food packaging materials should be wholly exempt from the final regulation. As fully described in the Coalition's November 1 submission, FDA has established a comprehensive regulatory framework for food-contact materials that leaves no room for regulation under the SCPA. Our prior analysis clearly demonstrates that FDA and California governmental agencies regulate all of the public health and environmental threats that are of concern to DTSC. Therefore, we urge DTSC to make this exemption explicitly clear in the final regulations.

If DTSC does not agree to fully exempt food packaging materials from the final regulation, the Agency should justify why it does not consider the SCPA duplicative regulation. Industry should not be required to go on a "fishing expedition" in order to identify any gaps in FDA's regulations. In SCPA 1, Section 69302.1(c) stated that "Any person requesting the Department to make a determination [regarding the regulatory nonduplication exemption] shall

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[3] 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."

[4] Although represented best in SCPA 1 § 69302.1(a)(1).

bear the burden to prove by clear and convincing evidence to the Department's satisfaction that [the regulatory nonduplication exemption] applies to the chemical in question." Thus, it was clear that industry had to demonstrate to DTSC that a product was already fully regulated for a hazard trait by a combination of federal or California programs. In SCPA 2, this language has been removed. The exemption in SCPA 2 now simply states that "The requirements of this chapter do not apply to a chemical or consumer product that the Department has determined is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination, address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the basis for the product being listed as a Priority Product." DTSC should, thus, be required to make explicitly clear its rationale for why food packaging materials should not be exempt.

Furthermore, the revised language in SCPA 2 appropriately places the burden of this exemption on DTSC. The removal of the language of SCPA 1's Section 69302.1(c) is indicative that DTSC has taken on the burden of informing industry of the public health and environmental threats and exposure pathways for which DTSC is asserting jurisdiction. (DTSC's jurisdiction would be based on the premise that no federal or California program regulates a given Chemical of Concern's hazard trait for a particular threat to public health or the environment.) Second, the language of SCPA 2 supports this conclusion, as Section 69301(b)(5) simply states that the requirements of the SCPA do not apply to Chemicals of Concern or Priority Products "that the Department has determined" are already regulated, thereby indicating that DTSC will bear the burden of the determination of whether Chemical of Concern's hazard trait is already properly regulated.

In addition, the language of the GCI legislation also supports this conclusion. California Health and Safety Code[5] Section 25257.1(c) provides a strong prohibition against regulatory duplication, stating that "the department *shall not duplicate* or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article" (emphasis added). This mandate against regulatory nonduplication adds further support for the conclusion that DTSC should have the burden of establishing the absence of existing regulation for a given hazard trait.

Finally, it is more appropriate for the burden to placed on DTSC. DTSC will be establishing a list of Chemicals of Concern and Priority Products. For each Chemical of Concern, DTSC must identify the hazard trait that is the basis for the listing. It would be logical for the Department to inform industry, at the same time DTSC issues the list of Priority Products, of the rationale for why the Priority Product is not exempt from the requirements of the

[5] The GCI legislation is codified at Health and Safety Code §§ 25251 – 25257.1.

regulation by identifying the hazard traits and exposure pathways that are not already regulated by FDA or California agencies.

The Coalition proposes below a modified SCPA 2 Section 69303.2(b) (dealing with the development of the list of Priority Products), that we believe would address our concerns:

> "Prior to finalizing the Priority Product list, the Department shall make the proposed list available on its website, for public review and comment, along with supporting documentation, including the Department's rationale, data and data sources, subject to article 9. The supporting information shall include:
>
> (1) ~~a~~An identification of the hazard trait(s) exhibited by, and potential exposure pathways for, each Chemical of Concern that is the basis for a product being listed as a Priority Product; and
>
> (2) For food packaging materials, the Department's rationale for its determination that the hazard trait(s) and potential exposure pathways that are the basis for the chemical being listed as a Chemical of Concern are not regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate."[6]

II. No Exposure Pathway

In addition to the nonduplication exemption, SCPA 2 has also retained the exemption by which products containing Chemicals of Concern may be exempt from the Alternative Assessment requirements, if DTSC has determined that there is no exposure pathway for the Chemical of Concern that would pose a threat to the public health or the environment. Similarly to the regulatory nonduplication exemption, the no exposure pathway exemption has been significantly simplified by its consolidated placement at the beginning of the regulation (*see* § 69301(b)(6)). By contrast, however, the "clear and convincing evidence" standard has not been removed. The Coalition is concerned that DTSC has failed to provide a rationale for this high burden of proof, and is imposing an unnecessarily stringent standard on industry. The Coalition recommends that, instead, DTSC utilize a standard of "weight of the evidence based on validated scientific data." It is always difficult to prove a negative, thus, requiring manufacturers to prove the absence of an exposure pathway by a "clear and convincing" standard is overly burdensome. We believe that a weight of the evidence standard is sufficiently rigorous to determine whether

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[6] The remaining text of this paragraph may be redesignated as paragraph (c), and all following paragraphs also should be redesignated accordingly.

there is significant exposure to the chemical from its intended use. Thus, the revised Section 69301(b)(6)(B) would read as follows:

> (B) Any person requesting the Department to make a determination pursuant to subparagraph (A) shall bear the burden to prove that, based on validated scientific data, the weight of the evidence demonstrates that subparagraph (A) applies to the product in question.

In addition, DTSC has retained the requirement that the exemption shall be determined based on "an evaluation of reasonably foreseeable uses, misuses and abuses of the product, and reasonably foreseeable proper and improper end-of-life management of the product." The Coalition believes that this standard should be limited to reasonably foreseeable uses. A food packaging material manufacturer should not be required to speculate on all the misuses and abuses to which their product could be subjected. It is difficult for any manufacturer to speculate on how a product could be misused, and placing the burden of safety for uses which a product is not intended would be a substantial and unfair burden on industry. Furthermore, in the event that a consumer does misuse or abuse a food container, it is not likely that the package itself will pose a new or significant safety concern, because the misuse or abuse would not likely change the intrinsic nature of the food container. The human and environmental exposure to the Chemical of Concern would not be increased by the misuse because, as noted by Dr. George Gray in his peer review (page 5), there is "little opportunity for exposure if the chemical is sealed, bound to a matrix or otherwise unavailable," as is the case with substances in food packaging materials. Instead, the contents of the misused package are what would be relevant from a health and environmental standpoint.

III. *De Minimis* Exemption

Another exemption available from some SCPA 2 requirements is the *de minimis* exemption.[7] "*De minimis*" is defined, in part, as a concentration less than or equal to 0.1% by weight. This part of the exemption is unchanged from SCPA 1. As the Coalition discussed in its comments for SCPA 1, it is unclear as to what the 0.1% by weight threshold refers. For food packaging materials, this threshold could be interpreted to apply to the amount of the chemical by weight of the consumer product as a whole, the amount of the chemical in relation to the finished package, or the amount of the chemical that could migrate from the finished food contact article into food. We believe that the exemption should be clarified so that, for food packaging materials, the exemption threshold applies to the amount of any chemical that could migrate from the package into food. This measurement is the most important from a health and environmental safety perspective, because it is based on the potential exposure that could result.

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[7] The application of the *de minimis* exemption is found in § 69303.2, although the definition of "*de minimis*" is found in § 69301.1(26).

It is not the presence of a chemical in a food packaging material that is of interest; instead, it is the level of migration of the chemical from the food packaging that would give rise to an exposure to a particular substance.

Although the 0.1% by weight threshold is unchanged from SCPA 1, DTSC has made other beneficial changes to the *de minimis* exemption. Most notably, industry now has the ability to make a self-determination as to whether a Chemical of Concern is present in a product at a level above the *de minimis* threshold. The Coalition considers this to be an appropriate revision, on the basis that a manufacturer is in the best position to have information on the composition of its products.

However, although industry now makes a self determination as to whether a product is eligible for the *de minimis* exemption, DTSC has added a notification requirement to this exemption (*see* § 69303.2(d)(3)(A)), whereby the Priority Product's manufacturer submits a "De Minimis Exemption Notification" to DTSC. As part of this Notification, the manufacturer must submit, for a formulated product, the maximum concentration of each Chemical of Concern in the product that is the basis for the Priority Product listing, and a description of all data and other information used by the manufacturer to determine and substantiate this concentration. Furthermore, DTSC has limited the exemption for formulated products by requiring the aggregation of Chemicals of Concern that exhibit the same hazard trait. Thus, if a Priority Product contains multiple Chemicals of Concern that exhibit the same hazard trait, the concentration of these Chemicals of Concern in the Priority Product must not total more than 0.1% in order for the Priority Product to qualify for the *de minimis* exemption.

The Coalition considers that the aggregation of chemicals with the same hazard trait is inappropriate from a toxicological perspective. DTSC is equating the aggregation of hazard traits with the aggregation of the risk that multiple chemicals exhibiting the same hazard trait will result in a particular toxic event. This often is not the case. For example, a product may contain two chemicals that exhibit the broad hazard trait of carcinogenicity, but that act by dissimilar biochemical mechanisms. Although exposure to each chemical may result in the same toxicological endpoint (cancer), there is no cumulative effect from both chemicals because the biochemical mechanism is different. Each of the two chemicals has its own biochemical mechanism that causes the toxic event. By contrast, two chemicals may cause cancer through the same biochemical mechanism; in this case, it may be appropriate to aggregate the exposures, as there could be a cumulative risk of the chemical exposure resulting in the same toxic event. It is important to note, however, that there may be uncertainties and complexities associated with aggregating exposures to chemicals that work through similar biochemical mechanisms, because such chemicals may still have differences in their toxicokinetic profile (such as in their absorption, distribution, metabolism, and excretion (ADME) profile, for example, or in their Physiologically Based Pharmacokinetic (PBPK) models). Therefore, only those Chemicals of Concern that exhibit the same hazard trait, and for which there is evidence that the biochemical

mechanism of exposure and the toxicokinetic profile are the same, may be subject to aggregation.

IV. Adverse Public Health Impacts

DTSC has added a new definition to describe "adverse public health impacts" (*see* § 69301.1(6)). Adverse public health impacts are one factor that DTSC will use in its evaluation of the relative threat of different chemicals to determine which chemicals will be placed on the list of Chemicals of Concern (*see* § 69302.2), and again in its evaluation of the relative threat of a Priority Product (*see* § 69303.2). Adverse public health impacts are defined as "impacts that directly or indirectly cause any of the following effects on human health: (a) acute toxicity; (b) carcinogenicity; (c) developmental toxicity; (d) reproductive toxicity; (e) epigenetic toxicity; (f) genotoxicity; or (g) organ, tissue or cellular toxicity not otherwise described above. We are concerned with two of these categories—epigenetic toxicity, and the catch-all, "organ, tissue, or cellular toxicity not otherwise described above."

The Coalition's comments for SCPA 1 described for DTSC the problems with using epigenetics as a toxicological endpoint of concern. We would like to reiterate again that the inclusion of epigenetics is inappropriate because it is a new field of toxicological analysis. As such, it has no reference database by which to judge any analysis, or historical controls for comparison. In his peer review, Dr. William Farland suggests that epigenetics is a valid endpoint, as long as it is toxicity-related. However, this suggestion assumes that we know which "epigenetic" changes are implicated in the etiology of disease; this is not yet the case. The appropriate toxicological endpoint for such effects would instead be the more conventional endpoints, such as reproductive or development toxicity or carcinogenicity, which are already listed. Thus, as epigenetics is an unproven and ambiguous area of toxicology, the Coalition believes it should be removed from the definition of an adverse health impact. Furthermore, no other regulatory agency (of which we are aware) uses such an ambiguous and amorphous endpoint for regulatory decision making purposes.

In addition, the catch-all provision of "organ, tissue, or cellular toxicity not otherwise described above" should be removed from the list of adverse impacts, because it is ambiguous, and fails to put industry on notice of the appropriate toxicological endpoints of concern.[8]

V. Chemical Removal Notice

SCPA 2 has added a requirement that, when submitting a Chemical Removal Notice under Section 69303.2 (d)(2), the manufacturer is required to certify that the Chemical of

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[8] In addition, similarly to epigenetics, the use of cellular toxicity as an endpoint is toxicologically ambiguous. Some studies address cytotoxicity, however, the impacts on living systems is, at best, speculative and has not been validated. Thus, cellular toxicity should not be considered to be an appropriate toxicological endpoint.

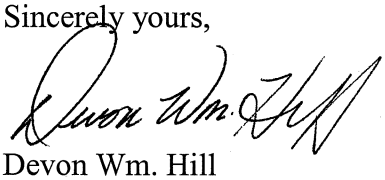
Concern has been removed "without adding another chemical or increasing the concentration of a chemical contained in the product or component to compensate for the removal or reduction of the Chemical(s) of Concern" (*see* § 69303.2(d)(2)(A)). In many cases it would be unlikely that a Chemical of Concern can be removed from a product without replacing it with another chemical that can provide equivalent functional performance. However, it would be reasonable to require that no additional Chemicals of Concern are used to replace the one that was removed. Thus, the Coalition believes that this section should be revised to read as follows:

> "(A) A statement certifying that any and all Chemicals of Concern that are the basis for the Priority Product listing have been removed from the product or component, whichever is applicable, or reduced to a level that meets the criteria specified in paragraph (3)(d), without adding another Chemical of Concern ~~chemical or increasing the concentration of a chemical already contained in the product or component~~ to compensate for the removal or reduction of the Chemical(s) of Concern that caused the listing of the product as a Priority Product".

* * *

We appreciate this opportunity to comment on SCPA 2, and we look forward to working with DTSC on the continued implementation of the GCI. Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

Enclosure

cc (via email only): The Honorable Linda Adams, Secretary, CalEPA
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Via Federal Express

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1001 I Street
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Re: Comments on the Safer Consumer Product Alternatives Draft Regulation

Dear Dr. Movassaghi:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the *Safer Consumer Product Alternatives* (SCPA) draft regulation issued on September 14, 2010 to implement Article 14 of chapter 6.5 of division 20 of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI).[1] These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry. This group has a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.[2]

Food packaging is an essential tool in ensuring the safety and quality of food. Materials that contact food are carefully designed to prevent the transfer of their components to food and to have no effect on the contacted food. These materials are also designed with technical properties that preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-

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[1] These comments follow up on our August 18, 2009 meeting with Dr. Maziar Movassaghi, and our comments of November 4, 2009 on the "Straw Proposal."

[2] Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, and the Recycled Paperboard Technical Association.

life of products. The U.S. Food and Drug Administration (FDA), using the legislative authority granted by the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act), has established a comprehensive regulatory scheme to ensure the safety of food-contact materials from both a public health and environmental perspective. This regulatory scheme is wholly consistent with the goals and purposes of the GCI, thus the duplication of this regulatory scheme by the SCPA would impose substantial burdens that do not benefit public health or environmental safety. One consequence of these additional burdens will be the inhibition of technological innovation and the development of safer and more environmentally friendly food packaging materials.

Our comments support the conclusion that food-contact materials are subject to a comprehensive regulatory program that protects the public health and environment from any adverse impacts that could potentially occur due to the use of food packaging materials. Through a combination of federal and state laws, the use of chemicals in food contact materials is controlled throughout the full life cycle of these products. As a result, if the SCPA continues to include food-contact materials, these products would be subject to duplicative and conflicting regulatory programs, in violation of section 25257.1(c) of the GCI. Furthermore, this wasteful, duplicative regulation will divert DTSC's finite resources from those substances that truly present a risk of harm to consumers. Therefore, DTSC should revise the SCPA to exclude food contact materials from the scope of the regulation, thereby preventing this duplicative situation and avoiding the waste of scarce public resources on these products, without providing any benefit to public health and safety.

We also are concerned that, although the SCPA is well-intentioned, the regulation's reach extends significantly beyond the authority established by the GCI. If enacted as proposed, the SCPA would implement a broad range of evaluation and reporting requirements for both DTSC and industry. We foresee two consequences of these new requirements. First, we are concerned that the scope of the regulations as proposed will create such an immense administrative burden on DTSC that it will not be feasible for the Agency to comply with the deadlines established in the SCPA. The regulation contains an abundance of new responsibilities for DTSC, many of which require time-consuming and difficult scientific evaluations. We believe that DTSC is not equipped, with financial support or personnel, to administer these responsibilities. This will result in long delays and regulatory uncertainty that will be detrimental to industry and consumers. Second, the regulations as proposed are so complex and unclear that the financial and administrative burden placed on industry will force industry and safe consumer products out of the California market.

We present our comments in three sections: (1) comments regarding concerns specific to food packaging materials; (2) comments regarding the SCPA generally; and (3) comments regarding specific sections of the SCPA.

I. Food Packaging Materials Specific Concerns

We have several concerns that relate specifically to the regulation of food-contact materials under the SCPA. As it currently stands, the SCPA includes food packaging and other food-contact materials within the scope of the consumer products that are intended to be covered by the regulation. We believe this will result in regulatory duplication, as food packaging materials already are regulated throughout their life cycle through a combination of federal and California state programs. Such duplication is prohibited by section 25257.1(c) of the California Health and Safety Code. Additionally, the exemptions available for certain chemicals are vague, and likely to be difficult for DTSC to administer on a chemical by chemical basis. As a result, we do not believe that the inclusion of food-contact materials within the scope of the SCPA will further the goals of the legislation. Moreover, this action could inhibit the development of new food packaging materials that ensure the safety of food and prevent food waste due to spoilage.

A. Food Packaging Materials Should Be Exempted From the SCPA to Prevent Duplicative Regulation

It is our position that food-contact materials are fully regulated throughout their life cycle, primarily by the FDA, and that the regulation of these materials is not legally permitted under the SCPA because of the proscription of section 25257.1(c) of the California Health and Safety Code. This section restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI.[3] Using the life cycle segments described in section 25253(a)(2)[4] of the GCI, we demonstrate below that food packaging materials are regulated throughout their entire life cycle by a combination of federal and California regulatory programs. We believe, therefore, that food packaging materials should be wholly exempt from the SCPA as this the further regulation would represent regulatory duplication that is prohibited by the GCI.

We note, as a preliminary matter, that the SCPA references life cycle analysis (excluding multimedia life cycle evaluations) in several different sections. The first, in the definitions section, describes the "life cycle" segments as "design, raw materials, resource inputs,

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[3] 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."

[4] The enumerated segments are as follows: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts (including sensitive subpopulations); environmental impacts; and economic impacts.

manufacture, transportation for distribution, use, operation, resource consumption, waste generation, maintenance, and ultimate disposition."[5] Another variant of the life cycle analysis is present in SCPA § 69305.4(a)(5), in reference to the life cycle analysis that is required as part of the Tier II AA Work Plan. Specifically, this section identifies the following life cycle segments: raw materials mining; intermediary material processes; manufacturing and packaging; distribution, transportation and marketing; use; product end-of-life; and reuse and recycling. These two variants are thus similar, but by no means identical.

The third variant, the language of which is duplicated several times in the SCPA,[6] makes its first appearance in Section 69302.1(a)(1) and notes that the life cycle analysis necessary to obtain an exemption from the chemical prioritization process requires addressing "the same public health and environmental threats [as in] . . . article 14 of chapter 6.5 of division 20 of the Health and Safety Code, and this chapter," or in other words, the GCI.[7] If the Agency determines there are "significant gaps, for one or more life cycle segments" DTSC will not grant the exemption. Yet, the SCPA fails to define those "public health and environmental threats," and "life cycle segments" to which it refers. Looking to the GCI instead, the Code vaguely references "critical exposure pathways" and "life cycle assessment tools," without providing further detail. Attempting to determine exactly what "threats" should be addressed in the life cycle analysis, and for which "segments" there may be gaps is, therefore, virtually impossible. As a result, companies do not have a consistent set of life cycle segments by which to perform their various required analyses. DTSC must decide on a single set of determinative life cycle factors for industry to consider and analyze. As it currently stands, compliance with the life cycle analyses listed in the SCPA is not practically feasible.

As there are several variants of life cycle analysis in the SCPA, for the purpose of these comments and for lack of better guidance, we are utilizing the factors enumerated in GCI § 25253(a)(2).

1. Life Cycle Segments Comprehensively Regulated by FDA

FDA, through the FFDCA,[8] regulates food packaging materials through almost all of the life cycle segments established in GCI § 25253(a)(2). Specifically, the FFDCA establishes a premarket approval requirement for components of food packaging materials that may become significant components of food. In addition to the health and safety concerns with the use of the

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[5] SCPA § 69301.2(a)(44).

[6] SCPA §§ 69302.1(a), 69302.3(h), 69303.1(a), and 69303.3(h).

[7] We note that in no place does the GCI refer to or use the term "public health and environmental threats."

[8] 21 U.S.C. §§ 301 *et seq.*

product, FDA also considers the potential environmental impact that may result from the use of a new food packaging material.

a. FFDCA Regulatory Framework

The regulation of food-contact materials was established by Congress as part of the 1958 Food Additives Amendments.[9] These amendments require FDA to regulate food-contact materials as food to the extent that there is any migration or exposure to the components of the packaging (or other materials used in contact with food). More specifically, Section 201(f) of the FFDCA defines food to mean "articles used for food or drink for man or other animals," including "articles used for components of any such article" (*i.e.*, food additives). The FFDCA further defines a "food additive," in Section 201(s), as a substance that is reasonably expected to become a component of food under the intended conditions of use, with certain statutory exceptions.[10] Thus, to the extent that there is any migration, FDA regulates a food-contact material in the same manner as any substance that is directly and intentionally added to food. Food additives, including food-contact materials, are subject to premarket authorization by FDA before they can be marketed, unless the use of the substance qualifies for one of the limited exceptions provided under the FFDCA. Accordingly, unless an exemption applies, a person intending to market a new food-contact material must first seek clearance from the FDA.

Like substances directly added to food, FDA regulates components of food packaging materials by the promulgation of food additives regulations, which set forth the conditions under which a particular substance may be used. FDA's food additive regulations may be found in Title 21 of the Code of Federal Regulations, Parts 170-189. For each of the clearances in these regulations for a food-contact substance FDA has conducted a detailed review of the substance's safety. In addition, as part of its promulgation of a new food additive regulation, FDA (as required by the National Environmental Policy Act[11]) conducts an environmental assessment of the proposed applications to determine if there would be any environmental impact from the manufacture and use of a new substance or whether the use and disposal of the new product would adversely affect the recycling of post consumer materials.[12,13]

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9 Pub. L. No. 85-929, 72 Stat. 1784 (1958).

10 As detailed below, examples of substances that are exempt from the definition of food additive are substances that are generally recognized as safe (GRAS) or prior-sanctioned for their intended use by FDA before January 1, 1958.

11 42 U.S.C. §§ 4321 *et seq.*

12 FDA has published guidance documents discussing the information and data that must be included for its environmental review. *See* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at

(continued ...)

Congress provided FDA with authorization to use a new regulatory procedure for the review of new food-contact substances and new uses of food-contact substances when it enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).[14] FDAMA added Section 409(h) to the FFDCA authorizing the Food Contact Notification (FCN) program. The FCN program has been operational at FDA since 2000, and now FDA reviews the overwhelming majority of food-contact substances under this program. Under the FCN program, manufacturers must submit information on the identity and use of the food-contact substance, along with information supporting the conclusion that the substance is safe for the intended use. While the system does not result in the promulgation of a new food additive regulation, the safety and environmental evaluation standards are the same as for the food additive petition process. (Arguably, FDA's evaluation of food-contact substances under the FCN program is even stricter than it was before the FCN program was available, as the Agency added additional chemistry and toxicity data requirements when it established guidelines for the new program.) If FDA does not object to a manufacturer's FCN, the proposed substance, along with the terms and conditions under which it may be used, is published on FDA's website along with the identity of the notifier.[15] FCNs are proprietary to the notifier and may only be relied upon by the notifier and its customers. Manufacturers who produce the same material must submit their own notification to FDA.[16]

(...continued)
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm *and* "Environmental Assessment Technical Assistance Handbook" at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm084224.htm.

[13] An article describing FDA's food additive approval process and safety evaluation was recently published by the former director of FDA's Center for Food Safety and Applied Nutrition and the former Director of the Office of Food Additive Safety. While the article focuses on food ingredients, *per se*, FDA regulates the safety of food-contact materials in a similar manner, thus, the article is instructive of the Agency's safety assessment. *See* "FDA's food ingredient approval process – Safety assurance based on scientific assessment" A.M. Rulis and J.A. Levitt, *Regulatory Toxicology and Pharmacology* 53 (2009) 20-31.

[14] Public Law No. 105-115, 105th Congress (Nov. 21, 1997).

[15] Effective notifications are published on FDA's website at http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm.

[16] Additional information on the FCN process and FDA's regulation of food-contact materials can be found in a recent chapter in a book published by the Food and Drug Law

(continued ...)

Once a material is cleared by FDA, the Agency continues to monitor public information and safety that may question whether the use of the material continues to be safe. Under the FCN, notifiers are required to submit to FDA any new toxicological data or other information that may come to their attention that could affect FDA's decision that the use of the substance is safe.

b. Data Required for FDA's Review

To evaluate the safety and environmental aspects of the use of a new food-contact substance, FDA requires a manufacturer to submit extensive data to the Agency. FDA has published guidance documents regarding its requirements for the data and information that must be included in a food additive petition or FCN.[17] These data include:

(1) a full chemical description of the food-contact substance, its impurity profile, and details regarding its manufacture;

(2) information on the technical properties of the substance for its intended use;

(3) data demonstrating the amount of the substance that may migrate from the article to food;

(4) calculations of the estimated dietary exposure to the substance and its impurities based on its anticipated use;[18]

(...continued)
Institute. *See* D.W. Hill and R.A. Bond, "Chapter 4: Food and Drug Packaging," in the Food and Drug Law Institute's *Food and Drug Law and Regulation.*

[17] FDA, "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" (Sept. 1999, updated Apr. 2002), at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm and "Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations" (Apr. 2002, updated Dec. 2007) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm.

[18] The dietary exposure is calculated by multiplying the amount of a component expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing the additive. This fraction is known as a "consumption factor." These calculations invariably represent a conservative estimate of the dietary exposure of the additive because they are based on the assumption that the component will always migrate at maximum levels, and that all food-contact materials of a given type will be made using the subject substance.

(5) all available toxicological data that the notifier has in its possession or that is publicly available must be provided for the substance and its impurities;

(6) certain minimum toxicological data, the volume of which depends on the estimated dietary exposure from the proposed use; FDA's tiered requirements for toxicological data for substances with a potential dietary exposure between 0.5 parts per billion (ppb) and 50 ppb mandate two *in vitro* genotoxicity studies demonstrating that the substance is not mutagenic or genotoxic; for substances with dietary exposures above 50 ppb, FDA requires a third genotoxicity study in the form of an *in vivo* chromosomal aberration study, and two subchronic feeding studies, generally one in a rodent species and one in a non-rodent species. For substances with exposures above one part per million in the diet, FDA requires a full panoply of toxicological data, including the data identified above as well as from a chronic two-year bioassay, a one-year feeding study in a non-rodent species, and multigenerational reproductive and developmental toxicity studies. Of course, if any of these studies indicate a hazard trait or toxicological endpoint of concern, FDA may require additional studies to demonstrate that the proposed use will be safe;[19]

(7) data that allow FDA to consider the potential environmental impact that may result from the clearance of a new food-contact material;[20] unless the proposed use of the food- contact substance qualifies for an exemption, petitioners and notifiers must submit information that the proposed manufacture of the food-contact substance will not affect compliance with any federal and state environmental laws related to any discharge to the environment, such as air and water emissions.

To put these toxicity thresholds into perspective, 1 ppm is equivalent to one drop of water diluted into 50 liters (roughly the fuel tank capacity of a compact car), 1 ppb is equivalent to one drop of water diluted into 250 chemical drums (50 m^3), and 1 part per trillion (ppt) is equivalent to one drop of water diluted into 20 Olympic-size swimming pools (50,000 m^3). The toxicity

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[19] *Id.*

[20] FDA's categorical exclusions are set forth at 21 C.F.R. §§ 25.30-34. The Agency set forth its rationale for why certain applications are exempt from the need for an environmental assessment in the Federal Register notice promulgating this rule. *See* 62 Fed. Reg. 40569-40600 (July 29, 1997). *See also* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm

studies required by FDA are all for chronic (i.e., long term) exposures. The rationale for requiring chronic toxicity data is that for substances entering the diet at such miniscule levels, acute toxicity almost never is a concern (that is, virtually nothing will be acutely toxic at low parts per billion levels). On the other hand, it is possible, at least in theory, for carcinogenic effects to be elicited at low dietary levels; hence, the toxicity endpoint of greatest concern for low-exposure substances is carcinogenicity. The genotoxicity screening assays are intended to provide an indication as to whether a given substance is likely to be a carcinogen.

Further, we note that information also must be submitted on the environmental fate resulting from the use and disposal of the food-contact substance, demonstrating that it will not affect the environment. In particular, information must be submitted that evaluates any potential environmental impact when the substance is disposed of, such as landfill leachate, incineration and the potential air emission and ash disposal from incineration. Any environmental impact that may result from manufacture, use, or disposal, such as aquatic toxicity or toxicity to terrestrial organisms, must be addressed.

FDA pays particular concern to any impacts that the proposed use of the substance may have on the ability to recycle post consumer packaging materials. If there is a concern that the new substance may create problems with the recycling processes currently being used, FDA will require further data and information or limitations to ensure that the proposed use will not create an adverse economical or technical impact on the ability to recycle food packaging materials.

In sum, FDA has in place a comprehensive and robust system of regulation for food-contact materials that establishes a large margin of safety. The regulations proposed by DTSC to implement the GCI would duplicate this system. FDA's regulatory scheme is consistent with the purposes of the GCI. Thus, the inclusion of these products in the SCPA 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.

c. Exceptions from Premarket Review

As noted above, there are limited exceptions to the need to obtain a food additive regulation or an effective FCN for the proposed use of a new food-contact substance. First, FDA may exempt a material from the need for a regulation of FCN under its Threshold of Regulation exemption procedure. FDA's Threshold of Regulation procedure, which is codified at 21 C.F.R. § 170.39, allows the Agency to exempt a substance from the need for a regulation or FCN if the proposed use of the substance meets certain criteria:

(1) the substance must not be a carcinogen and may not contain any carcinogenic impurities with a TD_{50} (*i.e.*, median toxic dose) value less than 6.25 mg/kg body weight per day;[21]

(2) the proposed use of the substance must not result in a dietary exposure exceeding 0.5 ppb or, if the substance is currently regulated for direct use in food, the proposed increase in the dietary exposure must be less than one percent of the established acceptable dietary intake (ADI) for the substance;

(3) the substance has no technical effect in the food; and

(4) the proposed use of the substance may not have a significant impact on the environment.

FDA adopted the Threshold of Regulation procedure after reviewing a large number of published studies indicating that there was little toxicological concern from the exposure to noncarcinogenic substances at levels below 0.5 ppb in the diet.[22] FDA reserves the right to determine if substances qualify for the exemption and provides response to companies submitting such a request.

The FFDCA also provides certain exceptions to the definition of a food additive that also apply to food-contact materials. Specifically, the Act excepts those materials that are considered to be generally recognized as safe (GRAS) or that were sanctioned by either FDA or the United States Department of Agriculture (USDA) prior to the adoption of the Food Additives Amendment in 1958. Food additives, as well as food-contact materials that qualify under these exemptions, are not technically subject to premarket review by FDA, although in many cases companies request FDA's review.

The FFDCA exception for GRAS substances as provided in Section 201(s) states that such a determination requires a general recognition "among experts qualified by scientific training and experience to evaluate [the additive's] safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use." FDA has promulgated regulations setting forth the criteria that the Agency regards as necessary to establish that the use of substance is GRAS. These eligibility requirements provide that a

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[21] The TD_{50} is the chronic dose level that would induce tumors in half the test animals at the end of a standard lifetime for the species.

[22] 60 *Fed. Reg.* 36595, July 17, 1995. A full report and all of the individual papers written as part of a study examining this issue were published in the August 1990 issue of *Regulatory Toxicology and Pharmacology*. *See* Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).

general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."[23] Moreover, FDA has clarified that "scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation."[24] The main toxicological data and other information that support a GRAS determination must be published, generally in peer-reviewed scientific journals.

FDA has a procedure to review and sanction GRAS determinations through a GRAS Notification process.[25] In addition, the Agency has listed or affirmed some materials as GRAS in Parts 182, 184, and 186 of the food additive regulations. A determination may be made without FDA review that a substance is GRAS, provided that sufficient published toxicological data exist that establish a general scientific recognition that a substance's use is GRAS. The standards for such a self-determined GRAS assessment are robust. As stated by two former FDA officials, Drs. Alan Rulis and Joseph Levitt, "many people mistakenly associate GRAS with a sort of "second" tier of safety protection based on a less-than rigorous standard compared to petitioned food additives. This is not true. In fact, the safety standard applicable to GRAS food ingredients is the *same* as for food additives; namely reasonable certainty of no harm."[26] The former directors went on to say that "[i]n fact, the GRAS criteria are in some ways more difficult to satisfy than the food additive criteria because of the additional requirement of public availability of the data and general recognition and acceptance of a safety conclusion based on those data."

The FFDCA also expressly exempts those materials that were sanctioned by USDA or FDA in letters issued by these Agencies before the passage of the Food Additive Amendments in 1958. In the experience of our members, the substances covered by prior sanctions and still used in commerce are limited, and many of the substances were subsequently petitioned or notified to

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[23] 21 C.F.R. § 170.30(a)(2).

[24] 21 C.F.R. § 170.30(b).

[25] *See* FDA, GRAS Notification Program, at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm.

[26] *See* A.M. Rulis and J. Levitt, p. 26.

the FDA. FDA very strictly interprets previously issued prior sanction letters, and limits the scope of the exclusion by construing prior sanctions as narrowly as possible.[27]

Substances also may be used without express premarket approval from FDA if they can additionally be shown to not migrate from the food-contact article. The standard for this assumption is strictly interpreted by both the Agency and industry. In general, a showing of no migration must be based on an analytical sensitivity demonstrating that there would be no migration at a level equivalent to 50 ppb and often lower in some situations.[28] The basis of the exclusion from premarket clearance is that, given the very low migration of the substance to food, the resulting dietary exposure among consumers will be negligible.

In sum, the exemptions from premarket approval for food-contact materials are strictly limited by the FFDCA. Only those materials that are subject to published toxicological data and generally accepted by the scientific community as safe may be considered to be GRAS and used without FDA review. Those substances covered by prior sanctions are limited, and the substances used in food-contact materials that do not migrate to food result in no exposure to consumers. In addition, these substances when used in food-contact articles are still subject to FDA regulation under Section 402 of the FFDCA.[29] Under no circumstances may any substance cause a health or safety concern when used as intended and may not affect the taste or odor of the food. Thus, it is our opinion that the substances that qualify for these limited exceptions do not result in exposures of concern and, therefore, subjecting them to the scope of the GCI would not promote the purposes of the statute. Including such materials within the scope of the GCI will duplicate the existing regulatory scheme which Congress and FDA have established.

d. The Current Regulation and Evaluation of Food-Contact Materials Is Consistent with the Hazard Category Endpoints

The SCPA aims to prioritize all chemicals used in products in California for a list of Chemicals of Concern, based on the "hazard trait" exhibited by that chemical.[30] "Hazard trait" is defined so as to eventually refer to the hazard traits identified by the Office of Environmental Health Hazard Assessment (OEHHA) as part of its implementation of the Toxics Information Clearinghouse, that is required by GCI § 25256.1. On August 10, 2010, OEHHA released a pre-

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[27] *See* 456 F. Supp. 207, 209 (d. Neb. 1978), *aff'd sub nom. United States v. Nielsen* (8th Cir. 1979), cert. denied 444 U.S. 832 (1979). *See also*, 21 C.F.R. § 170.38(d).

[28] The resulting dietary exposure for most food-contact substances, even if there were some migration below the level of detection, would be less than 0.5 ppb, a level below FDA's threshold of toxicological concern.

[29] 21 U.S.C. § 342(a)

[30] *See* § 69302.1(a).

regulatory draft proposal of the hazard traits by which a chemical would be evaluated to determine whether it belongs on the list of Chemicals of Concern. As a general matter, we consider the pre-regulatory draft to be as vague and ambiguous as the SCPA. Specifically, the OEHHA pre-regulatory draft calls for a new classification system for chemicals, ignoring established, internationally-recognized systems, recognizes numerous types of toxicity data on an individual basis, when many would be better suited to categorization, and includes types of emerging toxicity traits for which there is a distinct lack of scientific consensus.

These concerns are exemplified by the inclusion of epigenetics as a recognized hazard trait. Epigenetics is a new field of toxicological analysis. As such, it has no reference database by which to judge any analysis, or historical controls for comparison. Furthermore, the definition in the pre-regulatory draft proposal is overly broad and would be better suited as part of a discussion of systemic toxicity, as opposed to an endpoint of itself. Finally, epigenetics as a toxicological field is not yet the subject of scientific consensus—resulting in OEHHA unilaterally establishing a new hazard trait that has not been accepted by the wider scientific community. We consider epigenetics to be one example of the many problems with the pre-regulatory draft's list of hazard traits.

Because we consider that the hazard traits proposed by OEHHA are inappropriate for analyzing the toxicity of a substance, we have instead chosen to discuss various hazard traits using the categories established in the October 1, 2009 "Straw Proposal" for the implementation of the GCI. The hazard categories listed in this proposal for the evaluation of chemicals of concern were: (1) acute toxicity, (2) eye irritation, (3) genetic toxicity and mutagenicity, (4) reproductive toxicity, (5) carcinogenicity, (6) endocrine disruption, (7) respiratory sensitization, (8) skin sensitization, (9) bioaccumulation, (10) acute aquatic toxicity, and (11) hazards to the ozone layer. As discussed above, in the course of its evaluation for a food-contact material, FDA requires the submission of a substantial amount of toxicological data to support the safe use of a product. We will compare the Straw Proposal's hazard traits to the data required by FDA to demonstrate that all significant hazard traits are regulated by FDA.

(1) Acute Toxicity, Eye Irritation, Skin Sensitization, Respiratory Sensitization

The acute exposure endpoints identified in the hazard criteria are not relevant endpoints for exposures from food packaging materials. Substances used in food-contact materials are generally of low acute toxicity and are trapped within a matrix (*e.g.*, a polymer, coating or paper) that prevents their migration and limits exposure to levels that are not relevant for acute exposures. While FDA requires the submission of acute toxicity data when available, the Agency generally is not concerned with acute, single-dose toxicity data and, rather, is more concerned with potential carcinogenicity effects or other endpoints from repeated-dose studies.

(2) Genetic Toxicity and Mutagenicity

FDA requires genetic toxicity and mutagenicity testing for any chemical substance with a potential dietary exposure above 0.5 ppb. In addition, if structural alerts suggest that a substance may have genetic or mutagenic attributes, FDA may request that additional data be provided. Any GRAS determination must consider these toxicological endpoints, as well. In the case of materials that do not migrate, there would be no exposure, although the level of analytical sensitivity needed to determine whether the "no migration" threshold would be lower than 50 ppb also is based on these genotoxicity concerns.[31] In our experience, if a substance is determined to be mutagenic or genotoxic in screening tests, FDA will require (a) data demonstrating whether these affects are likely to be observed *in vivo*, (b) a cancer bioassay to resolve whether the material is a carcinogen, or (c) proof that potential dietary exposure will be insignificant even if the material is later determined to be a carcinogen; generally, this would be at a level that would not exceed 50 parts per trillion, 0.05 ppb, in the diet.

(3) Reproductive Toxicity

FDA requires that reproductive and developmental toxicity data be submitted for substances when the dietary exposure may be significant for these toxicological endpoints. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for reproductive or developmental toxicity, the Agency may request additional data. As with genotoxicity data, any GRAS determination must consider these toxicological endpoints as well. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.[32]

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[31] The use of 50 ppb in this context is a concentration that could migrate from the package, not a level of dietary exposure. The resultant level of dietary exposure from food is determined by the consumption factor and would be at least an order of magnitude less, or even more in some cases.

[32] In a 1999 paper, Dr. Ian Munro and colleagues established a safety evaluation procedure for use by the Joint Food and Agricultural Organization/World Health Organization of the United Nations (FAO/WHO) for flavoring substances implementing a threshold of toxicological concern approach involving a number of toxicological endpoints.[32] The study authors concluded that "toxicity endpoints, such as developmental toxicity, neurotoxicity, and immunotoxicity demonstrate considerably higher human exposure thresholds than the threshold value [established using carcinogenicity data], making it highly unlikely that these non-cancer endpoints are a relevant concern in applying the threshold concept." *See also*, Kroes, R., Galli, C., Munro, I., Schiltwe, B., Tran, L.-A., Walker, R., and Würtzen, G. (2000) "Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A Practical Tool for Assessing the Need for Toxicity Testing," *Food and Chem Toxicol*; 38: 255-312. The Kroes

(continued ...)

(4) Carcinogenicity

The FFDCA prohibits the use of carcinogenic food additives, including substances used in food-contact materials that become components of food. Specifically, Section 409(c)(3)(A) of the Act (also known as the "Delaney Clause") states that no food additive shall be deemed by FDA to be safe if the additive is found "to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of safety of [the additive], to induce cancer in man or animal."[33] Thus, it is not possible to use a substance considered to be a carcinogen that would be a food additive when used in food-contact materials.

The Agency has established standards for the presence of any carcinogenic impurities that may be present in food-contact materials. The standard that FDA has established for these materials is known as the "constituents policy."[34] FDA sets an extremely strict standard for carcinogenic impurities. The Agency uses data from animal carcinogenicity studies, together with extrapolation procedures, to calculate the potential risk from the estimated daily exposure to the carcinogenic impurities as a result of the particular use. In order to determine that there is a reasonable certainty of no harm, FDA requires that the dietary exposure to a carcinogenic

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study reviewed an expanded databases to establish if additional toxicological endpoints were more sensitive than the carcinogenic endpoints of a variety of chemical substances. The report indicates that none of the specific non-cancer endpoints (*i.e.*, developmental toxicity, developmental neurotoxicity, and immunotoxicity) was more sensitive than cancer endpoints for the same substances. The results of a more recent analysis were published by Kroes and colleagues in 2004. The authors conclude that, based on their examination of metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific toxicological endpoints, including neurotoxicity, teratogenicity, developmental toxicity, and immunotoxicity, carcinogencicity is the most sensitive toxicological endpoint. *See* Kroes, R., Renwick, A.G., Cheeseman, M., Kleiner, J., Mangelsdorf, I., Piersma, A., Schilter, B., Schlatter, J., van Schothorst, F., Vos, J.G., and Würtzen, G. (2004) "Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet," *Food and Chem Toxicol*; 42: 65-83.

[33] FFDCA § 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A).

[34] 47 Fed. Reg. 14,464 (Apr. 2, 1982). Although this Advanced Notice of a Proposed Rulemaking was withdrawn by the agency in a November 26, 2004 Federal Register notice (69 Fed. Reg. 68,831, 68,831), the impetus of the withdrawal was administrative only, and FDA has since made clear that the constituents policy remains a valid means by which it evaluates minor carcinogenic impurities of food additives.

impurity must not exceed the calculated upper-bound lifetime risk from all sources of exposure and be lower than a risk of 1 in 1 million.[35]

(5) Endocrine Disruption

The proper assessment of the endocrine disrupting potential of a particular chemical is a topic of much current discussion. Whether the *in vitro* endocrine disrupting effect exhibited by a chemical at the extremely low doses of oral exposure associated with food packaging actually translates to an adverse physiological effect is in our opinion, at best, very controversial. Moreover, the health effects of chemicals acting through an endocrine mode of action should generally be captured by traditional toxicological tests, which are designed to detect adverse health effects acting through any means, including interaction with the endocrine system.

FDA and other bodies around the world that regulate food-contact materials are monitoring current scientific information on this subject. At this time, however, no regulatory body in the world that is responsible for food safety has established separate endocrine disruption data requirements for food-contact materials. Instead these regulatory bodies rely on information from reproductive, developmental and other well established, validated toxicology studies to understand the potential health effect of chemical regardless of their mode of action. While industry and government continue to monitor this issue, it is our opinion that there is not sufficient scientific information or agreement on the data at the present time to establish endocrine disruption as a regulatory criterion.

(6) Bioaccumulation

FDA considers the biopersistence and bioaccumulation of a proposed food-contact substance as part of its evaluation of food additive petitions and FCNs. If a substance is suspected of being bioaccumulative, the Agency requires further data on its absorption, distribution, metabolism and elimination to determine the potential bioaccumulation in the body. Any GRAS evaluation of a substance would also take this outcome into account. With regard to the other materials that may not be subject to FDA's review, the Agency considers that a daily exposure of 0.5 ppb in the diet is an insignificant addition to the diet from a cumulative exposure standpoint (except for carcinogens). If a substance is present at levels below 0.5 ppb, its bioaccumulation potential is considered to be insignificant.

(7) Acute Aquatic Toxicity and Hazards to the Ozone Layer

As stated above, FDA requires in its review of food-contact materials that the substance not have an adverse environmental impact during its manufacture, use, and disposal. In addition, the manufacture of food-contact materials—like any other consumer product—is subject to

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[35] *Id.* at 14,468.

federal, state, and local environmental laws that govern discharges to the air and water (*e.g.*, the laws administered by the California Air Board and Office of Environmental Health Hazard Assessment). Most importantly, because of their inert design there is not likely to be any exposure from a food-contact material that could have an effect on aquatic toxicity or the ozone layer at any level of concern. The possible levels of migration of a substance from a food-contact article are very low, generally in the part per million range or lower, and these toxicological endpoints are simply not relevant to packaging or other food-contact articles.

2. Regulation of Other Life Cycle Segments

As described above, the FFDCA regulates a significant portion of the life cycle segments of food packaging materials. As a result, there are only five remaining segments to which the FFDCA does not reach: materials and resource consumption; water conservation; production, in-use, and transportation energy inputs; energy efficiency; and economic impacts. We believe that food packaging materials are fully regulated during these life cycles by California regulatory programs, or are otherwise not subject to California jurisdiction.

The life cycle analyses contemplated in the SCPA are comprehensive; the consequence is that the regulation reaches many activities that take place outside California. While (for the sake of current argument) we do not take issue with California regulating resource consumption activities that take place in-state, we note that many of the activities contemplated as part of the life cycle analysis occur outside of California and are, thus, not subject to DTSC's jurisdiction. However, for purposes of these comments, we will assume that the full life cycle of a product occurs in California.

a. Resource Consumption

We have grouped two consumptive segments, "Materials and resource consumption" and "water conservation," in this category. These consumptive activities are covered by a variety of California regulatory programs. Specifically, materials and resources consumed in California are regulated by various California agencies, such as the Department of Conservation (mining and oil, gas, and geothermal energy management), the Department of Forestry and Fire Protection, the Natural Resources Agency (water, energy, minerals, coastal and marine life), and the California Environmental Protection Agency (air quality, soil quality, and waste recycling and reduction). Any impact on worker safety is regulated by the Division of Occupational Safety and Health in the Department of Industrial Relations. Collectively, California's agencies regulate all aspects of resource consumption that could potentially impact public health or the environment in California.

b. Energy Use

This category also groups together two segments, production, in-use, and transportation energy input, and energy efficiency. Similarly to resource conservation, energy use in California

is regulated by a plethora of agencies. Of note, the California Climate Action Team's[36] efforts to reduce energy emissions, the Energy Commission's energy efficiency programs, and California's Public Utilities Commission's energy efficiency programs combine to address the energy impacts of any industrial activities for food packaging in California.

c. Economic Impacts

Although all of the life cycle segments listed in the H&S code are vague to a certain extent, this segment is by far the most unclear. We consider the economic impacts of any public health or environmental threat are already encompassed within the prior segments.

The above discussion demonstrates that food-contact materials are regulated throughout all life cycle segments. DTSC should, therefore, exempt food-contact materials from the requirements of the SCPA.

B. The SCPA is Preempted by Federal Law

Although we believe that the regulation of food-contact materials is prohibited by the duplication provision of the Section 25257.1(c), there are also serious questions whether the SCPA would be preempted by Federal law. The Supremacy Clause of the Constitution of the United States grants to Congress the power to preempt state law. U.S. Const. art. VI, cl. 2. "[S]tate law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). The same is true of state law that conflicts with federal regulation. *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes."). Where the State does not completely exclude federally licensed commerce,[37] the test for preemption "is whether both regulations can be enforced without impairing the federal superintendence of the field."[38]

Of the three types of preemption (*i.e.*, express, conflict and "field" preemption), only two are relevant here—conflict preemption and field preemption. Conflict preemption exists if a private party's compliance with the state and federal laws is impossible, or the state or local law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California v. ARC America Corp.*, 490 U.S. 93, 100 (1989). *See also Dowhal v.*

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36 Composed of CalEPA, the Business, Transportation and Housing Agency, the Department of Food and Agriculture; the Resources Agency, the Air Resources Board; the Energy Commission; and the Public Utilities Commission.

37 "That no State may completely exclude federally licensed commerce is indisputable." *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963).

38 *Id.*

Smithkline Beecham Consumer Healthcare, 88 P.3d 1, 7 (Cal. 2004). If a conflict is found "a holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Florida Lime,* 373 U.S. at 142-43.

Field preemption exists "where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Fidelity Fed. Sav.,* 458 U.S. at 153. Similarly, the federal law or regulation "may touch 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." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

As detailed above, FDA has established a comprehensive regulatory framework for food-contact material. The scope of FDA's regulations leaves no room for the SCPA to regulate food-contact material. The SCPA unduly interferes with the well-established federal regulatory scheme and would likely be held preempted by a court.

Additionally, the proposed regulations contain a provision under which certain chemicals or products would be prohibited for use in California.[39] If any of the chemicals that would be prohibited have been approved by FDA for use in food-contact material, such prohibition would be preempted under principles of conflict preemption because in such a case, the SCPA would have banned a chemical that FDA previously had cleared for use in food-contact materials. When a federal and state law are in direct conflict, the state law must yield to the federal law. *ARC America Corp., supra.*

C. Non-Listing of Priority Chemicals Due to Regulatory Duplication

As noted above, food packaging materials are subject to a combination of federal and state programs that regulate these products throughout their life cycle, thus they should be wholly exempted from the requirements of the SCPA. However, if DTSC decides that food packaging materials should not receive a blanket exemption, many manufacturers instead are likely to avail themselves of the exemption provided in section 69302.1(a)(1), whereby a chemical that exhibits a hazard trait and would otherwise be a Chemical of Concern, may be exempted from SCPA's reporting requirements under the regulatory nonduplication exemption. Under this alternative, DTSC will need to review each individual chemical that exhibits a hazard trait to determine whether it is regulated throughout its life cycle. This would be a time- and resource-consuming effort if food packaging materials were the only products of concern, but they are not; there are likely to be thousands of exemption requests from chemicals used in all types of products.

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39 *See* SCPA § 69306.5(b).

Furthermore, as noted above, both the SCPA and GCI are unclear as to the "threats" that are to be addressed in the life cycle analysis to obtain this exemption. We consider that the only "threat" to be evaluated under this analysis is the hazard trait that caused the chemical to considered a Chemical of Concern. For example, if a substance is listed as a Chemical Under Consideration because it is a reproductive toxicant, it should be this trait (and this trait only) that should be evaluated under the life cycle analysis. It would unnecessarily expand the scope of the SCPA to require a full life cycle analysis for any and all potential threats, when it is not those threats that are considered to be the "hazard trait." Furthermore, several of these life cycle segments (energy use, resource consumption) are irrelevant to the determination of whether a chemical exhibits a hazard trait. We consider, therefore, that these life cycle segments (as discussed above in § I.A.2) are also irrelevant to the determination of whether a chemical is already fully regulated.

D. The Burden of Proof

To qualify for either of the exemptions in section 69302.1, the person requesting the exemption must demonstrate that the chemical meets the requirements "by clear and convincing evidence to the Department's satisfaction." With regard to the regulatory nonduplication exemption, the Department will review the existing regulatory programs with reference to a full life cycle analysis, and if "significant gaps" are identified in the regulatory programs, the DTSC may regulate the product through those segments. This section also contains a rebuttable presumption that the exemptions do not apply, unless otherwise proven.

DTSC has failed to provide a rationale for this high burden of proof. In its Initial Statement of Reasons (ISOR) accompanying the SCPA, DTSC simply states that this standard is necessary to show that the burden of proof for the exemptions is on the applicant. We do not take issue with DTSC placing the burden of proof on the applicant; however, we do not believe that the "clear and convincing" standard has any rational relationship to the requirements for the exemption. The determination of whether a chemical is fully regulated by existing federal or California programs is a factual inquiry—either the chemical is regulated or it is not. It is difficult, therefore, to understand why DTSC has imposed a legal evidentiary standard on a factual inquiry. Furthermore, the imposition of the clear and convincing standard goes beyond the authorizing legislation, and is not necessary. Indeed, GCI § 25257.1 provides a strong prohibition against regulatory duplication, which the "clear and convincing" standard would appear to contradict by placing a significant barrier before a chemical could be exempted from the SCPA. Thus, we believe that this evidentiary standard to obtain an exemption from the SCPA is inconsistent with the spirit of the authorizing legislation and is not necessary.[40]

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[40] *See* Gov. Code §§11349.1, 11349.3.

Finally, DTSC applies the "clear and convincing" standard inconsistently within the SCPA. The regulatory nonduplication exemption appears in its pertinent form four different times in the regulation.[41] In sections 69302.1 and 69303.1, both the regulatory nonduplication and exposure pathway exemptions are available, and the clear and convincing standard applies. In sections 69302.3 and 69303.3, however, only the regulatory nonduplication exemption is available, and there is no requirement that the nonduplication be shown by clear and convincing evidence. The SCPA is unclear, therefore, when the clear and convincing standard applies, and even if the standard itself is tied to the exposure pathway exemption only, rather than both exemptions.

E. Exposure Pathway and Regulatory Duplication

SCPA § 69302.2 requires DTSC to prepare two lists relating to the threats posed by a given chemical – a list of Chemicals under Consideration and a list of Priority Chemicals. As part of its preparation process, DTSC must identify the hazard trait(s) exhibited by the chemical, and the potential exposure pathways for each chemical. It is possible that DTSC could choose to list a chemical based on a hazard trait for which the exposure pathway is through the consumption of food packaged in a food-contact material. As discussed above, FDA thoroughly regulates food contact materials and their components thereof throughout the product's life cycle. Therefore, if DTSC listed a chemical in such a scenario, DTSC would be exceeding its authority in violation of Section 25257.1(c) of the California Health and Safety Code, which prohibits regulatory duplication.

F. *De Minimis*

The second exemption available for some SCPA requirements is the *de minimis* exemption.[42] "*De minimis*" is defined as "a concentration less than or equal to the lower of: (1) 0.1% by weight; or (2) the lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination." As it relates to food packaging materials, it is very unclear to what the 0.1% by weight threshold refers. This threshold could be interpreted to apply to the components of a finished food contact article, a chemical that comprises one ingredient of a component, or the amount of the chemical that could migrate from the finished food contact article into food. FDA considers this latter measurement most important from a health and safety perspective.

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[41] §§ 69302.1(a), 69302.3(h), 69303.1(a), 69303.3(h). There is also a regulatory nonduplication provision contained in § 69306.7(a), but this provision applies to a regulatory response required by DTSC, as opposed to the regulation of the product, itself.

[42] The application of the *de minimis* exemption is found in § 69305.3, although the definition of "*de minimis*" is found in § 69301.2(23) and (24)

Occasionally, FDA sets limits on the amount of a chemical that may be used in a finished product. For example, in 21 C.F.R. § 178.2010 ("Antioxidants and/or stabilizers for polymers"), FDA has set use limits for a commonly used antioxidant known as Irganox 1010.[43] FDA has determined that the use of Irganox 1010 at these levels is safe from both a public health and environmental perspective. It would be inappropriate, and potentially preemptive, for the SCPA to establish regulatory thresholds contrary to those established by FDA.

There are a number of other concerns with this exemption. First, the exemption is only available for Priority Products that contain a Priority Chemical at or below the *de minimis* threshold. The ISOR states that this provision is necessary "to allow DTSC and manufacturers to focus their resources on those Priority Products that pose the greatest threats to public health and the environment."[44] If this is the case, we question why the exemption should be limited solely to Priority Products. We believe that DTSC should also allow the exemption for Products Under Consideration. If a Priority Chemical is not going to present a threat to public health or the environment when used at *de minimis* levels in a Priority Product, it will present no greater threat when used at the same level in a Product Under Consideration. It would be logical to apply the *de minimis* exemption to both lists of products. Furthermore, it would permit some manufacturers respite from burdensome assessment and reporting requirements when their product is not expected to pose a threat to public health or the environment.

Second, the exemption has to be granted by DTSC, rather than allowing industry to make a self-determination. This will create a time- and resource-consuming administrative burden for DTSC for a factual enquiry that requires no regulatory assistance. Whether a Priority Chemical is present in a Priority Product at more than 0.1% is a matter of fact, not interpretation. Industry should, therefore, be permitted to take a self-determined *de minimis* position as to the composition of its products. It is unnecessary for DTSC to require industry to submit substantial amounts of costly paperwork for a substance that DTSC has acknowledged is used at a level that does not constitute a threat to public health or the environment.

Finally, the language of the definition itself is very vague. The *de minimis* level may be set at "The lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination." These thresholds "include, but are not limited to" seven different existing reference databases. When a list of potential sources is not limited in scope, it makes it difficult, if not impossible for industry to be on notice

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[43] Listed in 21 C.F.R. § 178.2010 as "Tetrakis [methylene(3,5-di-*tert*-butyl-4-hydroxyhydro-cinnamate)] methane (CAS Reg. No. 6683-19-8)."

[44] *See* Initial Statement of Reasons (ISOR), p. 76, ll. 27-29.

of the requirements with which it must comply, and by what standards DTSC will judge a *de minimis* level request.[45]

II. General Comments

The SCPA's stated objective is to "create a systemic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety."[46] While industry's paramount interest is the health and safety of the products that they produce, our members are concerned that the SCPA is extremely broad and goes well beyond what is necessary to implement the requirements of the GCI.

A. Scope of Information

We are concerned that the scope of information sought by DTSC is not within the ability of industry to provide. We consider this problem from two perspectives. The first concern is the sheer volume of information that DTSC proposes to require under the SCPA, and the second concern is the complexity of obtaining the necessary information from all participants in the supply chain for a product.

According to section 69301.6, DTSC may request a responsible entity to provide (1) chemical and product data, (2) information describing the types, categories, and classes of products that contain Priority Chemicals, (3) identification of intentionally-added chemicals and chemical ingredients, including quantities used in a product, (4) chemical and product market data, (5) analytical protocols, and (6) information on reformulation or redesign of a product. We are concerned that DTSC does not fully appreciate the difficulties involved with obtaining much of this information. To illustrate, using a hypothetical scenario: Company wishes to package its potato chips in Supplier's plastic bag. The plastic bag is a multi-layer film, comprised of three different layers, each bound together with an adhesive. Each layer is composed of a different type of plastic. Each plastic is formulated with a base resin, and a variety of processing aids and additives that give the plastic its technical properties. Each base resin is a formulated product manufactured with processing aids and additives. Furthermore, each adhesive is a formulated product. The compositions of the film layers and adhesives, the plastics, the base resins, the processing aids, and the additives are all trade secret information. Most of these substances are present in the finished packaging at extremely low levels, but the SCPA would require

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[45] *See Tidewater Marine Western, Inc. v. Bradshaw*, 14 Cal. 4th 557, 568-69 (1996) ("One purpose of the APA is to ensure that those persons or entities whom a regulation will affect have a voice in its creation, as well as notice of the law's requirements so that they can conform their conduct accordingly.) (internal citations omitted).

[46] *See* 45-Day Public Notice and Comment Period for Proposed Rulemaking, page 7.

responsible entities to obtain an enormous amount of data regardless of the level of the substance used or the potential exposure.

Moreover, obtaining the requested information will be a complex process of revealing business relationships and trade secret information. In many cases, due to intra-industry trading, this may even involve disclosure of trade secrets to a direct competitor. This will be an extensive burden for a responsible entity, without providing a commensurate benefit to public safety, considering that these materials have already been determined by FDA to be safe for their intended use.

B. Feasibility of the Regulation

We also are highly concerned that DTSC has given itself more responsibility than is feasible to manage. The SCPA requires a substantial number of evaluation, reports, and applications, all of which must be submitted to, and reviewed and evaluated by DTSC, with DTSC then providing, and enforcing, a regulatory response. Specifically, DTSC is required to undertake the following:

- Review and evaluate petitions to designate chemicals on one of the chemical/product lists
- Develop and update lists of
  - Chemicals of Concern
  - Chemicals Under Consideration
  - Priority Chemicals
  - Products Under Consideration
  - Priority Products
- Review, evaluate, and reevaluate requests for exemptions
  - Regulatory duplication
  - No exposure pathway
  - *De Minimis*
- Review, evaluate, and respond to the different types of AAs:
  - AA Work Plans
  - Tier I AA (review only)
  - Tier II AA
- Review and evaluate applications for AA accreditation
- Review and evaluate Chemical/Product Removal Intent/Confirmation Notifications
- Develop and enforce appropriate regulatory responses
- Review and evaluate claims of trade secret information and confidentiality

We note that these are only the "big ticket" items, and do not include other requirements, such as updating the DTSC website, drafting guidance documents, and consulting with small businesses. Based on this list, even if the SCPA were to apply only to food packaging materials,

it would require a legion of chemists and toxicologists to review, evaluate, and respond to the mountains of paper that DTSC will need to handle.

C. Scope of the regulation

If finalized in their current form, the regulations will impose heavy assessment and reporting burdens on industry that are beyond the authority established in the GCI. DTSC had previously indicated that the evaluation and reporting requirements of the alternatives assessments (AAs) would be imposed solely on Priority Products. In the SCPA, the scope of the AAs has been significantly expanded. For example, the designation of a chemical merely as a Chemical under Consideration may result in the need for expensive and time consuming AA. The SCPA requires a Tier I AA for products containing a Chemical under Consideration or Priority Chemical. This will be a substantial burden on industry because, given the number of factors that the Department may consider when compiling the list of Chemicals under Consideration, the amount of products containing a Chemical under Consideration is likely to be very large and, thus, AAs will be required for many products currently on the market in California. Of course, for those products designated as Priority Chemicals or Priority Products, the assessment and reporting burdens are significantly greater. If DTSC implements the SCPA as is, the practical result is likely to be the withdrawal of a substantial number of products from the California market as companies choose to withdraw from the market rather than undertake the costly AA requirements when these products have already been subject to review by FDA. For example, FDA has reviewed and evaluated almost 1000 FCNs, while the Agency's indirect food additive regulations clear the use of over 3000 substances.[47] These substances have already undergone an extremely time-consuming and expensive evaluation,[48] thus the prospect of repeating the process under the SCPA is likely to result in these products leaving the California market. This result is clearly not to the benefit of either industry or California consumers.

III. Section Specific Concerns

(1) § 69302.1

As an alternative to the life cycle exemption, manufacturers may wish to utilize the "no exposure pathway" exemption also present in SCPA § 69302.1(a). To obtain this exemption, there must be no exposure pathway by which a chemical may pose a public health or environmental threat during the useful life or the end of life management. However, the term "exposure pathway" is not defined in the regulation. It is possible for a chemical to be bound

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47 *See* http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=iaListing. This FDA database contains 3,237 records.

48 Before the FCN program went into effect, it was common for FDA to take several years to review a Food Additive Petition. Indeed, some product reviews went on for over 10 years.

up in a product so that there is no threat to public health or the environment during the product's useful life or at end-of-life; however, this enquiry is very product-specific.

(2) § 69302.3

This section provides the factors that DTSC may consider when determining whether to place a chemical on the list of Chemicals under Consideration. This section provides for over 100 factors ranging from chemical properties to public health impacts to existing data on exposure potential, without providing any indication or guidance as to which factors are weighed more heavily. DTSC should indicate the relative priority of these different factors.

(3) § 69303.2

Paragraph (a) requires that a product containing a Priority Chemical will be designated as either a Product under Consideration, or a Priority Product. Logically, there should be one set of factors that would lead to this determination. However, this paragraph presupposes that a chemical will be designated under either of these categories by evaluating whether a product would be a Product under Consideration or a Priority Product under the factors specific to those designations.

(4) § 69305.4

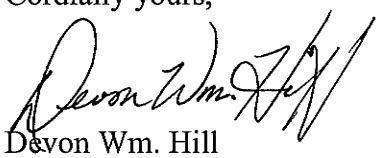
Paragraph (a)(3) requires, for a Tier II AA Work Plan, the submission of information on the supply chain for a product, including "any other person in the supply chain for the product." This requirement is very vague, as it could be read to mean any person who has supplied a component of a product, and their ingredient suppliers, and so on. This information would be very time consuming to obtain, so DTSC should clarify what it means by "any person."

IV. Conclusion

Food packaging is important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products to reduce food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food-contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI. In the opinion of our members, a separate duplicative regulate scheme would inhibit technological innovation and development that is important to ensure the safety of food and provide consumers with even safer and more environmentally friendly food packaging materials. Thus, the further regulation of food-contact materials under the GCI is prohibited by Section 25257.1(c) of the Health and Safety Code.

For the reasons set forth above, we respectfully request that the DTSC exclude food-contact materials and substances used as components of food-contact materials from the scope of any regulations promulgated to implement the GCI.

Cordially yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

cc: The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
Scott Reid, Cabinet Secretary, Office of the Governor
John Moffatt, Legislative Affairs, Office of the Governor
Maziar Movassaghi, Acting Director, DTSC
Jeff Wong, Chief Scientist, DTSC
Odette Madriago, Chief Deputy, DTSC
Hank Dempsey, Special Advisor, DTSC

Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

American Chemistry Council

American Cleaning Institute

American Forest & Paper Association

California Chamber of Commerce

California League of Food Processors

California Manufacturers & Technology Association

California Paint Council

California Restaurant Association

California Retailers Association

Can Manufacturers Institute

Chemical Industry Council of California

Citizens for Fire Safety Institute

Consumer Healthcare Products Association

Consumer Specialty Products Association

Grocery Manufacturers Association

Independent Lubricant Manufacturers Association

Industrial Environmental Association

Metal Finishing Associations of Northern and Southern CA

National Paint and Coatings Association

Natural Products Association

Personal Care Products Council

Plumbing Manufacturers International

TechAmerica

Toy Industry Association

Western Plant Health Association

Western States Petroleum Association

# # #

April 25, 2013

Ms. Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

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

Dear Ms. Buttle:

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

GCA appreciates DTSC's ongoing efforts to develop a regulatory system that attempts to fulfill the legislative objectives as well as the Director's stated goals of being meaningful, practical, and legally defensible. We have long supported these regulatory and programmatic goals and we appreciate the most recent changes which we deem important improvements to the revised proposed regulation.

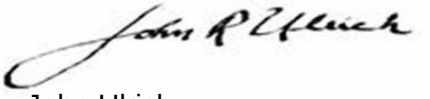
While GCA members view the latest revisions as positive and responsive to a number of important industry concerns and comments, there remain several nagging provisions in the revised proposed regulation which we continue to view as seriously problematic and in direct conflict with the spirit and intent of the enabling legislation and its grant of authority. Specifically, GCA continues its strong objection to the proposed regulation's treatment of that which constitutes exemption from duplicative and conflicting regulations. In the proposed regulation, DTSC has reserved for itself a level of authority not envisioned by the enabling legislation and if enacted, would threaten the legitimacy of the entire regulation.

Additionally, those provisions which GCA believes fail to adequately protect trade secrets and other confidential business information strike at the very core of innovation. The regulated community is willing to share the full range of confidential information with the state's regulatory authorities to enable them to exercise their responsibilities under the SCP regulations but to dictate that said information be systematically shared with the public and the global market place is unnecessary, inappropriate, and threatens serious damage to the core of California's economy. The Green Chemistry Alliance has repeatedly and consistently commented on these very important issues (See also Appendix II)

Notwithstanding the widely divergent views of the Department and the regulated community regarding the aforementioned issues, the revisions proposed by the Department are positive steps toward making the regulation workable (See Appendix I).

We appreciate the Department's willingness to consider and respond to these aspects of our previous comments. For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. You may also visit GCA's website www.greenchemistryalliance.org.

Sincerely,



John Ulrich
Co-Chair
Chemical Industry Council of California

Dawn Koepke
Co-Chair
McHugh, Koepke & Associates

Attachment

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

Appendix I

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

Green Chemistry Alliance Key Issues – General Support

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

- **§ 69501.1 Definitions**

  (53) "*Priority Product*" – the revision further clarifies that it refers to the product-chemical combination. This is important to help avoid an inappropriate designation for a product from the same category that does not utilize the candidate chemical as an ingredient. It also helps to minimize the potential for a regulatory treadmill, i.e., when a chemical of concern is successfully replaced the product is no longer a priority.

  (57) "*Reliable Information*" – is a critical component to the operation of the proposed regulation, and 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. The changes to the current definition would shift the criteria for evaluating such information to be somewhat more broadly applicable to any information considered in the Chemical-Product Prioritization, and additionally prescribe that such information is to be a "scientific study or other scientific information."

  While we regard these changes as generally positive, they continue to fall short of instituting a full "weight of the evidence" determination in the application of such information. The standard of merely relying on "other scientific information" without being obligated to consider the weight of scientific evidence still leaves open the possibility of decisions being founded upon conclusions that would be undermined if a full consideration of available science were conducted. The prioritization and selection decisions associated with these regulations are incredibly important, with the potential for major economic and other impacts upon Californians. The Department should ensure that the best scientific judgment of the state is brought to bear, and that dictates consideration of the full range of available information. 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 scientists, rather than allowing decision making through a politicized policy process. If DTSC fails to exercise measured judgment in evaluating current science, it will have effectively abdicated on that responsibility.

- **§ 69502.2 Candidate Chemicals Identification**

  The Department's decision to recast the larger universe of chemicals under consideration for prioritization to designate them as "candidate chemicals" was a major step in the January draft toward a more rational approach to these laws. We take note of the changes to the process of adding additional "Candidate Chemicals" beyond the initial listing. In particular, we consider as positive the addition of a specific requirement to

consider “Availability of Information” and the various considerations regarding the scientific rigor.

While we appreciate these nuanced changes, we believe they should also be mandated for consideration chemicals from the initial lists prescribed under these regulations. As noted in our February 28, 2013 comments, we continue to question the inclusion of certain lists in this process, noting that some of the lists itemized do not seem to meet the criteria that would be applied to the addition of subsequent “lists”. It would therefore be appropriate to extend these criteria for scientific rigor to any chemical identified as a candidate chemical, regardless of its origin, including those selected from the initial “list of lists.”

- **§ 69503.2 Product-Chemical Identification & Prioritization Factors**

  We appreciate the Department’s decision in this draft to explicitly frame this prioritization as applying to particular “product-chemical combinations.” This reflects the practical implication of the changes made to the process in the January draft, which we support. As with the process for identifying Candidate Chemicals mentioned above, we view as positive the express inclusion of the considerations of scientific rigor in prioritizing Chemical-Product combinations under the regulations. We note some concern within the business community that these standards may be intended to negate inclusion of non-published information from industry. It is our expectation, however, that the State’s scientists will be in a position to judge the scientific merit of such information per these regulations.

- **§ 69503.5(c) Priority Products List, Alternatives Analysis Threshold**

  GCA greatly appreciates the change allowing the Department to determine an alternatives analysis threshold different from the PQL for either an intentionally-added or a contaminant chemical of concern. Unquestionably, this is the most significant and important change made in this draft from the business community’s perspective. There are numerous approaches used by federal and California agencies that we have suggested previously on which DTSC can pattern its scientific methodology. As DTSC personnel have repeatedly suggested, during the APA notice and comment process for proposed priority products, stakeholders can provide scientific information to support a “Safety Case” for acceptable concentration levels of the chemical below a threshold which the Department can use in establishing an appropriate, science based concentration.

  Prior to this revision, we were very concerned about the Department’s refusal to consider establishing reasonable *de minimis* standards, and the impact this would have in rendering the regulation far less predictable. It is our belief that it will often be the case that an appropriate threshold level exists above the level of detection. Enabling a stakeholder to make the scientific case for such recognizes that the State’s scientists are able to make judgments based upon the scientific merit, which is consistent with the spirit of the enacting legislation (AB 1879, 2008; SB 509, 2008). While this does little to provide predictability to the extent a more general *de minimis* standard would, it at least has the potential to render the process far more rational, manageable, and science-based.

  The proposed threshold methodology raises the question of how the Department will deal with different manufacturers of the same product-chemical combination providing submittals that may document differing thresholds. This situation is likely to arise, given that this consideration will be evolving around the limits of detection and therefore at our technological and scientific understanding. The Department must find ways of avoiding

the appearance of arbitrary decisions under these laws, and would therefore be well-advised to address specifically its intent in such circumstances.

- **§ 69505.1 & 69505.8 Alternatives Analysis (AA) & Public Comments on AA Reports**

  Another significant improvement in the latest revision is the practicality in the process for public comment on the Final AA Reports, and DTSC's responsibility to collect, review, respond, and determine whether an AA Addendum is needed.

  The January draft introduced the notion of public comment on various stages of the alternatives analysis and placed the duty on the Responsible Entity to respond to each comment. GCA expressed concern that such a process would be cumbersome and costly and would have the potential to mire the entire process, while contributing little of the end result. The revised proposal provides a more rational process placing the state's scientists and regulators in a more appropriately responsible role in implementing the regulation, and better-enables protection of confidential information during the development of the AA.

- **§ 69506.7 End of Life Management Program**

  GCA also wishes to favorably acknowledge and support the revised language in this section which provides a manufacturer with flexibility when a regulatory response calls for an end of life management program. Specifically we support the Department's proposal to delete certain program mandates and replace said language with new, more flexible language stating, "*If a manufacturer's alternative end-of-life management program relies on other persons, the manufacturer shall provide written substantiation of their agreement to participate at a level* necessary to insure successful implementation of the plan as proposed."

# # # #

Appendix II

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

Green Chemistry Alliance - Select Issues of Concern

- **§ 69502.2(a)(1)(C) Endocrine Disruptors**

  Subparagraph (C) as revised states "Chemicals included as Category 1 endocrine disruptors by the European Commission in the candidate list of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006" (*i.e.,* REACh). The revision to (C) indicates that there are "Category 1" endocrine disruptors in the SVHC Candidate list.

  GCA wishes to point out that there is no process under SVHC categorization or in any other part of the REACh regulation for categorization of endocrine disrupting chemicals. As such the reference to "Category 1 endocrine disruptors" should be eliminated from the SCP regulations. However, Article 57f of the REACh regulation does identify chemicals as "Equivalent level of concern having probable serious effects to human health or the environment under Article 57f." NOT all of the 16 chemicals and Groups that are Candidates under the Article 57f rationale are based on their potential for endocrine disruption. The Department should take care to understand the finer distinctions in the REACh regulation.

- **§§ 69503.2(b)(2) Other Regulatory Programs**

  GCA remains concerned that the standard the Department proposes to justify deference to other regulatory programs is seriously flawed and could allow the Department's interpretation to intrude into whole programs administered by other departments. As enacted, there are two distinct considerations in statute relating to exemption on grounds of duplicative and conflicting regulations, namely the 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 the proposed Safer Consumer Products regulation would conflict.

  However, the exemption standard cited by the Department in its proposed regulation responds to only the second of the two statutory considerations noted above. Section 69503.2(b)(2) states, *". . . 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."*

  GCA continues its strong objection to the proposed regulation's treatment of that which constitutes exemption from duplicative and conflicting regulations. In the proposed regulation, DTSC has reserved for itself a level of authority not envisioned by the enabling legislation and if enacted, would threaten the legitimacy of the entire regulation.

- **§ 69509(f) and (g) Assertion of a Claim of Trade Secret Protection**

  We remain concerned that the decision to restrict trade secret protection only to patented materials is short-sighted and at odds with California's long-established practices as well as norms of intellectual property protection. 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 to the market (that is the role of patents). In many, perhaps most, cases involving chemical formulations and processes, benefits derive from maintaining the competitive advantage of a unique formulation or process and the choice is to protect the innovation via other CBI routes. Unfortunately, this option would be eliminated under this revision, seriously compromising its compatibility with genuine innovation in chemical development and application.

  More specifically, the revision in this section further limits the conditions for claiming chemical identity a trade secret. GCA is highly concerned that chemical identity is often a core trade secret for a product in situations where the chemical is critical to product performance, quality, safety and cost and is rarely, if ever, patented. The state, federal and international approach in these cases is to claim the chemical identity as a trade secret, but to disclose a descriptive generic name that is appropriate for public use.

  California's remaining claim to economic greatness is very heavily invested in research and development and capitalizing on the extraordinary scientific and intellectual heritage of our unparalleled system of higher education. Ironically, GCA and its member industries have absolutely no problem sharing the full range of confidential information with the state's regulatory authorities to enable them to exercise their responsibilities under the SCP regulations. However, to dictate that said information be systematically shared with the public and the global market place is unnecessary and threatens serious damage to the core of California's economy.

# # # #

Appendix III

Green Chemistry Alliance Comments Incorporated by Reference

GCA Comments on Revised Proposed SCP regulation Feb. 28, 2013
http://www.cicc.org/pdf/SCP-Reg-Revision-GCA_Ltr_Final02-28-13.pdf

GCA comments on Proposed SCP regulation Oct. 11, 2012
http://greenchemistryalliance.org/Media/SCP%20Regulation%20GCA%20Ltr%20Final%2010-11-12%20copy.pdf

GCA comments on SCP informal draft Jan. 13, 2012
http://greenchemistryalliance.org/Media/GCA%20SCP%20Draft%20Reg%20Comment%20Ltr%20%201-13-12-Final.pdf

Comment letter on revisions to SCPA Dec. 3, 2010
http://greenchemistryalliance.org/Media/DTSC_SCPA_Revisions_GCAcomment_20101303.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4lJ1

Comment letter to DTSC Nov. 1, 2010
http://greenchemistryalliance.org/Media/GCA_Comments_re_EPC_Evaluation_of_proposed_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4lJ1

Comments to CEPC on need for EIR on regulations October 26, 2010
http://greenchemistryalliance.org/Media/GCA_Comments_re_EPC_Evaluation_of_proposed_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4lJ1

Comment letter to DTSC July 22, 2010
http://greenchemistryalliance.org/Media/GCA-Comment-Ltr7-22-10-Final.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4lJ1

Comments - Safer Alternatives Regulations May 27, 2010
http://greenchemistryalliance.org/Media/FinalGCAComments-SaferAlternativesRegs05.27.10.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4lJ1

# # # #

April 25, 2013

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

Re: Comments on 15-day Revisions to Proposed Regulations - Safer Consumer Products

Based in Washington, D.C., the Grocery Manufacturers Association (GMA)[1] is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

GMA appreciates the opportunity to submit the following comments in response to DTSC's April 2013 15-Day Revisions to the Proposed Regulations for Safer Consumer Products. We recognize the DTSC staff efforts that have gone into these revisions. In particular, we appreciate and strongly support Director Raphael's ongoing direction to make the Safer Consumer Products regulation practical, meaningful and legally defensible. Applying and balancing these concepts can be a pathway to achieving the Green Chemistry Initiative's objectives.

GMA has filed substantial comments to all previous iterations of the regulations, including detailed comments on the January 2013 Post Hearing Changes, which we incorporate here by reference. (For a copy of all previous comments, please see: http://www.gmaonline.org/issues-policy/product-safety/chemicals-management/green-chemistry/state-comments/).

[1] GMA represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of 48 chief executive officers from the Association's member companies. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over $1 trillion in added value to the nation's economy.

REVISIONS. The revised proposal includes only a few substantive changes. There are several improvements that GMA supports:

- **§69501.1 (a)(53).** The revision further clarifies that a Priority Product means a product-chemical combination. This is important in helping to avoid an inappropriate designation for a product from the same category that does not utilize the candidate chemical as an ingredient. It also helps to minimize the potential for a regulatory treadmill – when the chemical of concern is successfully replaced, the product is no longer a priority. **GMA recommends that DTSC finalize the regulation with this change intact.**

- **§69503.5 (c).** For AA Threshold, the revision adds an option, but not a requirement, for the department to specify a threshold for both intentional ingredients and contaminants. GMA warmly welcomes this change versus the automatic and untenable use of a PQL for contaminants and any level of an intentional ingredient. It is completely appropriate for the Department to set safe levels of exposure for product-chemical combinations. There are numerous approaches used by federal and California agencies that have been identified in previous GMA comments on which DTSC can pattern its scientific methodology. As DTSC personnel have repeatedly suggested, during the APA notice and comment process for proposed priority products, stakeholders can provide scientific information to support a "Safety Case" for acceptable concentration levels of the chemical below a threshold which the Department can use in establishing an appropriate, science based concentration. **GMA would prefer that the Department be required to set the AA Threshold for every product-chemical combination and recommends that "may" be changed to "shall" in this section of the finalized regulation. However, the proposed Department option in the revised approach is significantly better than the approach proposed in the January update.**

- **§69505.8.** The revision also changes the process for public comment on Alternative Analysis (AA). Under the revision, Public Comments would be sought on a Final AA, after which DTSC would review the comments and identify any that need to be addressed by the Responsible Entity (RE) in an AA Addendum. While this adds an additional step to an already cumbersome and overwhelming AA process, it is an improvement over the previous requirement that the RE to respond to all Public Comments provided on the Preliminary AA. In addition, this approach is a significant improvement over the Certified Assessor concept that was eliminated in the January update. **GMA recommends that DTSC finalize the regulation with this change intact.**

The revised proposal contains several changes that raise concerns for GMA:

- **§69505.5 (c).** The step of Identifying Relevant Factors for examination in the AA process has been accelerated into the Preliminary AA. While GMA strongly supports the inclusion of the Relevant Factor step in an AA, we are concerned that the Preliminary AA timeline is already much shorter than is appropriate. Under revisions made in the January 2013 update, extensions for the Preliminary AA Report were eliminated. Including this additional requirement into the already challenging 180-day timeline increases the likelihood that Responsible Entities will not be able to timely comply with

the Preliminary AA requirement. **GMA recommends that the Relevant Factor requirement be returned to the Final AA Report; however, if DTSC is determined that it is essential for the First Stage, the option of an extension for the Preliminary AA must be restored.**

- **§69509 (f) and (g).** The revision further limits the conditions for claiming chemical identity a trade secret. GMA has repeatedly raised strenuous concerns on the Trade Secret section related to the protection of Chemical Identity. The proposal allowing a claim if a patent is applied for, makes clear that there is little appreciation for the distinction between trade secrets and patents, and violates California's trade secret law. Chemical identity is often is a core trade secret for a product in situations where the chemical is critical to product performance, quality, safety and cost and is rarely if ever patented. The state, federal and international approach in these cases is to claim the chemical identity as a trade secret, but to disclose a descriptive generic name would is completely adequate for public use. **GMA recommends that chemical identity always be claimable as trade secret, particularly in this case where the claim will be related to the identification and development of alternatives for a priority product.**

- **§69501.1 (a)(57).** After making some improvements in the definition for "Reliable Information" in the January update by adding a list of criteria for the quality of information that would be viewed as 'trustworthy', those changes have been downgraded in the April revisions by removing them from the Reliable Information definition and placing them in two specific sections of the current proposal (Additions to Candidate Chemical List; Product Chemical Identification and Prioritization). The previous positioning within the Reliable Information definition made the important concept of information quality operative across the entire Regulation, for all Department, Responsible Entity and other Stakeholder actions and decisions. It also better conformed this California regulation to federal and international chemical regulations where reliability and quality of information is an integrated concept. The new positioning creates several concerns. First, it establishes reliable information as *de facto* that which emanates from several sources independent of the quality of that information. Second, it limits the applicability of information quality criteria to only two areas of DTSC consideration. This suggests that DTSC, Responsible Entity and/or Stakeholders need not consider information quality in their actions and decisions on any other Section of the regulations — a position that seems completely out of step in a science-based regulation. GMA reiterates that even the previous improved Reliable Information definition in the January update did not go far enough to address the absence of emphasis on weight of evidence evaluation. Not utilizing a weight of evidence approach violates standard scientific protocols used in other California, US and International regulatory programs and will preclude the potential for California Green Chemistry's program from building a reputation as a meaningful, science-based program. **GMA recommends that the data quality criteria be restored to the definition of Reliable Information and that all evaluations under the regulations be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.**
- **§69501.1 (a)(57).** While changes were made in this section, a repeatedly raised but not addressed concern is that there is an absence of emphasis on a weight-of-evidence evaluation of information and on ensuring decisions by DTSC and other stakeholders are

driven by conclusions from the most relevant and highest quality studies. This issue could be addressed by adding the following points into this section of the regulations or into the Final Statement Of Reasons:

> *In evaluating information to make decisions and substantiate conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts", DTSC, responsible entities and stakeholders should be guided by the following principles:*
>
> - *All evaluations – determining candidate chemicals, petitions, priority products, AA thresholds, alternative analysis, and regulatory responses – must rely on the best available scientific information regarding possible adverse impacts and exposures of substances, and employ consistent, objective methods and models to derive realistic determinations of adverse impacts at environmentally relevant levels of exposure.*
> - *Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.*
> - *All evaluations must be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.*

- **§ 69502.2 (a)(1).** In revisions to the citations for the SCP candidate chemical list sources in this section, items (B), (C), (G) and (I) are cited as being classified "by the European Commission" or included as Substances of Very High Concern (SVHC) Candidates "by the European Commission". While these processes are conducted under European Union laws, both Classification and SVHC approaches are conducted by the European Chemicals Agency (ECHA), which works together with Member States, but has ultimate responsibility for both regulations. The proper citation would be "…by the European Chemicals Agency (ECHA)". In addition, the revision to (C) indicates that there are "Category 1" endocrine disruptors in the SVHC Candidate list. The SVHC process has no "Category" designation and the term "Category 1" should be dropped. The official Reach terminology for these listings is "Equivalent level of concern having probable serious effects to human health or the environment under Article 57f." There are presently 16 chemicals and Groups that are Candidates under this rationale, some, but not all, of which are based on potential endocrine disruption.

OVERALL REGULATION. Beyond the above noted revisions, the currently proposed regulation makes and affirms a number of strategic choices that will help in creating a program to improve public health and the environment for all Californians:

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

progress on in the initial years of the program, while sending an important signal to the marketplace. GMA encourages DTSC to continue to use a similar approach, considering hazard and exposure for focus Candidate Chemicals beyond 2016.

- DTSC continues to indicate that in the first round it will select up to 5 Priority Products – product-chemical combinations. GMA has advocated and supports this approach to enable focused learning and building on success in the initial stages of implementation.
- The proposal would also require the listing of Priority Products to be established and updated through APA rulemaking. This provides a more formal framework for these decisions, and is welcomed; however, this benefit is undermined by relaxed standards for Priority Product decision-making (addressed in more detail below).
- DTSC's approach to the alternatives analysis (AA) process continues to expect companies to conduct the Alternative Analysis, reaching their own decisions on any product changes and preserves other improvements that were noted in GMA comments on the July and January proposals. In particular, the clarification in the January update that an AA should be focused on the CoC and potential replacement chemicals (rather than all ingredients in the product) is an appropriate and very positive improvement.

In GMA comments on the July 2012 Proposed Regulation and the January 2013 updated proposal, a number of serious concerns were raised that have not been addressed and that we continue to believe will prevent the overall program from being a deliberate science-based effort, focused on real improvements in the safety of consumer products. Despite the noted improvements, some changes raise additional troublesome concerns and, where changes were made, they frequently do not go far enough to address the previously raised concerns. Some aspects of the updated proposal will not only be impractical and unworkable, but could result in arbitrary decisions and may stifle innovation. The regulations will impose unnecessary costs and administrative burdens on companies doing business in California and will require a large DTSC staff to manage the paperwork and process, even when the number of priority products is limited. The net result is that the regulation establishes the basis for a potentially arbitrary and precautionary approach that will not improve public health and the environment. The following continue to be issues of major concern to GMA:

- GMA has repeatedly raised concerns about the non-quantitative product-chemical prioritization process, a so-called 'narrative process', which is not a suitable standard for identifying high priorities that can make meaningful improvements to public health and the environment in California. Several changes have weakened the process to the point where virtually any ingredient in any product could arguably be selected as the product-chemical combination. Those changes included definitional changes making "adverse impacts" equivalent to "adverse effects"; an increased emphasis on "presence" as an exposure criterion; the shift from the term "ability" to cause effects to "potential" to cause effects; and the elimination of the following language in the "Key Principles" that had been in every previous regulation draft: "…potential for exposure in quantities that would contribute to or cause adverse impacts…" Taken together, these changes create a completely unpredictable regulatory process with no certainty for businesses in California.
- GMA appreciates the insertion of the statutory language that prohibits DTSC from superseding other state and federal regulation. However, the Department continues to maintain complete discretion to determine whether its regulation "would provide equivalent or greater protection".

- GMA is extremely concerned about the elimination of the exemption for products in the supply chain of statutorily exempted products. DTSC does not have authority to regulate the supply chain of exempted products and such action would supersede the regulatory scope of other agencies, which is prohibited by the statute.
- GMA strongly objects to the proposed regulations because they would impose on businesses that import their products into California significant burdens, which vastly outweigh any purported legitimate benefit. California lacks the legal authority to set the "rules of the game" governing the interstate and international market for consumer goods sold in California in a manner designed solely to benefit California economic interests.
- GMA continues to have critical workability and trade secret concerns in the AA section: timelines are too short; the absence of focus on consumer acceptance; limited economic feasibility criteria; the requirement on external economic impact analysis; and the requirement to disclose trade secrets on operating margin, chemical identity and retail sales outlets demand for clearly proprietary information that go beyond DTSC's statutory authority.

California deserves a credible, workable, and successful program that can achieve this part of the Green Chemistry Initiative's objectives, and complement the other five planks of the Initiative. GMA strongly supports the noted improvements in the revised regulations but still has many significant concerns. As proposed, the regulations currently do not achieve the balance of being practical, meaningful and legally defensible which will make implementation more difficult. GMA is a member of the Green Chemistry Alliance (GCA) and supports the Alliance's forthcoming detailed comments. In addition, GMA is a member of the Food Packaging Coalition (FPC) and supports the Coalition's comments.

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

Sincerely,

John Hewitt
Director, State Affairs
Grocery Manufacturers Association
1215 K Street, Suite 1700
Sacramento, CA 95814
916-508-6278

cc The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA

Debbie Raphael, Director, DTSC
Odette Madriago, Chief Deputy Director, DTSC
Jeff Wong, Deputy Director Science, Pollution Prevention & Technology, DTSC
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor

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April 25, 2013

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

RE: COMMENTS ON SAFER CONSUMER PRODUCT PROPOSED REGULATIONS

Dear Director Raphael:

James Wilie
Environmental Program Manager
T 916-785-2981
F 916-231-1346
james.wilie@hp.com

Thank you for the opportunity to review and comment on the California Department of Toxic Substances Control's (Department or DTSC) April 2013 proposed Safer Consumer Products (SCP) regulations (Proposed Regulations). HP has been actively engaged throughout this process and submitted comments on prior versions of these Proposed Regulations. Although there are comments HP has submitted that have not been incorporated or addressed that HP believes would improve these Regulations, our comments below and in the appended attachments focus on the most recent changes made by DTSC to the current version of the Proposed Regulations.

Hewlett-Packard (HP) strongly supports the changes in Article 5 to make the Alternatives Analysis more practical so that the regulated community can better meet the requirements. These changes also should allow the analyses to focus on the most important factors and enable the use of more standard environmental tools. Positive changes include:

- Modification of the First Stage AA to allow the analysis to focus on relevant factors;
- Modification of the Second Stage AA to eliminate duplicating analyses already conducted in the First Stage AA; and
- DTSC facilitation of public comment review on Final and Abridged AA Reports by determining which comments and issues need to be addressed in an AA Report Addendum.

In addition to these changes in Article 5, HP also supports the addition of the provision for DTSC to be able to set an Alternatives Analysis Threshold under Section 69503.5(c). HP has provided other additional comments in support of specific changes made in the Proposed Regulations in the attachments.

The most critical areas in need of adjustment in the Proposed Regulations are listed below. HP recommends the following:

- Remove "repair, refurbish, maintain, or make non-material alterations" from the definition of "Assemble".
- Establish relevant factors for the Second Stage AA at the end of the First Stage AA and include as part of the work plan. Note this change may require moving Section 69505.6(a) to 69505.5(f).

We have also prepared a list of detailed comments to the Proposed Regulations that are in the attachments.

HP appreciates the opportunity to comment on the Proposed Regulations and look forward to continuing our work with the Department in creating a balanced regulation that meets the goals of AB1879.

Regards,

James Wilie
Hewlett-Packard
Environmental Program Manager

Cc: Jennifer Morris, HP
Helen Holder, HP
Barbara Hanley, HP
Jon Dickinson, HP

Attachments

ATTACHMENT 1
ARTICLE 1

Article 1 - General			
Section	**Title**	**Comment**	**Proposed Text**
§ 69501.1(a)(12)	Alternatives Analysis Threshold	HP supports the changes to this definition and the addition of a provision for DTSC to be able to set an Alternatives Analysis Threshold under section 69503.5(c).	
§ 69501.1(a)(15)	Assemble	This definition adds “repair and refurbishment” to the scope of “assembler.” While this will serve to create additional potentially responsible entities, we are concerned with covering refurbishment of products that were potentially not in scope when they were manufactured. Entities that repair, refurbish, and maintain certain products, such as electronics, are not able to specify or control substances within those products. If repair and maintenance are brought within the scope of the regulation, entities performing those services will have no choice but to stop repairing, refurbishing, or maintaining the products of interest. Creating barriers to the refurbishment and reuse of products, such as electronics, could lead to even more Priority Products entering the waste stream if serviceable products are not maintained through their entire service life because the entities that perform this valuable function could not comply with the requirements. HP suggests removing “repair, refurbish, maintain, or make non-material alterations” from the definition of “Assemble”.	"Assemble" means to fit, join, put, or otherwise bring together components to creat a consumer product.
§ 69501.1(a)(59)	Replacement Candidate Chemical	HP appreciates the clarification of the definition of "Replacement Candidate Chemical" regarding cases where the increase of an existing component in a formulation could be considered a replacement chemical.	
§ 69501.5(a)(3)	Exemption determinations and recissions	HP supports posting decisions on exemptions per§ 69501(b)(3).	
§ 69501.5(b)(7)	Public comment facilitated by DTSC	See comment for § 69505.8.	

ATTACHMENT 2
ARTICLE 3

Article 3 -- Process for Identifying and Prioritizing Product-Chemical Combinations			
Section	**Title**	**Comment**	**Proposed Text**
§ 69503.5. (c)	Alternatives Analysis Threshold	See comment for § 69501.1(a)(12).	

ATTACHMENT 3
ARTICLE 5

Article 5 -- Alternatives Analysis			
Section	**Title**	**Comment**	**Proposed Text**
§ 69505.1. (d)(2)	Public Comments on Stage 1 AA	See comment for § 69505.8.	
§ 69505.2. (a)(2)	Draft Abridged AA Report	HP supports the elimination of draft Abridged AA Reports. Since Abridged AA Reports are only done if there is no functional or technically feasible alternative, and must be submitted in lieu of a Preliminary Report, there is no need for draft Abridged AA Reports.	
§ 69505.4. (b)(2)	Abridged AA - Factors	HP supports eliminating the requirement to identify relevant factors for Abridged AA Reports because Abridged AA Reports are only prepared if there is no functionally acceptable and technically feasible alternative. In these circumstances, since the alternatives have not been eliminated based on environmental or human health criteria, there is no need to complete this analysis for non-viable alternatives.	
§ 69505.5. (c)(1)(A)	Scope of Stage 1 Analysis	HP strongly supports the modification to the First Stage AA to allow the analysis to focus on relevant factors.	
§ 69505.6. (a)(1)	Relevant factors for Second Stage	HP strongly supports this modification to the Second Stage AA that eliminates duplicating analyses conducted in the First Stage AA. HP also support the focus on Life Cycle in the Second Stage. Both of these changes should make it easier to comply with the requirements and to use standard tools for analysis.	
§ 69505.6. (a)(1)	Exposure in Stage 2 AA	HP supports this change combining the exposure pathway determinations that were in Sections 69505.6(a)(1) and 69505.6(a)(3) into the First Stage in Section 96505.5(c) as a part of determining relevance.	

ATTACHMENT 3
ARTICLE 5

Article 5 -- Alternatives Analysis			
Section	**Title**	**Comment**	**Proposed Text**
§ 69505.6. (b)	Comparison of Priority Products and Alternatives	HP supports narrowing the comparison to relevant factors as determined in the First and Second Stage. This change will greatly reduce the amount of analysis required, and also avoid repeating analyses in the Second Stage that have already been completed in the First Stage.	
§ 69505.7. (b)(4)	Public Comments on Stage 1 AA	See comments for § 69505.8	
§ 69505.7. (g)(2)(A)	Scope and Comparison of Alternatives - Matrix	HP appreciates the clarification that matrix in the Final AA Report is a summary only, and does not require detailed information for each factor.	
§ 69505.7. (i)(1)	Supporting information - response to comments	See comments for § 69505.8.	
§ 69505.7. (k)(1)	Work plan content	HP recommends that the relevant factors for the Second Stage AA be established and included as part of the work plan. Note this change may require moving Section 69505.6(a) to 69505.5(f).	
§ 69505.8.	Public Comments on AA Reports	HP supports DTSC facilitation of public comment review on Final and Abridged AA Reports by determining which comments and issues need to be addressed in an AA Report Addendum.	

April 25, 2013

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

Re: Safer Consumer Products Revised Regulations

Dear Ms. Von Burg:

On behalf of the International Fragrance Association North America (IFRA North America) and its members, we appreciate the opportunity to comment on the Department of Toxic Substances Control's (DTSC) Safer Consumer Products Revised Regulations (Regulations).

IFRA North America is the principal trade association representing the interests of the U.S. fragrance industry. Our members create and manufacture fragrances for personal care, home care, industrial and institutional use as well as home design products, all of which are manufactured by consumer goods companies. Our Association also represents companies that source and supply individual fragrance ingredients, such as essential oils and other raw materials, which are used in perfumes and fragrance mixtures.

For the past several years, IFRA North America has been actively engaged in the process of California's Green Chemistry Initiative through providing written comments on the draft Regulations, direct communications with DTSC leadership and active participation in industry groups such as the Green Chemistry Alliance (GCA). While we recognize that DTSC has made a number of improvements in the revised Regulations, we remain concerned that the Regulations continue to fall short in achieving the creation of a meaningful and practical regulatory environment in the state of California. In effect, the Regulations would result in unnecessary expense and lost opportunities for industry stakeholders, while delivering negligible improvements to the overall safety of human health and the environment.

In particular, we are concerned that DTSC has declined to identify an established threshold level with regard to the Alternatives Analysis Process. Further, the protection of trade secrets

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and confidential business information (CBI) largely remains inadequate. We therefore incorporate all of our previous comments, by reference, and respectfully request that DTSC consider each argument and specific revision outlined therein as applied to the Regulations. Further, we kindly request your consideration of the comments below.

A Fixed De Minimis is Necessary to Provide Predictability and Eliminate Improbable Risks

A continuing concern for IFRA North America's membership is the lack of a specific default concentration threshold which would determine whether a manufacturer is subject to the Alternative Analysis Process based on negligible risk. As we understand from the most recent version of the Regulations, DTSC can assign a threshold for a designated Chemical of Concern in a priority product. Unfortunately, this approach does not address the concern that setting a variable threshold for each chemical of concern in a priority product will result in an extremely burdensome and potentially highly politicized process, forcing industry to incur unnecessary expenses that have no bearing on objective safety. It is crucial for the regulated community to have consistency as it progresses through this substantial and comprehensive transformation in the way all consumer products and their ingredients are created and formulated. Though this holds true for all businesses, it is especially true for small and medium sized companies of which the vast majority of our membership is comprised.

IFRA North America continues to support an established "de minimis" level of a concentration of 0.1%. We urge DTSC to adopt other federal and international regulations for this precedent including, but not limited to: the Occupational Health and Safety Administration's (OSHA) Hazard Communication Standard requirements for development of Material Safety Data Sheets (MSDSs), the Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI) program, the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals Program (REACH), the European Union's Classification, Labeling and Packaging (CLP) Regulation and the United Nation's Globally Harmonized System for Classification and Labeling (GHS).

Provisions Related to Trade Secret Protection Continue to Remain Inadequate

IFRA North America continues to be gravely concerned with the insufficient trade secret protections in the Regulations. As we understand, the trade secret protections 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 would not be masked. Essentially, this denies an often used mechanism to protect CBI that is relied upon by multiple industries to provide an effective probability of securing return on research and development investment.

There are two key related points that we urge DTSC to recognize: patents are often an inadequate route to protect confidential chemical identities, and a trade secret chemical identity may not qualify for a patent. By forcing manufacturers to choose a patent application approach rather than utilizing trade secret protections, the Regulations would have the unintended consequence of placing U.S. companies in the unsustainable position of having to disclose their most economically valuable trade secrets. This approach would severely impact formulators such as perfume makers and IFRA North America urges DTSC to protect confidential chemical identities from disclosure and revise the section on trade secrets to reflect this critical need.

Conclusion

IFRA North America and its member companies continue to remain committed to protecting the safety of both the public and the environment and are optimistic that a workable solution can be achieved. Nonetheless, we remain concerned that the Regulations would result in a disincentive to innovate or even do business in the state of California due to a lack of predictability and protections of legitimate confidential business information.

We appreciate your consideration of our comments and would be happy to provide more information or discuss any of this in detail. If you have questions, please do not hesitate to contact me or Megan Ekstrom, IFRA North America's Manager of Regulatory Affairs, at 571-312-8005 or mekstrom@ifrana.org.

Sincerely,

Jennifer Abril
President

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April 25, 2013

Ms. Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Via Electronic Submission

Re: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) Department Reference Number: R-2011-02 (April 2013)

IPC – Association Connecting Electronics Industries appreciates the opportunity to comment on the above referenced draft Safer Consumer Products Alternatives Regulation. We recognize and appreciate the effort DTSC has invested in developing the current draft. We support the proposed solicitation of public comments at the end of the alternatives assessment process and the use of an alternatives analysis threshold that is higher than the substance's PQL for certain substances. However, we remain concerned that the Candidate Chemicals list remains overly broad.

IPC supports DTSC's proposal to solicit public comment on alternatives assessment at the end of the alternatives assessment (AA) process. Stakeholders generally are not scientific experts and their feedback could misguide the AA process. The process for evaluating AAs would be better served by qualified experts.

IPC supports DTSC's proposal to specify an alternatives analysis threshold for certain Candidate Chemicals rather than using the PQL as the alternatives analysis threshold for every Candidate Chemical. Relying solely on a substance's PQL presumes that the mere presence of an identified Candidate Chemical is reason to suggest potential harm. Establishing an alternatives analysis threshold for Candidate Chemicals would help ensure valuable resources are spent on evaluating Candidate Chemicals present in Priority Products in greater quantities. Using valuable resources on insignificant uses of chemicals would result in a minimal benefit to human health and the environment at great cost to industry and DTSC. Specifying an alternatives analysis threshold will help ensure that the most significant uses of Candidate Chemicals are addressed.

As detailed in our February 28, 2013 comments submitted to DTSC, IPC strongly encourages DTSC to use a scientifically based approach in the Safer Consumer Products Regulation. Substances that exhibit the greatest hazards, such as those known to cause cancer, developmental or reproductive harm, be persistent, bioaccumulative and toxic (PBT) in the environment, and pose the greatest exposure to consumers, should be given priority. When evaluating consumer products to be covered by the regulation, DTSC must consider the level of exposure to the priority chemicals in order to ensure the utmost protection to human health and the environment.

By considering both hazard and exposure when identifying chemical-product combinations to be evaluated, DTSC will make the biggest reduction in risk to human health and the environment.

Thank you for the opportunity to comment on the draft regulation. Please do not hesitate to contact me should you have any questions.

Sincerely,

Stephanie Castorina
Manager, Environmental Programs

Madriago, Odette@DTSC

From: t-tajima@jeita.or.jp
Sent: Tuesday, April 23, 2013 9:26 PM
To: GCRegs@DTSC
Cc: m-sato@jeita.or.jp; '木村　　司様'; t-hayakawa@jeita.or.jp; s-shigemitsu@az.jp.nec.com; 'Hisaichi Suzuki'
Subject: Comments on Safer Consumer Products Regulation
Attachments: Comments on Safer Consumer Products Regulation _JP_2013.04.24.doc

Dear Mr. Jackie Buttle

Please find attached to this mail the comments on the Four Electrical and Electronics Industry Associations of Japan : JEITA (Japan Electronics & Information Technology Industries Association), CIAJ (Communications and Information Network Association of Japan), JEMA (Japan Electrical Manufacturers' Association) and JBMIA (Japan Business Machine and Information System Industries Association)

Yours truly,

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Japan Electronics & Information Technology Industries Association
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Comments on Safer Consumer Products Regulation

page	Clause/ Subclause	Comments	Proposed change	page
7	SS69501.1. Definition (6) "Adverse public health impacts"・・・	This definition here says the "Public health includes occupational health". As this regulation takes care of "consumer products", this definition to include "occupational health" does not sound adequate.	英語: The sentence "Public health includes occupational health" should be deleted.	
16	SS69501.2. Duty to Comply and Consequences of Non-Compliance.	The total lead-time through supply chain to produce a consumer product is, though each player trying hard to reduce it, quite long, and each portion of the supply chain is always keeping some amount of inventory at each stage.	The restriction to a product containing Chemical of Concern should consider sufficient time frame by balancing the time to allow to eliminate those inventory in a reasonable manner and the hazard caused by them. This is to avoid unnecessary disposal of materials and half-products, which may cause another kind of environmental impact.	
23	Article2. SS69502.2. Candidate Chemicals Identification.	We are concerned that the process to identify the Candidate Chemicals is quite dependent on DTSC's study and decision. At considering Candidate Chemicals, quite a lot of them are not scientifically proved to be hazardous, but concerned. In such a circumstance, each stakeholder should have each different opinion. Without receiving all of these opinions and holding discussions among them, the determination may not be considered fair.		

25	SS69502.2 Candidate Chemicals Identification. (b) Additions to the Candidate Chemicals List	We understand the importance of updating/adding the Candidate Chemicals to the list, however, we also would like to emphasize that such chemical information should also consider other regulations such as EU REACH. It would be burdensome for the industry if they need to take care of each of the regulations, which have the same kind of purpose worldwide and individually, therefore, we want this regulation to closely work with other countries'/areas' authority to take care of chemical controls, with the view to harmonize the approach.		
27	SS69502.3. Candidate Chemicals List. (c)(1)	As written in Article 2 Section 69502.2, some of the chemicals are not explicitly hazardous, and some do not have enough information either to say yes or no to such nomination. Under such situation, also considering such public comment information may not directly be aware by chemical manufacturers by the reason we mentioned in "Section 69501.2 Duty to Comply and Consequences of Non-Compliance., (b)(1)(B)/(C), (2)(A)", the public comment period (forty-five(45)days) sounds too short. We hope that the time frame like defined in EU REACH should be considered.		
28	Article 3. Process for Identifying and Prioritizing Product –Chemical Combinations SS69503.2. Product-Chemical Identification and	Adding to California regulations, federal laws and international agreements, other major areas' (such as EU) regulation shall also be considered This is with the view to try to harmonize the scope or the chemicals in the list.		

	Prioritization(b)(2) Other Regulatory Programs			
36	Article 5. Alternatives Analysis (Comment 1)	The activity related to AA seems quite dependent onto each company's activity. It is understandable that each company has its right to research and develop by its own, but, on the other hand, the possible alternative chemicals to the same kind of products should be quite limited, therefore, each of those companies may come up with the same conclusion, sometimes with the report to say "no alternative". If they come up with such possible same kind of result, all of those various but the same activity multiplication seem wasteful both from social cost or environmental burden point of view. We want DTSC to consider establishing some kind of body like EU SIEF for AA activity either at Priority Product or Chemicals of Concern level, while each company can detain the right to individually investigate and report. At the same time DTSC should provide the information openly to those who need them, unless they are categorized as "trade secret", so that those who would perform AA activity could refer to some of the information.		

36	Article 5. Alternatives Analysis (Comment 2)	In case of semiconductor industry, due to its advanced technology nature, the selection of a chemical takes a long research and development time, including the approval phase by the assembly product. Sometime, starting from the very first stage of selecting the potential alternative to actual first mass-production out, it takes like ten (10) to fifteen (15) years. The importance of reducing or elimination the Chemicals of Concern is fully understood by the industry, however, considering above, the time frame needed to switch to an alternative sometimes takes such time mentioned above. We hope that DTSC would understand such nature of the industry at considering AA activity.		
P36、P37	69505(a) (b)	69505(a) and (b) stipulate that the Department of Toxic Substances Control (hereinafter "DTSC) must release 'guidance materials' and 'example of Alternative Analysis (hereinafter "AA")' on its website for the implementation of AA, before Responsible entities implement AA. Meanwhile, impact assessment on public health and environment etc. in AA required for implementation by Responsible entities have issues in that it is generally not easy to be conducted*1, and the results may easily vary depending on the conductor of the impact assessment when the implementation method is not specifically provided. In order to respond to the issues above, we would request DTSC to verify*2 the feasibility of specifically implementing AA with use of 'guidance materials' and 'example of AAs' by Responsible entities, prior to the release of the 'guidance materials' and 'example of AAs' on the website. To be specific, we request a public consultation be launched prior to release, and the 'guidance materials' and 'example of AAs' be	We propose adding the following underlined parts to § 69505(a) and (b). § 69505. Guidance Materials. (a) Guidance Materials. Before finalizing the initial list of Priority Products, the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article, <u>after conducting public review for comments</u>. The Department shall periodically revise and update the guidance materials after conducting public review for comments. (b) Sample Alternatives Analyses. The Department shall also post on its website examples of AAs that are available in the public domain at no cost, <u>after conducting public review for comments</u>. The posting must indicate, for each AA, the name of the person	

		established/released after taking sufficient time and communication with industries and academic/evaluation organizations. *1: Unlike impact assessments for chemical substances and preparations, implementation of impact assessment for articles are particularly difficult due to the identification of the exposure scenario and few generally-accepted evaluation methods. *2: Examples of verification: ・ Is the impact assessment method feasible for various products, or for products by various manufacturers with different specifications of the covered product? ・ With respect to the implementation of AA, is the evaluation of the current product/substance or the trial production/evaluation of the alternative product/substance economically reasonable?	or entity that prepared the AA.	
50	SS69505.7. Alternatives Analysis Reports. (d) Responsible Entity and Supply Chain Information.	As written in "trade secret", the player's information in the supply chain is a part of business confidential information. At the same time, the names of the further upstream or the downstream in the supply chain to a player than the direct supplier or the customer are not disclosed, therefore, such information cannot be provided.	This portion shall be deleted entirely.	
59	Article 6. Regulatory Response SS69506.1 Applicability and Determination Process. (d)(1)	Many companies selling consumer products in California have a headquarter function (to read such regulations) located outside of California. For them, to receive public consultation information may take time. Sometimes, it takes time to read English, when it is not their native tongue. Considering this, forty-five (45) days seems too short to comment.	The public comment period should be longer, such as sixty (60) days.	
61	SS69506.3. Product Information for Consumers. (c)(2)(A)	We are concerned with the possible confusion related to the change management if the (c)(2)(A) is strongly required. We foresee that some of the products have some label while others do not under the	We suggest that website or POP (point of purchase) card information at the shop should also be selected.	

		same product name in the same sales area in the market at a changing time. That may confuse some of the consumers, while it is not practical to say that all the labels on the product package would be changed over a night.		
64	SS69506.7. End-of-Life Management Requirements.(c)	This section seems to say that each company is requested that they not only fund but establish and maintain a management system to the end-of-life. We believe such system should be established mostly by the district government We understand that somebody should fund such activity, but the establishment and maintenance of its system is a different issue. This should cause chaos in end-of-life management, if each company tries to have its own and different system. We hope that such system should be considered as a part of waste management of California government, and through such study, funding method shall also be discussed.	We propose that EU WEEE method be studied.	
73	Article 9. Trade Secret Protection SS69509. Assertion of a Claim of Trade Secret Protection.	The trade secret mentioned here seems too much onto the engineering and know-how issue. However, in the daily course of business, those information related to supply chain or the plan of R&D are confidential business information. Especially, the consumer product companies or its direct upstream companies are NOT mostly chemical manufacturers. Most of the cases, their names are unknown.	We request that the definition of trade secret shall be reconsidered to include those information. Also, from this point of view, we want DTSC to consider to limit requested information to minimum level to achieve the purpose of this regulation..	

KOCH INDUSTRIES INC

CORPORATE ENVIRONMENTAL EXCELLENCE

April 25, 2013

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

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

RE: Safer Consumer Products Regulations, R-2011-02, OAL Notice File Number 2-2012-0717-04

Dear Ms. Buttle:

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

Generally, the minimal changes to the Proposed Regulations fail to address the majority of concerns raised by KII as well as the Trade Association Comments. KII recognizes that this short 15 day comment period is limited to the changes made to the Proposed Regulations and provides the following comments to address those changes.

Reliable Information: The definition of "reliable information" has been amended to provide some clarification as to how DTSC will review scientific information submitted to DTSC or relied upon as part of an alternative assessment (AA). It is unclear whether in subparagraph (4) if DTSC intends to include scientific information that is developed by industry for compliance purposes. This may include data generated as part of US EPA's DFE programs or in response to EU's REACH directive requirements for dossier preparation.

- **Recommendation** – KII requests that DTSC clarify that the information contemplated by Section 69501.1(57)(A)(4) would include such information developed or commissioned by industry.

Alternative Analysis Threshold Value: DTSC has retained the Practical Quantitative Limit (PQL) as the AA Threshold Value for Chemicals of Concern (CoC) present in the product as a contaminant. The continued use of the PQL as a Threshold Value is inappropriate for two reasons. First, PQL is a relative value that is dependent upon the analyte, matrix and the instrumentation used. As a result, the PQL for different laboratories will vary depending upon analytical technique, lab capabilities, and/or the material or matrix being tested. Second, PQL is an analytical limit and has no relationship to the level at which a particular chemical could be deemed to be either safe or hazardous. As such, use of the PQL as a Threshold Value is arbitrary. DTSC has added the possibility of establishing an AA Threshold value greater than the PQL for CoCs present both as contaminants and intentionally added substances. We welcome the change to allow a threshold approach to be applied to a CoC. There are a number of scientifically valid methods utilized by various U.S. and international regulatory bodies to determine a safe threshold value and DTSC should incorporate these into the scientific methodology. As in previous drafts, DTSC has retained great discretion, and the regulation continues to lack clarity.

- **Recommendation** – The PQL is inappropriate as an AA Threshold value and should be removed. An AA Threshold approach should be required for all Priority Product/CoC combinations and contaminants. The AA Threshold Value should be a specific value, established for the Priority Product/CoC combination and based upon reliable information and methodology incorporating risk of exposure to the substance within a product in its intended end use.

Public Comments: The public comment portion has been revised from the previous version. While limiting public comments to the final AA report possibly offers some improvement, it still fails to address the fundamental problem with the use of public comments within the framework of this regulation and indeed the fundamental problem with this entire effort. We appreciate the need for and encourage open and transparent government. In this instance however, the DTSC is placing the public in the role of scientific, policy and economic decision maker and in so doing DTSC is abandoning its role as the governing authority. Further it remains highly inappropriate to require reports from private entities, possibly containing sensitive information, to be subject to public review. To do so creates the potential for anticompetitive issues and numerous legal complications. In addition, there has been no framework or criteria presented by which DTSC would evaluate the public comments and identify those to which the responsible entity must respond.

- **Recommendation** - Public comments should be eliminated from the regulatory compliance obligation for Responsible Entities. In the alternative, DTSC should outline the specific criteria that will be used to evaluate the public comments and identify the methodology for determining which comments DTSC will require responsible entities to address as part of an amended AA report.

Confidential Business Information: Finally, it is unfortunate that DTSC continues to ignore the comments of industry attempting to educate the Department about intellectual property and the importance of protecting trade secrets. We refer back to the comments submitted by KII and the Trade Association Comments on Article 9. The minor changes made by DTSC in the current draft of the Proposed Regulations do not address these important concerns. This further underscores that the lack of understanding by DTSC of the concerns raised by several trade association comments, GCA and industry generally. The revisions fail to make a distinction between the different forms of intellectual property (IP) that may need to be protected and the well-established methods for protecting the same. As a patent is just one option a manufacturer of a new substance or a new use of an

existing substance has to protect this IP, DTSC is ignoring trade secrets which in many cases may be a more suitable option for the responsible entity. Therefore, if a responsible entity tried to avail itself of the limited "protection" DTSC attempted to provide, it would actually have the opposite effect, and in most cases result in the disclosure of the information to the public and competitors.

KII supports and incorporates by reference the Trade Association Comments submitted in response to the 15 day comment period on DTSC's Proposed Regulations. As currently written, the Proposed Regulations will likely result in increased cost of products in California, impacts to the availability of products, increases cost disparities, and due to compliance risk concerns may encourage California businesses to seek more attractive business environments outside the state, all with little discernible benefit to citizens of California.

Should you have any questions, KII would welcome the opportunity to provide further clarification. Please contact our California representative, Dawn Koepke (dkoepke@mchughgr.com, 916-930-1993) for further information or to schedule a meeting.

Sincerely,

Anne Monine

Anne Monine
Corporate Director, Environmental Excellence

Good Afternoon,

It has come to the attention of registered refurbishers across the nation that you were looking for review of the language and for notes regarding language edits as it pertains to the Safer Consumer Product Regulations, DTSC Reference Number: R-2011-02

The wording in:
Section 69501.1 Definitions, “End-of-Life” number 30 (page 12 line 25 of the April 2013 text): "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs ~~first~~”

Should be changed to: "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs **last**”

This will help to insure that reusable equipment can be reclaimed for its highest and best use.

Thank you,

Tamara Gillard
Executive Director
MN Computers for Schools
www.mncfs.org
#651-779-2700 x2580

ISO 14001:2004 Certified

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Thank you.

This is regarding the Safer Consumer Product Regulations, DTSC Reference Number: R-2011-02

The wording in In section 69501.1 Definitions, “End-of-Life” number 30 (page 12 line 25 of the April 2013 text): "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first”

Should be changed to: "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs last”

This will help to insure that reusable equipment can be reclaimed for it's highest and best use.

As the Director of a electronic recycling non profit, this is so important to our ability to grow "green jobs" for America.

Nancy Jo

OUTDOOR POWER EQUIPMENT
INSTITUTE

April 25, 2013

via electronic mail gcregs@dtsc.ca.gov

Deborah O. Raphael, Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814-2828

re: comments on Proposed Safer Consumer Products Regulations (April 10, 2013 draft)

Dear Ms. Raphael:

I am pleased to submit the comments of the Outdoor Power Equipment Institute on the revised proposed Safer Consumer Products Regulations (Regulations) released by the DTSC on April 10, 2013.

The Outdoor Power Equipment Institute is the major international trade association representing the manufacturers and their suppliers of consumer and commercial outdoor power equipment such as lawnmowers, garden tractors, utility vehicles, trimmers, edgers, chain saws, snow throwers, tillers, leaf blowers and other related products. The products manufactured by this industry are "complex durable goods", composed of 100 or more manufactured components, with a service life of several years, and typically not consumed, destroyed, or discarded after a single use.

The OPEI is concerned with the revised definition of "Assemble" (Section 69501.1 (15))

The addition of "repair, refurbish, maintain, or make non-material alterations" places this definition at variance with manufacturers' conventional understanding of the term "assemble" and by reference "assembler" (Section 69501.1 (16)). Outdoor power equipment manufacturers, like other complex durable goods manufacturers, rely on authorized service vendors to perform repair and maintenance. These businesses do not assemble new equipment, and should not be included in the regulation under this definition.

Revise Section 69501.1 (15) as follows: "Assemble" means to fit, join, put, or otherwise bring together components to create~~, repair, refurbish, maintain, or make non-material alterations to~~ a consumer product.

We appreciate the opportunity to provide comments on this regulation.

Best regards,

Daniel J. Mustico
Director, Industry Affairs
dmustico@opei.org

PC Rebuilders & Recyclers, LLC (PCRR) Comments on Proposed Regulation on Safer Consumer Products (R-2011-02, April 2013)

By Willie Cade, CEO of PCRR and Co-Chair of Project Group 1.1 on Environmentally Sound Testing, Refurbishment, and Repair of Used Computing Equipment for the Partnership for Action on Computing Equipment of the Basel Convention of the United Nations Environment Program.

Please accept these comments on the Proposed Regulations for Safer Consumer Products (Proposed Regulations). My company along with over 2,000 other organizations in the United States refurbish computers that are either Microsoft Registered Refurbishers or Microsoft Authorized Refurbishers. I would like to provide input on the Proposed Regulations. My company sells equipment in California and through organizations with its headquarters and website based in California I believe that I could be subject to these Proposed Regulations.

In the interest of time and my limited resources I will confine my comments to a few sections of the Proposed Regulations.

In section 69501.1 Definitions, "Assemble" number 15 (page 9 line 35 of the April 2013 text) the phrase "repair, refurbish, maintain, or make non-material alterations" was added in April 2013 post hearing. Using the definitions of **Refurbishment**: "Process by which used computing equipment is modified to increase its performance and functionality or to meet applicable technical standards or regulatory requirements, including through such activities as cleaning, data sanitization and software upgrading" and **Repair:** "Process of fixing specified faults in computing equipment and/or replacing defective components of computing equipment to bring the computing equipment into a fully functional condition," as provided by the Basel Convention COP 11 web site a Refurbisher would have the Duty to Comply under Section 69501.2 if the manufacture has failed to comply. Given that our equipment can be 3 or 4 years old and we have limited direct access to any Original Device Manufacturer (ODM) or Original Equipment Manufacturer (OEM) information my company could not comply. I also believe that all PCs, cell phones and most other consumer electronics require to be maintained and that non-material alterations, such as adding a software applications, would subject all owners of such equipment with the Duty to Comply as outlined in Section 69501.2.
I request that the Phrase "repair, refurbish, maintain, or make non-material alterations" be removed from the Proposed Regulations.

In section 69501.1 Definitions, "End-of-Life" number 30 (page 12 line 25 of the April 2013 text) is defined as "the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first" suggests that all used goods would be subject to Section 69506.7 End-of-Life Management Requirements. The US EPA's Electronics Environmental Benefits Calculator (EEBC) Version 3.1 Copyright © July 2012 provides the following results for every 100 desktop computers and LCD screens and 100 laptops reused for a year; will prevent 2,770 metric tons of air emissions, the energy saving equal to 56 households or removing 24 passenger cars from the road per year. It is important to note that 25% of the PCs we receive at PCRR from corporations have been used less than 500 hours ("lightly used") or 3 months of use Monday through Friday from 9 to 5 pm therefore it would counterproductive to require End-of-Life treatment of these used products. These results are considerably better than purchasing the highest rated EPEAT products. I also anticipate that the percent of products that are "lightly used" will increase because individuals have more devices that they can use to access the internet and their e-mail as demonstrated by recent research from J, Yu et al[1]. For these reasons I believe the above definition would be detrimental for the environment. I recommend that the last word of the definition "first" be replaced with "last." For the sake of clarity it may be helpful to include a definition of End-of-Use consistent with the current definition.

I also request in Section 69506.3 (b)(7) Product Information for Consumers that DTSC require ODMs and ODMs to provide complete repair manuals be made publically available via their website. This will divert a considerable number of products from the waste process because they can be repaired. As mentioned above the EEBC clearly demonstrates the environmental benefit of reuse and repair.

Respectfully submitted

Willie Cade

April 24th, 2013

[1] J. Yu, E. Williams, M. Ju, and Y. Yang, ―Forecasting global generation of obsolete personal computers‖, *Environmental Science & Technology* 44 (9), 3232–3237 (2010)

Personal Care Products Council
Committed to Safety, Quality & Innovation

April 25, 2013

Via Electronic Mail
Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

RE: Revisions to the Proposed Safer Consumer Products Regulations

Dear Ms. Buttle:

The Personal Care Products Council (Council)[1] is pleased to submit the following comments on California's Safer Consumer Products proposed regulation that was developed by the Department of Toxic Substances Control (DTSC) and publicly released on April 10, 2013. Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in California and throughout the United States, and therefore have a strong interest in the scope and applicability of this regulation.

INTRODUCTION

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

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

The Council has filed comments to all prior iterations of the regulation, including the January 2013 revised proposal, all of which are incorporated herein by reference. We would specifically draw attention to our prior arguments asking DTSC to address the potential small business impacts of the regulations, as well as the need to exempt OTC drugs from the scope of the regulation in order to avoid inevitable conflicts with mandatory federal drug requirements. Although we have continuing concerns about the Safer Consumer Products regulation, it is evident from the April 2103 "revised" proposal that DTSC has addressed some of our previous objections and made important modifications. Therefore, in an effort to preserve the positive changes and ameliorate the negative aspects of the regulation, the Council respectfully submits the following comments for your consideration:

§69501.1 (57): Definition of "Reliable Information"

The definition of "reliable information" is critically important to the regulation, given that it is cited repeatedly in a number of different contexts and forms the basis of several important DTSC decisions, from whether a chemical has a particular hazard trait to the adequacy of engineering controls. The changes to the definition would broaden the criteria for what constitutes "reliable information" to include "scientific information", including information that was "prepared for" any international, federal, state, or local regulatory agencies for compliance purposes. This change also appears to clarify that reliable information can be scientific information prepared by industry scientists.

Despite the positive change, however, it still falls short of instituting a full "weight of evidence" determination in the application of such information. For example, single studies published in peer-review journals may identify suggestive evidence of a specific hazard, but these studies are not conclusive by themselves. It is only through evaluation of the full weight of evidence that a clear understanding of a causal relationship between exposure to a substance and an outcome of concern can be conclusively determined. Likewise, it is only through scientific debate and exchange that these conclusive results emerge.

The Council strongly encourages DTSC to incorporate a weight of evidence approach to the scientific process, explaining how it will be followed throughout the chemical and product prioritization process as well as through evaluation of the alternatives assessment, and ultimately how it will be used in determining the regulatory response.

§69503.5(c): Alternatives Assessments Threshold (AAT)

The Council applauds the modification to the AAT process that allows DTSC to set an AAT different from the Practical Quantification Level (PQL) for either an intentionally-added or a contaminant chemical of concern. For our purposes, this was the most significant and important change made to the regulation.

For our members, the importance of this revision lies principally in being able to make a "safety case" for a proposed Priority Product before conducting a full alternative assessment. In this, stakeholders can now provide information to support a scientifically justified AAT concentration for a chemical of concern. A second value is the opportunity to exclude meaningless AA's for exceptionally low contaminant levels of a CoC. The intent of the statute was to offer significant risk reduction to the citizens of California by incentivizing companies. Allowing the valuable reformulations efforts to be expended on low value targets such as these contaminants is counter-productive.

While a specific threshold value for all contaminants would lend greater predictability to companies formulating products, the compromise contained in this revision is at least an improvement and provides tacit acknowledgment that, in many cases, a threshold above the level of detection is necessary.

DTSC should be cognizant, however, that situations will arise where different manufacturers utilizing the same chemical of concern may argue for – and document reasons for – differing thresholds. DTSC, in order to avoid the appearance of making arbitrary decisions, must be ready to respond to such situations and explain its reasoning behind any decision.

§69505.1 and §69505.8: AA Report Addendum and Public Comment

Another important change was made to the public comment process for alternative assessments (AAs). In the previous version of the regulation, DTSC required responsible entities to publish their Preliminary AAs on DTSC's website for public comment. Responsible entities would then be required to read and respond to all public comments in their Final AA Report. The Council, in its comments to the January 2013 version of the regulation, recognized that DTSC was looking for some form of "quality control" over the AA reports, but noted that this unfortunate provision would result in an onerous and extremely cumbersome process that would yield no real benefits.

In the revised regulation, DTSC will now provide a public comment period for the Final AA Report (not the Preliminary) and DTSC (not the manufacturer) will then review any public comments and identify within 30-days any issues that it determines need to be addressed by the responsible entity in an AA Report "Addendum". In other words, DTSC will effectively act as an intermediary to determine which comments warrant a response in an Addendum. The due date for the AA Report Addendum will be determined by DTSC based on the "the scope and complexity of the issues the Department is requiring the person to address."

This modification comports with one of our recommended changes following the January 2103 draft. Specifically, the Council recommended that, if public comments on AAs were to be allowed, DTSC should

at a minimum "screen" the comments so that companies would only need to respond to substantive, scientifically sound public submissions. As such, we applaud this revision.

§69509(f) and (g): Trade Secrets

With regard to trade secret protection for chemical ingredients or their hazard traits, the prior regulation provided that a trade secret claim would be temporary, only existing while a patent application was pending. This "chemical identity masking" would cease the moment a patent application was granted or denied. In the April 2013 revisions, however, DTSC modified this provision to state that such masking is allowed until "the information subject to the trade secret is made public" (which may include through publication of the patent application).

Despite this proposed change, the Council believes the regulation continues to conflate two distinct forms of intellectual property protection in a manner which seriously erodes existing statutory and common law property rights currently granted to owners of trade secrets. Consider that chemical identity is often a core trade secret for a product in situations where the chemical is critical to product performance, quality, safety and cost and is rarely, if ever, patented. The state, federal and international approach in such cases is to claim the chemical identity as a trade secret (while disclosing only a generic, descriptive name adequate for public use).

The patent system has a critical role to play in protection of intellectual property, but it applies only in limited circumstances where the interests of the innovator coincide with making the innovation systematically available to the market. It is then incumbent upon the inventor to defend the innovation by patent litigation. This may not be economically reasonable or meaningful, as in the case of foreign imitators not easily constrained by judicial decision. In many cases involving chemical formulations and processes, benefits derive from maintaining the competitive advantage of a unique formulation or process and the choice is to protect the innovation, not via patent, but trade secret. Unfortunately, this option would be eliminated under this revision, seriously compromising its compatibility with genuine innovation in chemical development and application.

A company will make a strategic business decision as to whether to seek trade secret protection, which lasts indefinitely (or until the information becomes public), or file for patent protection, which provides exclusive rights to the patent holder for 20 years. A company may not elect to file a patent on every discovery that provides them with a competitive advantage. In many cases, particularly where the discovery or invention is a product formulation that cannot readily be analyzed or which is not discernible by inspection, an entity will choose trade secret protection over prospective patent

protection, due to the potentially unlimited time frame for maintaining the economic advantage obtained from the trade secret.

For all of these reasons, the Council urges DTSC to again revise this section in order to better reflect current law and afford better protection of trade secrets.

§69506.7: End-of-Life Management

In the January 2013 draft regulation, there was a mandatory requirement to provide an upfront financial guarantee, including providing compensation to retailers, when "end-of-life management" was to be the selected regulatory response. In the April 2013 revisions, DTSC has eliminated the requirement that manufacturers provide compensation to retailers and other entities that agree to participate in an end-of-life collection program. DTSC states that this provision was eliminated so that these issues can be addressed by affected parties as part of the initial agreement process. The Council applauds this change.

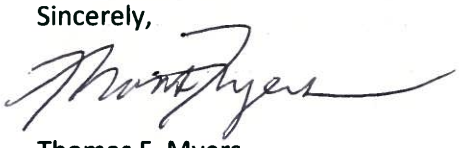
CONCLUSION

While the Council largely views the April 2013 revisions as positive and responsive to some of our previously stated concerns and comments, there remain several difficult provisions in the revised proposed regulation – particularly with regard to the lack of clarity around the concept of regulatory duplication – which we continue to view as seriously problematic and in direct conflict with the spirit and intent of the enabling legislation and its grant of authority.

Although the revised regulation may ultimately provide some benefit to public health and the environment, we believe it continues to create regulatory inconsistencies and impose unnecessary costs and burdens upon industry. We further believe that it is critical that DTSC construct a program that is workable from the onset, with a narrowly drawn scope and requirements that are not cost-prohibitive.

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

Sincerely,



Thomas F. Myers
Associate General Counsel

April 25, 2013

Via email to gcregs@dtsc.ca.gov

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

15-DAY PUBLIC NOTICE AND COMMENT PERIOD NOTICE OF PUBLIC AVAILABILITY OF ADDITIONAL POST-HEARING CHANGES
SAFER CONSUMER PRODUCTS
Department Reference Number: R-2011-02
Office of Administrative Law Notice File Number: Z-2012-0717-04

Dear Ms. Buttle:

On behalf of Plumbing Manufacturers International (PMI), we are submitting the following comments in regard to the April 10, 2013 revisions to the proposed text of the Safer Consumer Product regulations.

Additionally, PMI has filed comments to all prior iterations of the regulations, including the July 2012 proposal, which we incorporate here by reference.

PMI is the leading national and technical trade association of plumbing products manufacturers in the United States. Our 31 manufacturers and allied members include many of the well-known companies selling plumbing products in the United States for decades. Our collective group of manufacturers is responsible for at least 90% of all the fixtures and fittings sold in the U.S. market.

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

As a Green Chemistry Alliance (GCA) Coalition member, we endorse the comments that will be filed by the GCA separately. These comments are intended to amplify certain issues of particular importance to PMI.

PMI continues to appreciate the extensive effort DTSC has once invested in the effort to develop a regulatory system that fulfills the objective of being meaningful, practical, and legally defensible. We acknowledge that improvements have been made to the proposed regulation.

Some of the more significant improvements include:

- Revisions to the definition of manufacture to no longer include assembly.

- Revisions to include processes for removal of a chemical or a product, in lieu of an alternatives analysis.

• Revisions to the Practical Quantitation Limit [PQL] including the definition and application to the alternatives analysis threshold.

• The incorporation of additional opportunities for input including the preliminary alternatives analysis

• Revisions to the provisions for priority product notifications, alternatives assessment process factors, and end-of-product-life processes.

PMI continues to have concerns with provisions of the regulations as revised. These include:

- **Economic Analysis** – the regulations do not specifically mention or mandate and essential economic analysis. Although the department may commit to perform an economic analysis as it implements the regulation, during the process by which chemicals of concern and priority products are identified, it is important that such an essential process by specifically set forth in the regulation.

- **Regulatory Duplication** – the provisions as revised do not yet provide the necessary clarity and certainty that the regulations will not apply to consumer products that are adequately regulated today at the federal or state level.

- **Trade Secrets** – the provisions as revised to not yet provide the necessary clarity and certainty that proprietary, essential manufacturer information that is considered a trade secret will remain confidential.

In conclusion, PMI urges DTSC to fully endorse and adopt our comments and requests for further revisions to the Safer Consumer Product Alternatives regulation.

Sincerely,

Len Swatkowski
Technical Director
Plumbing Manufacturers International
1921-G Rohlwing Road, Rolling Meadows, IL 60008
p: 847.481.5500 x 105 f: 847.481.5501 c: 614.406.2352

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
Barbara C Higgens, Executive Director, PMI
Jerry Desmond Jr., Desmond & Desmond

PMI members include: American Standard Brands, Inc. * Amerikam, Inc. * Bradley Corporation * BrassCraft Mfg. Co. * Chase Brass & Copper Company * CSA International * Delta Faucet Company * Dornbracht Americas * Duravit USA * Elkay Manufacturing Company * Fisher Manufacturing Company * Fluidmaster, Inc. * Hansgrohe, Inc. * International Association of Plumbing and Mechanical Officials * InSinkErator * Kohler Company * KWC America, Inc. * Lavelle Industries * LSP Products * Moen Incorporated * Mueller Brass Company * NEOPERL, Inc. * Pfister * Sloan Valve Company * Speakman Company * Symmons Industries Inc. * T & S Brass and Bronze Works, Inc. * TOTO USA * VitrA USA * Water Pik * WCM Industries, Inc.

The Procter & Gamble Company
NA Regulatory & Technical Relations
One Procter & Gamble Plaza (C-6)
Cincinnati, OH 45202
www.pg.com

April 25, 2013

Via e-mail GCRegs@dtsc.ca.gov

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Comments on the Revised Safer Consumer Products Regulation (Z-2012-0717-04)
Additional Post-Hearing Changes (April 10, 2013)

Dear Ms. Buttle:

The Procter & Gamble Company (P&G)[1] appreciates this opportunity to comment on the revisions to the proposed Safer Consumer Products Regulation[2] ("proposed regulation") released on April 10, 2013, by the California Department of Toxic Substances Control ("DTSC" or "Department") for a 15-day public comment period. Additionally, P&G has filed comments on all prior iterations of the proposed regulation, including the most recent January 2013 proposal, which we incorporate by reference.

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

Director Raphael has often described her vision for creating a regulatory program to implement the Green Chemistry Initiative as one that is "practical, meaningful and legally defensible." We see evidence of this vision in the following provisions of the April 2013 proposed regulation which P&G supports as **positive changes**:

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

- **§69503.5(c) Alternatives Analysis (AA) Threshold.** The revisions make clear that the Department may specify an AA Threshold concentration for any Chemical of Concern that is an intentionally-added ingredient or a concentration that is greater than the applicable Practical Quantitation Limit (PQL) for Chemical of Concern that is a contaminant. This is a very positive change that provides a manufacturer (or other Responsible Entity) with the opportunity to provide DTSC information about the hazards and exposures of the Chemical of Concern/Priority Product during the APA process to demonstrate the product's safety through manufacturing, use and disposal. This discussion will enable the Department to establish an appropriate AA Threshold for proposed Priority Products using a science-based approach. P&G would prefer that the language of the final regulation replace "may" with "shall" to require the Department to apply science-based reasoning for selection of an appropriate AA Threshold for every Chemical of Concern/Priority Product combination and provide more predictability to the regulated community. We thank the Department for their receptivity to our repeated request for a "Safety Case" opportunity which we believe will create a more rational and manageable process.

- **§69505.8 Public Comments on AA Reports.** The revisions specify that the Department will provide a public comment period for the Final AA Report; will review any public comments received; and within 30 days of the close of the public comment period notify the submitter of the Final AA Report of any issues that require attention in an AA Report Addendum. This provision is a significant improvement over the previous requirement that the manufacturer (or other Responsible Entity) respond to all public comments provided on the Preliminary AA. The new provision significantly reduces the administrative burden of the previous proposal and narrows the focus to thoughtful issues of direct relevance to the AA process raised during the public comment period. P&G supports the revisions and continues to acknowledge the improvement of this approach over the impractical Certified Assessor concept that appeared in earlier iterations of the proposed regulation.

We commend the Department for these positive revisions in the proposed regulation. However, in the following discussion we identify a critical component of the proposed regulation that requires significant strengthening to adequately protect a functioning, competitive marketplace and to align with important protections offered in California Civil Code.

Article 9: Trade Secrets. We remain greatly concerned with the fundamental misunderstanding of trade secret protection and the patent process evident in Article 9 of the proposed regulation.

- **§69509 (f) and (g).** These are problematic revisions that further limit the conditions for claiming chemical identity a trade secret. The language allows a manufacturer to secure only *temporary* masking protection for a precise chemical identity while a patent application is pending.

These provisions eliminate a manufacturer's ability to consider whether to maintain confidential information as a trade secret, or alternatively, to file a patent application and thereby waive trade secret protection upon publication of the patent application. Many companies rely on a combination of trade secret and patent protection in order to protect their technologies and inventions. In some cases, where the trade secret is not readily discernible from the product, electing for trade secret protection is the preferred intellectual property

protection scheme. A manufacturer may never file a patent for a particular technology. Patents provide limited overall protection due to the following considerations:

- Patents require full disclosure of the manufacturing process and product composition in the patent application, which is disclosed once the patent is published;
- Patent protection exists for a finite period of time (usually 20 years) during which the patent owner has exclusive use of the technology;
- Patent rights are limited to the geography in which the patent is initially filed; and
- The strength of the patent protection depends on whether a manufacturer actively enforces against cases of infringement, which can often be difficult to investigate and prove.

Under federal Uniform Trade Secrets Act and California state law, a manufacturer may claim as a trade secret any non-publicly disclosed information from which the manufacturer derives or may derive an economic advantage. Importantly, the manufacturer may claim trade secret for as long as reasonable measures are taken by the manufacturer to maintain the information as a secret. There is no requirement under federal statute for the holder of the trade secret to seek patent protection in order to maintain ownership interest in the trade secret. **Thus, the requirement in this section of the proposed regulation to file a patent application in order to obtain trade secret protection is inconsistent with federal and state law.**

A relevant issue for trade secret protection is whether the information is readily ascertainable by proper means (e.g., reverse engineering). If information can be readily determined through analysis or study of a product, that information fails the trade secret criteria. P&G has several technology examples that we protect from competition through trade secret designation. Examples include novel mixed polymer systems and low levels of unique catalysts that are extremely difficult to reverse engineer. We rely upon trade secret protection instead of patents to leverage the economic advantage obtained from the unlimited time period of protection, and to prevent disclosing knowledge to competitors of certain chemical use combinations that deliver superior performance benefits.

We strongly oppose the proposed regulation's refusal to protect precise chemical identity unless the manufacturer can demonstrate that a patent application is pending. This is problematic in multiple ways. As previously discussed, there are reasons a manufacturer may not pursue a patent and instead rely on trade secret protection. The proposed regulation not only fails to acknowledge trade secret protection as a means for protecting confidential information, but also disregards chemical identity as legitimate intellectual property worthy of trade secret protection. As we have discussed in previous written comments, chemical identities are often a core trade secret, the disclosure of which is unnecessary considering that the public can interpret hazard trait information independent of a specific chemical identity. We fully support comments provided by the American Chemistry Council that discuss the sufficiency of generic chemical names in association with hazard trait information to meet statutory requirements and to enable an appropriate level of information to the public for understanding the safe use of chemicals.

Finally, we again stress to the Department that substantial portions of a manufacturer's AA report will require trade secret protection. Precise identification and detailed, data-based comparisons of Chemical(s) of Concern

and potential alternatives will reveal how those ingredients interact with the formula matrix to deliver desired results. This is key information that, if disclosed by DTSC for public review during program implementation, will decode confidential formulary science to competitors. Similarly, operating margin and identification of retail sales outlets are key pieces of information to a competitor about a manufacturer's financial strength and marketing strategy. These examples reflect information a manufacturer may consider trade secret and for which protection will be needed to preserve competitiveness.

* * *

P&G is a member of, and active participant in, the Green Chemistry Alliance (GCA), a group of major trade associations and companies that represent numerous broad industrial sectors in California. We support the written comments of the Green Chemistry Alliance, as well as those of our individual Industry trade associations, including the American Chemistry Council (ACC), the American Cleaning Institute (ACI), the Consumer Specialty Products Association (CSPA), the Grocery Manufacturers Association (GMA) and the Personal Care Products Council (PCPC). P&G incorporates the written comments of these trade associations by reference.

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

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

Sincerely,

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cc: The Honorable Matt Rodriguez, Secretary, CalEPA, MRodriquez@Calepa.ca.gov
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April 25, 2013

Deborah O. Raphael, Director
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Sacramento, CA 95812-0806

Comments on Text of Proposed Safer Consumer Products Proposed Regulations—Additional Post-Hearing Changes, April 10, 2013

Submitted via Electronic Mail

Dear Director Raphael:

Thank you for the opportunity to comment on the latest version of the Safer Consumer Products Regulations.

I strongly support many of the additional revisions to the proposed regulations, which increase clarity and the availability of information on the Department's website.

I am concerned, however, that the revisions in § 69505.5 Alternatives Analysis: First Stage on page 47 appear to conflict with the existing information in § 69505.2 on page 40.

In § 69505.5 (c), Step 3. Identification of Factors Relevant for Comparison of Alternatives, responsible entities are directed to compare priority products with alternatives under consideration based on factors that contribute to adverse public health and environmental impacts.

In § 69505.2, Removal/Replacement Notifications in Lieu of Alternative Analysis (b) (F) 2, the proposed regulations state that replacement chemicals that are on the list of Candidate Chemicals that are already in use to manufacture the same product, in lieu of the Chemical of Concern, are exempt from alternatives analyses.

This means that the candidate chemical, N-methylpyrrolidone, a developmental toxicant, could be used as a replacement chemical for methylene chloride paint strippers, without conducting an alternatives analysis, even though safer, non-Candidate chemicals are currently available in paint strippers.

Julia Quint, Ph.D.

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As a authorized e-waste collector in California and also a computer refurbisher and re-seller, I wish to comment on the proposed regulation: Safer Consumer Product Regulations, DTSC Reference Number: R-2011-02

THE WORDING IN SECTION 69501.1

Definitions, "End-of-Life" number 30 (page 12 line 25 of the April 2013 text): "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first"

Should be changed to: "End-of Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs last"

This will help to insure that reusable equipment can be reclaimed for it's highest and best use.

Thank you,

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April 25, 2013

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

I. Introduction

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

RMA has been actively engaged in the rulemaking process for the SCP Regulation. We are encouraged by the changes DTSC made to section 69505.8 Public Comments on Alternative Analysis (AA) Reports, which now specifies that a public comment period will be provided for Final Reports instead of the Preliminary AA Reports. RMA also continues to support the application of end-of-life requirements for only finished products that are required to be managed as hazardous waste.

However, RMA has continued concerns about the application of the April 2013 SCP proposed regulations to tires. First, RMA does not support DTSC accepting public comments on Abridged AA Reports. Second, RMA does not support the requirement that responsible entities submitting an Abridged AA Report must complete Step 3 in the first stage of the AA; Identification of Factors Relevant for Comparison of Alternatives. Third, RMA has continued concern that the development of the Priority Products Work Plan does not provide a mechanism to remove chemical/ product categories based on public comments. Fourth, we have continued concern that the regulations lack adequate protection for confidential business information and trade secrets. Fifth, the AA threshold fails to provide a workable definition of a de minimis

threshold. Last, RMA has concern that the AA process does not provide adequate time for tire manufactures to research, develop, and test potential alternative chemicals in tires. RMA would like to see these changes incorporated into a revised Safer Consumer Products regulation. However, at a minimum we would like to see these changes explained further in the Initial Statement of Reasons (ISOR) for the California Safer Consumer Products regulation.

II. Alternatives Analysis

A. RMA supports the public comment process for Final AA Reports instead of Preliminary or First Stage AA Reports (Section 69505.8)

The January 2013 SCP proposed regulation specified that after completing the first stage of the AA, DTSC will post on its website notice for public review and comments on Preliminary AA Reports, draft Abridged AA Reports, and Alternate Process AA Work Plans submitted to the Department. (January 2013 SCP Proposed Regulation, §69505.1(d)(2)). Additionally, the January 2013 SCP proposed regulation specified that responsible entities must include in the Final AA Report a summary of the public comments submitted and a "description as to how the comments are addressed in the report or an explanation as to why the comments are not addressed in the AA report." (January 2013 SCP proposed regulation, §69505.7(i)(1)). DTSC made several changes to the public comment process on AA reports in the April 2013 SCP Proposed Regulation.

The April 2013 SCP proposed regulation specifies that after completing the Second Stage of the AA, Final AA Reports and Abridged AA Reports received by the Department will be posted on DTSC's website for review and public comment. (April 2013 SCP proposed regulation, §69505.8). The Department will review public comments it receives on Final AA Reports and Abridged AA Reports and notify responsible entities whether the responsible entity needs to address any issues raised in public comments by submitting an AA Report Addendum.

RMA supports the inclusion of a public comment process after a responsible entity has submitted a Final AA. Final AA Reports include consideration of the steps in the first stage of an AA and the second stage of an AA. The first stage of the AA includes: (1) identification of product requirements and functions(s) of chemical(s) of concern, (2) identification of alternatives, (3) identification of factors relevant for comparison of alternatives, (4)initial evaluation and screening of alternative replacement chemicals, (5)consideration of additional information, and (6) preliminary AA preparation. The second stage of AA includes: (1) identification of factors relevant for comparison of alternatives, (2) comparison of the priority product and alternatives, (3) consideration of additional information, (4) alternative selection decision, and (5) final AA report preparation. DTSC indicates in the Revised ISOR that "the activities required to be conducted during the second stage of the AA and the content requirements of the Final AA Report are necessary to ensure the Priority Product has been adequately evaluated." (Revised ISOR, page 141 of 225). We agree that the inclusion of a public comment period on Final AA Reports provides opportunity for interested stakeholders to provide feedback on the selection of an alternative chemical in the priority product. Additionally, we support the change in the April 2013 SCP proposed regulation that DTSC will receive and review the public comments and then determine if any comments need to be further

addressed by a responsible entity in an AA report addendum. RMA does not support the inclusion of the public comment period for Abridged AA reports.

B. RMA recommends that DTSC is best suited to review Abridged AA Reports and that DTSC should not submit Abridged AA Reports for public comment (Section 68505.8)

The April 2013 SCP proposed regulation specifies that DTSC will post Final AA Reports and Abridged AA Reports on their website for public comment. Responsible entities can submit an Abridged AA Report if they determine that after completing the first five steps of the first stage of the AA there is no functionally acceptable and technically feasible alternative chemical. (April 2013 SCP proposed regulation, §69505.4(b)). The first five steps of the first stage of an AA include: (1) identification of product requirements and functions(s) of chemical(s) of concern, (2) identification of alternatives, (3) identification of factors relevant for comparison of alternatives, (4)initial evaluation and screening of alternative replacement chemicals, and (5)consideration of additional information.

In the Revised ISOR, DTSC indicates that the Abridged AA is "necessary to allow for a more efficient and effective use of the responsible entities and DTSCs limited resources by providing a more streamlined process while ensuring that key information is reviewed and evaluated by the responsible entity." (Revised ISOR, page 141 of 225). DTSC acknowledges in the Revised ISOR that "some responsible entities will determine during the first stage of the AA that an acceptable alternative is not readily available." (Revised ISOR, page 141 of 225). Responsible entities may be able to quickly determine during the first stage of the AA that there are no, technically feasible or functionally acceptable, alternative chemicals that will enable a priority product to meet State and Federal safety and performance regulations.

For example, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet Federal Motor Vehicle Safety Standards (FMVSS). Any change in the composition of tires typically requires feasibility studies and lengthy, multiple tests to ensure that the tires continue to meet FMVSS. The chemical ingredients in tires are present because they impart critical functions to meet FMVSS and the composition of tires cannot be modified without great care. Changes in tire composition could affect critical attributes such as stopping distance, tire wear, tire fuel efficiency and other safety-related components.

DTSC further specifies in the Revised ISOR that the purpose of the Preliminary AA report is to provide adequate detail to ensure that the second stage of the AA will provide sufficient detail to support the selection of an alternative chemical. (Revised ISOR, page 140 of 225). Additionally, DTSC indicates in the Revised ISOR that entities are not required to fill data gaps during the first stage of the AA. Id.

Manufacturers are best suited to determine whether an alternative chemical exists that will enable the Priority Product to comply with other State and Federal safety and performance regulations. RMA recommends that DTSC review the Abridged AA Reports to determine whether a responsible entity has provided adequate justification for maintaining the Chemical of

Concern in the Priority Product and notify responsible entities if additional information is needed.

C. Responsible entities that submit an Abridged AA Report should not have to complete Step 3 in the first stage of the AA; Identification of Factors Relevant for Comparison of Alternatives. (Section 69505.4(b) and Section 69505.5(c))

DTSC has included in the April 2013 SCP proposed regulation an additional step in the First Stage of an AA. The First Stage of the AA now includes Step 3 which specifies that a responsible entity must identify factors relevant for comparison of alternatives. (April 2013 SCP proposed regulation, § 69505.5(c)). Relevant factors for comparison of alternatives includes consideration of whether the factor makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts. Responsible entities that determine based on available information that there are no technically feasible or functionally acceptable alternative chemicals for the CoC should not have to identify factors relevant for comparison of alternatives. RMA recommends DTSC exclude from the First Stage of the AA, Step 3 for entities who submit an Abridged AA Report.

III. RMA recommends that DTSC revise section 69503.4 (Priority Products Work Plan) to clarify that the Department will revise the work plan to add or remove product categories in response to public comments.

Section 69503.4, in the April 2013 SCP proposed regulation, specifies that DTSC will issue a Priority Product Work Plan that identifies the product categories DTSC will evaluate to determine which chemical-product combinations DTSC will add to the Priority Products list, within one year after the effective date of SCP regulations. The Priority Product Work Plan must include a general description of DTSC's decision to select the product category. DTSC will issue subsequent work plans no later than one year before the three year expiration date of the current work plan. Section 69503.4 also includes provisions for revising the work plan to add one or more additional product categories, and specifies that prior to issuing a final work plan, DTSC will hold a public work shop. However, section 69503.4 does not contemplate removal of chemical-product combinations.

Section 69503.2 (Product-Chemical Identification and Prioritization Factors) lists the factors DTSC will use to prioritize product-chemical combinations. These factors include: the potential for the public, aquatic, avian, or terrestrial animal or plant organism to be exposed to the Candidate Chemical(s) in the product and the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts. DTSC will consider a number of factors including the market presence of a product (statewide sales by volume, statewide sales by number of units, and/or intended product use(s), and types of age groups of targeted customers) to determine whether there is exposure to a Candidate Chemical in the Priority Product. (April 2013 SCP proposed regulation, § 69503.3). DTSC will base their decision to identify and list a priority product on information that is "reasonably" available.

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

> 17 (d) Public Input. Prior to issuing each work plan, the Department shall hold one or more
> 18 public workshop(s) to provide an opportunity for oral comment. <u>"The Department will revise each work plan, to add or remove product categories, based on public comment provided at the workshop."</u>

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

IV. <u>RMA strongly recommends DTSC revise section 69509 to adequately protect trade secrets and confidential business information</u>

RMA has continued concern that the April 2013 SCP proposed regulations are not sufficient to protect trade secrets and confidential business information. The April 2013 SCP proposed regulations require an extensive amount of information to support a claim of trade secret protection. These requirements as outlined in section 69509(a)(1) – 69509(a)(12) require information to substantiate a claim for trade secret protection that is beyond what is required by Federal law. Additionally, section 69509 is limited to protection for trade secrets rather than the broad category of confidential business information. We recommend that DTSC expand the scope of section 69509 to protect Confidential Business Information (CBI), which is, arguably broader than trade secrets.

Under the April 2013 SCP proposed regulations, a person who asserts a claim for trade secret protection must indicate how much the information would be worth to competitors and how easy it would be for competitors to acquire or duplicate the information. (§69509(a)(6)). This information is extremely difficult for companies to quantify. Consequently, the information provided is likely to be based on broad assumptions and/or guess-work. RMA recommends that DTSC limit the information required to substantiate a claim for trade secret protection to information that is required under federal regulations. For example, the information required to assert a claim for business confidentiality under the Chemical Data Reporting (CDR) rule does not require a responsible entity to provide information on how much the information would be worth to competitors or the ease by which competitors could acquire or duplicate the information. We recommend DTSC limit the information that is required to substantiate a claim for trade secret protection to the information required in the CDR rule. 76 Fed. Reg. 50816.

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

A "hazard trait submission" is defined as "any health, safety, or environmental study of, or health, safety, or environmental information regarding a chemical submitted to the Department." (April 2013 SCP proposed regulation, §69501.1(a)(37)). Hazard trait submissions include the "precise chemical identity." Id. DTSC specifies in the Revised ISOR, for the April 2013 SCP proposed regulations, that they have included the definition of a hazard trait submission to "implement and make more specific Health and Safety Code section 25257(f)." Health and Safety Code section 25257(f) specifies that hazard trait submissions for chemicals, including chemical ingredients, cannot be protected as trade secrets.

Section 69509(f) in the April 2013 proposed regulation limits trade secret protection to chemical names for an alternative chemical for which there is a patent that is pending, until the patent is granted or denied. This section essentially forces responsible entities to file a patent application in order to keep the information as a trade secret.

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

B. Department Review of Claims for Trade Secret Protection

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

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

RMA members have a property interest in the ingredients in their tires. Ingredients in tire formulations have a recognized economic value. Tire manufacturers spend significant resources developing new tire formulations to improve performance characteristics. Tires differ not because of taste, color or appearance, but because the tire industry is always striving to achieve better performance. Protection of confidential business information is important for tire manufacturers because they are always trying to gain an advantage over their competitors. All RMA members exercise practices to ensure tire formulations are kept confidential and not revealed to the public, and therefore competitors. Public disclosure of chemical identities will make the results of these investments in tire performance available to other companies who will not have to make similar investments.

V. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis (Section 69503.5(c) and Section 69505.3)

RMA continues to support the inclusion of an Alternatives Analysis Threshold in the final Safer Consumer Products regulation. Prior drafts of the Safer Consumer Product regulation included a *de minimis* exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1% for all other chemicals. RMA recommends that DTSC revise the April 2013 SCP proposed regulations to include a default Alternatives Analysis Threshold Exemption of 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence. Additionally, we recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit similar hazard traits or environmental/toxicological end points.

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

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

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

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

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

VII. Conclusion

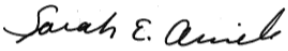
The tire manufacturing industry supports sustainable production and the development of methods to reduce the risks of exposure to chemicals used in products. However, the April 2013 SCP proposed regulation grants virtually unreviewable authority to DTSC to require substitution of chemicals in tires.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

As written, the April 2013 SCP proposed regulation cannot be applied to tires in a feasible way. RMA recommends that DTSC change the regulation to: (1) revise section 69505.8 to exclude Abridged AA Reports from the public comment process; (2) revise section 69505.4 to specify that Abridged AA Reports do not have to complete step 3 (Identification of Factors Relevant for Comparison of Alternatives) of the first stage of the AA as contained in section 69505.5; (2) revise section 69503.4 to ensure DTSC will revise the work plan to remove

chemical/product categories in response to public comment; (3) revise Article 9 to provide adequate protection for confidential business information which includes trade secrets; (4) revise section 69505.3 to provide a workable definition of the AA Threshold and (5) provide adequate time in section 69505.1 for tire manufacturers to research, develop, and test potential alternative chemicals in order to submit a Final AA Report.

RMA again thanks the California Department of Toxic Substances Control for this opportunity to comment on the April 2013 SCP proposed regulation. Please contact me at (202) 682-4836 if you have questions or require additional information.

Respectfully Submitted,



Sarah E. Amick
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Rubber Manufacturers Association

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April 25, 2013

Jackie Buttle
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulation, April 2013 revision

To Whom It May Concern:

On behalf of the San Francisco Estuary Institute (SFEI), I would like to thank you for the opportunity to provide comments on the Department of Toxic Substances Control (DTSC) proposed regulation for Safer Consumer Products (R-2011-02). The Institute's mission is to provide scientific support and tools for decision-making regarding water quality issues, and it was founded specifically to inform implementation of the Comprehensive Conservation and Management Plan for the San Francisco Estuary. One of the key focus areas in the Plan is pollution prevention and reduction. Since 1993, SFEI has administered the Regional Monitoring Program (RMP), the water quality monitoring program for San Francisco Bay. The RMP is a collaborative effort of many stakeholders, including regulatory agencies, dischargers, scientists, and the public. RMP stakeholders and SFEI scientists are working together to protect water quality in order to minimize health risks to aquatic life and people.

The watershed of San Francisco Bay covers approximately 40 percent of the State of California. Many of the thousands of chemicals that are used in consumer products are released into the environment and ultimately end up in the Bay. The reduction of the use of toxic chemicals in products through the Safer Consumer Products regulations is one of the easiest and most cost-effective methods for preventing environmental contamination. We applaud DTSC for its efforts and provide four comments on the regulation:

- Expand the lists identified in Section 69502.2 (Candidate Chemicals Identification) to include six additional lists.
- Establish a definition for "associated chemicals" to include degradates, metabolites, and reaction products of Candidate Chemicals, and use this phrasing consistently throughout the regulation text.
- Improve the definition of "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" to eliminate an inappropriately narrow focus on persistent and bioaccumulative compounds.
- Leverage existing information management efforts such as the California Environmental Data Exchange Network (CEDEN, www.ceden.org) to create a

chemical occurrence database to track studies that identify the presence or absence of Candidate Chemicals in the California environment.

These comments are discussed in detail below:

Expand the lists identified in Section 69502.2 (Candidate Chemicals Identification) to include six additional lists.

The following lists should be considered for addition:

1) Stockholm Convention list of Persistent Organic Pollutants (http://chm.pops.int/Convention/ThePOPs/tabid/673/Default.aspx)
2) Chemicals listed by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as having health or environmental hazards (http://www.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html)
3) Canadian Health Measures Survey Environmental Chemicals list (http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/chms-ecms-cycle2/overview-vue-eng.php)
4) CECs recommended for initial monitoring by the California State Water Resources Control Board's Science Advisory Panel (http://www.waterboards.ca.gov/water_issues/programs/swamp/cec_aquatic/docs/cec_ecosystems_rpt.pdf)
5) Oregon Priority Persistent Pollutant list (http://www.deq.state.or.us/wq/SB737)
6) Washington Puget Sound Chemicals in Toxics Assessment list (http://www.ecy.wa.gov/puget_sound/toxicchemicals/chemicals.html)

These lists will significantly improve the ability of DTSC to identify chemicals potentially harmful to the California environment.

Establish a definition for "associated chemicals" to include degradates, metabolites, and reaction products of Candidate Chemicals, and use this phrasing consistently throughout the regulation text.

Inconsistent use of phrases to describe candidate and associated chemicals, may inappropriately limit implementation of the regulation. For example, while in some instances a more complete phrase, such as "Candidate Chemical(s), or its/their degradate, metabolite, or reaction products," in other cases a more limiting phrase such as "chemical or its degradation products" is employed. The latter phrase ignores metabolites and reaction products, which in some cases may be the signals of exposure or the causes of health or environmental harms.

We recommend establishing a definition for "associated chemicals" that includes degradates, metabolites, and reaction products of a Candidate Chemical, and using

consistent phrasing such as "Candidate Chemical and/or associated chemicals" throughout the regulation to assure all such chemicals are appropriately included.

Improve the definition of "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" to eliminate an inappropriately narrow focus on persistent and bioaccumulative compounds.

The definition of "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" (Article 1. 69501.2. (67)) should be expanded or clarified to include the presence or detection of the chemical in the environment. Currently, the DTSC inappropriately limits this definition to chemicals that are persistent and bioaccumulative. Many chemical contaminants, particularly those commonly detected in wastewater, may not be considered persistent or accumulative by traditional definitions, but are instead considered 'pseudo-persistent' because of their continuous release to (and therefore continuous presence in) aquatic environments. Bisphenol A, a chemical that is metabolized rapidly, such that it is not considered persistent or bioaccumulative, but nevertheless can cause health harm with chronic exposure, is an example of one such chemical.

Recommended changes are provided using the underline and strikeout conventions observed in the latest version of the Safer Consumer Products regulation:

Section 69501.1. Definitions

(58) "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that meet the definition of reliable information:

(A) Monitoring data that shows the chemical or its degradation products, metabolites, or reaction products to be any of the following: 1. Present in household dust, indoor air, or drinking water, or on interior surfaces; 2. Present in, or released from, products used in or present in homes, schools, or places of employment; 3. Present, a~~A~~ccumulative or persistent in the environment; or 4. Present, a~~A~~ccumulative in aquatic, avian, animal, or plant species.

(D) Exposure or environmental modeling that indicates one or both of the following: 1. Exposure point concentration(s) associated with adverse impacts; or
2. Environmental presence or accumulation of a chemical.

Leverage existing information management efforts such as the California Environmental Data Exchange Network (CEDEN, www.ceden.org) to create a chemical occurrence database to track studies that identify the presence or absence of Candidate Chemicals in the California environment.

Development of a chemical occurrence database to track studies that have identified the presence/absence of Candidate Chemicals in the California environment is recommended. These chemical data are routinely generated, but are not readily accessible for comprehensive assessments. A centralized database or a federation of individual databases containing chemical occurrence data, and potentially hazard data as well, could be developed and maintained in collaboration with existing environmental monitoring programs in the State.

Existing information management efforts in the State, such as the California Environmental Data Exchange Network (CEDEN, www.ceden.org), could be leveraged to assist with this data compilation. The statewide CEDEN database is regularly populated and updated through automated replication procedures with databases managed at four Regional Data Centers (RDCs) located in the San Francisco Bay Area, South Coast, Central Coast, and Central Valley. This approach allows regional organizations with local expertise to be the stewards of their region's data. RDCs meet regularly to work on issues related to data vocabulary and standardization of data across the State. CEDEN also exchanges data with USEPA's Water Quality Exchange (WQX) and is working with various state and federal agencies (e.g., California Department of Fish and Game, US Geological Survey) on incorporating their existing databases into the CEDEN system. Currently, mostly water quality data are stored in CEDEN; however, one of CEDEN's goals is to incorporate new data types and more data on emerging contaminants. Since the infrastructure and standardization process already exists with CEDEN, working with this group would be a cost-effective and efficient approach to managing Candidate Chemical data.

We thank the Department for the opportunity to comment on the latest revision to the Safer Consumer Products regulation. We look forward to providing staff with scientific support and tools for decision-making regarding water quality issues as they relate to implementation of the regulation.

Sincerely,

Rebecca Sutton, Ph.D.
Senior Scientist

Meredith Williams
Interim Executive Director

San Francisco Estuary Institute
4911 Central Avenue
Richmond, CA 94804

April 25, 2013

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

Re: Safer Consumer Products Regulation

Dear Director Raphael:

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

The revised regulation is scientifically sound and is consistent with the feedback that DTSC has received from its science panel and peer reviews.

We believe that implementation of the regulation should be immediate and robust to meet expectations established by the enabling legislation, retain public support, and protect the environment and public health.

Sierra Club California reserves the right to exhaust all administrative remedies if the department does not go forward with the adoption of the regulations.

Thank you for the work you and your staff have put into developing these regulations.

Sincerely,

Annie Pham
Policy Advocate

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California Department of Toxic Substances Control
RE: DTSC Reference R-2011-02

Hello –

Regarding the Proposed Regulations for Safer Consumer Products, I am concerned that some provisions may actually impede the re-use of electronic products (notably computers) that could still have a great deal of practical useful life. As a nonprofit professional very interested in the availability of technology to underserved and low-income populations, I support much greater availability of ethically refurbished products.

To the point, I suggest a small but important change in the wording of section 69501.1, Definitions, "End-of-Life", number 30:

Current text: "End-of-Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first."

I'd request that the final word be changed from "first" to "LAST".

This could be very beneficial, by greatly expanding the volume of products remaining available in the consumer market.

Cordially,

Stephen Brown
Associate, Customized Programs Group
TechSoup: The Technology Place for Nonprofits and Libraries
http://www.techsoup.org

California Department of Toxic Substances Control,

This is regarding the proposed Regulations for Safer Consumer Products, DTSC Reference R-2011-02. I am concerned that some provisions may impede the reuse of electronic products that could still have a great deal of useful life. I am very interested in the availability of technology to underserved and low-income populations.

I suggest a small but important change in the wording of section 69501.1, Definitions, "End-of-Life", number 30:

Current text: "End-of-Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs first."

Proposed change: "End-of-Life is defined as the point when a product is discarded by the consumer or the end of the useful life of the product, whichever occurs <u>last</u>."

The final word in the phrase needs to be changed from "first" to "LAST".

Sincerely,

Jim Lynch
TechSoup Global, San Francisco

Toy Industry Association, Inc.
www.toyassociation.org

April 25, 2013

Ms. Jackie Butte
Acting Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Subject: Comments on the California Department of Toxic Substances Control – April 10, 2013 Revised Proposed Regulations: Safer Consumer Products

Dear Ms. Butte:

The Toy Industry Association (TIA) is pleased to provide comments regarding the Department of Toxic Substances Control (DTSC or Department) April 10, 2013 Revisions to the Proposed Regulations for Safer Consumer Products (Proposed Regulations) under Assembly Bill 1879 and Senate Bill 509 (2008). These comments are in addition to, and incorporate by reference TIA's previous comments submitted to the Department on July 20, 2010, November 1, 2010, December 3, 2010, December 30, 2011, May 30, 2012, October 11, 2012 and February 28, 2013.

TIA is a not-for-profit trade association representing more than six-hundred (600) toy makers, marketers and distributors, large and small, located throughout North America. California is responsible for roughly 22.0% of the nation's total toy industry activity, more than any other state. Additionally, Toy Industry Association members employ more than 32,000 employees in California with a direct economic impact of more than $6 billion to the state.

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

TIA appreciates the Department's efforts to attempt to address concerns, and the work it has invested in the development of this regulatory package. We remain concerned about the current structure and requirements of this proposed regulation, and continue to believe that

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without further changes many provisions will be unworkable and the regulation will not achieve its intended purpose.

The April 2013 revisions to the Regulation include few areas of substantive change. As such, TIA urges the Department to consider previous comments submitted detailing additional changes needed in order to create the transparency and predictability necessary to both operate and achieve the goals of a program of this magnitude.

TIA still recognizes major areas of concern that have not been addressed including, but not limited to:

- **Lack of exemption for inaccessible components;**
- **Inadequate protection for trade secrets and confidential business information;**
- **Categorical exclusion of children's products from the definition of "complex durable product";**
- **Regulatory duplication applicability;**
- **Overly cumbersome process for an Alternatives Analysis Threshold Notification and;**
- **Inclusion of retailers as responsible entities.**

Specific to the April 2013 revisions, TIA appreciates that the Department has improved the process for public comments on Alternatives Analysis (Sections §69505.8). TIA supports the Department review of public comments, and the revision providing that the public review and comment process is limited to Final AA Reports.

TIA still has concerns related to the AA process and feasibility of the timeframes for completion. As drafted, the Preliminary AA must be completed within 180 days, with a one-time possible extension. In our assessment, the Preliminary AA will require significantly more time in order to thoroughly identify and examine possible alternatives. Vetting each alternative to determine if it is viable and worthy of further consideration in the Final AA takes significant study and time per alternative. In addition, with more time to identify and consider various alternatives in the Preliminary AA, innovation is more likely. TIA requests that DTSC extend the time for the Preliminary AA to one year, with a status report required after 180 days, in order to give manufacturers the appropriate time to thoroughly assess all relevant alternatives.

TIA acknowledges the Department's clarification in the definition of Alternatives Analysis Threshold (AAT) (Section §69501.1). The language added stating that DTSC may specify an AAT greater than the Practical Quantification Limit (PQL) for contaminants, and set an AAT for intentionally-added ingredients is an improvement which has the potential to provide some predictability in the process and ease the burden for manufacturers. However, this is inconsistent with other states, such as Washington State, in approaches for determining applicability of the program. These inconsistencies remain an issue of concern for TIA.

Additionally, we still have concerns regarding the workability of the current Alternatives Analysis Threshold structure. TIA questions how DTSC expects entities to file an "AA Threshold Notification in Lieu of AA" stating with certainty that their priority product contains a priority chemical as a contaminant if it cannot be reliably and repeatedly measured, and how DTSC will determine the PQL which will vary and may differ between manufacturers of similar products.

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

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

TIA continues to urge the Department to seriously consider compromise and progress toward reaching a workable solution that is consistent with existing requirements in other states. Product safety is a vital consideration for toy manufacturers. A core requirement of our industry is to perform rigorous testing to stringent federal requirements and in many cases stringent international environmental and safety regulations. Considering the strict regulations and burdens already imposed on our industry consistency between states on key issues is critical to workable Green Chemistry Regulations

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

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

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

Respectfully,

Jennifer Gibbons
Director of State Government Affairs

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

Via E-Mail GCRegs@dtsc.ca.gov
25 April 2013

Jackie Buttle, Acting Regulations Coordinator
Department of Toxic Substances Control
Regulations Section
P.O. Box 806
Sacramento, CA 95812-0806

Re: Unilever Comments on Revised Text of Proposed Safer Consumer Products (SCP) Regulation

Dear Ms. Buttle:

I am contacting you with Unilever's comments in response to the revised text of the *Proposed Safer Consumer Products Regulations* released for public comment on April 10, 2013 by the California Department of Toxic Substances Control (DTSC).

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

We support the comments which these organizations are sending in separately, but there are several additional comments which we would like to make regarding the relatively few changes made in the April 10 draft.

Alternatives Analysis Threshold

DTSC proposed several changes to the Alternatives Analysis (AA) Threshold. In Section 69503.5(c), DTSC has included the ability for it to specify (1) an AA Threshold concentration for an intentionally added ingredient and (2) an AA Threshold concentration greater than the applicable Practical Quantitation Limit (PQL) for any Chemical of Concern (COC) that is a contaminant. Unilever agrees with this addition to the regulation and the revision of the definition for *Alternatives Analysis Threshold* under Section 69501.1(a)(12). We should have the ability to determine the safe level for intentionally added ingredients as well as contaminants in products. There will always be contaminants, many naturally occurring at very low levels, which can be measured by modern analytical methods. There must be a threshold for all these contaminants.

Definition of Reliable Information and Quality of Available Information in Determining Product-Chemical Combination

Unilever does not agree with the proposed changes to the definition of *Reliable Information* under Section 69501.1(a)(57). First, the only information that would be defined as reliable information would be "a scientific study or other scientific information."

All of the sources mentioned are appropriate for making proper and robust decisions. These include deliberative scientific bodies that review the information in studies and judge weight-of-evidence and other factors, such as the National Academies and reports from government agencies. Their assessments and conclusions can be considered reliable.

Unfortunately, defining everything from all other sources as “reliable” is scientifically inaccurate and has the potential to drive controversy into a program that is intended to be science-based. In particular, (A)1. Information “(p)ublished in scientifically peer reviewed reports or other literature” may not lead to the scientifically robust analyses. “Other literature” is too open-ended and could include significant amounts of unreliable and non-scientifically generated information.

Peer reviewed studies are not always scientifically robust and could be subject to significant bias by virtue of the credentials of the peer reviewers chosen. More importantly, not all scientific studies are designed to determine conclusions based on robust test designs with appropriate controls. They can just as easily be designed to show that a hypothesis has merit (i.e., a proof of principle evaluation) and warrants further, more robust study designs.

Unilever’s earlier comments discussed the need to only use studies which are determined to be the most reliable, using the globally accepted method for rating the quality and reliability of studies developed by the Organization for Economic Cooperation and Development (OECD). This methodology has been successfully used by the U.S. EPA in assessing high production volume chemicals. It is also the basis for assessing studies done on over 5000 chemicals submitted to the European Chemicals Agency as part of its REACh program.

Unilever believes it would be best for California to harmonize its regulations with the International approach under the OECD Manual.

Identification of Factors Relevant for Comparison of Alternatives

Unilever agrees with the addition of language to identify factors relevant for comparison of alternatives (Section 69505.5(c)). The authorizing statute (AB1879) specifies a broad list of life-cycle factors that should be considered as part of the alternatives analysis (the A-M factors). There is probably no situation where all of the A-M factors would have material differences among alternatives that are under consideration, and the reality is that in most cases there will probably only be a few relevant factors. The addition of a step to identify only the relevant factors that are necessary for comparison during the alternatives analysis is very pragmatic and should add to the efficiency of the program without diminishing protection of public and environmental safety.

Public Comments on AA Reports

The changes made to the ability for the public to comment on the Alternatives Analysis are a step in the right direction from the previous draft, with the addition of language describing the ability of the public to comment on Alternatives Analysis reports under Section 69505.8. We also believe it is appropriate for DTSC to screen the comments and identify which elements are necessary to be addressed. Even with this revised language, we still see significant issues with the potential to disclose business confidential information which could jeopardize a company’s ability to innovate and compete in an open marketplace.

Unilever’s recommendation, as made in our comments dated February 2013, continues to be that DTSC be the only group which can review and assess the full AA reports, since it is required to maintain business confidentiality and cannot disclose confidential business information contained in a company’s submission. In supporting this recommendation, we stated the following:

> “the general public will not be able to understand, in the depth required, all the technical and economic information which leads the manufacturer to the best decision in the AA

process. Companies employ experts in chemistry, toxicology, environmental toxicology, microbiology, process engineering, chemical engineering, procurement, manufacturing, transportation, finance, etc. to help define, develop, and then launch new products. Because companies do not want to divulge information, which it considers confidential, to the general public and thus, to their competitors, the public AA reports will be subject to considerable redaction and therefore have limited utility."

Conclusion

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

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

Regards,

Dr. Jack Linard
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Unilever
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cc: Dr. Patrizia Barone, Director Regulatory Affairs Unilever NA

WORKSAFE
safety, health, and justice for workers

Jackie Buttle
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April 25, 2013

Dear Ms. Buttle:

Please accept this submission in response to the April 10, 2013 revisions of the proposed *Safer Consumer Products Regulations*, DTSC reference number R-2011-02.

Worksafe has submitted comments about these long-overdue regulations for more than three years, including earlier informal and formal drafts in 2012 and 2013.

With this letter, we also incorporate by reference all our prior comments about these regulations, including, but not limited to, those submitted about the formal drafts of the regulations dated October 11, 2012 and February 28, 2013, and those submitted about informal drafts dated December 30, 2011 and May 28, 2012. By reference, we also incorporate Worksafe's comments submitted to DTSC about plans to implement AB 1879 prior to the Brown Administration.

At this point, our message is focused: It's time to put the regulations on the books. Get this process started, evaluate it, and make improvements as needed. Stop pandering to the chemical industry and forgetting that there are many companies in California that actually welcome these regulations.

The people of California -- workers, consumers, employers and the general public -- have waited far too long for these new rules to reduce the use of toxic substances in some products they use. The Department has already bowed to many of the claims about what the chemical industry requires or believes. It's time to remember this green chemistry initiative is about public health, not private profit. Where profit is involved, it should be for doing the right thing, not adversely affecting people's health and that of their communities and environment.

The current SCPR proposal has significant weaknesses that we noted in all our earlier comments, and for which we recommended improvements. DTSC incorporated a few of those recommendations along the way. Since the missing ones would better protect environmental, public, and occupational health, we have incorporated our previous comments as stated above.

To keep things short, Worksafe supports the comments from the CHANGE coalition, of which we are a member.

To supplement the coalition's comments, we again vehemently disagree with the re-naming of the list of chemicals of concern. It's a sop to industry that only will undermine the usefulness of these regulations; the phase also deceives the public about the true nature of these authoritative lists.

When it comes to "economically feasible", DTSC can find better examples of the definition or similar ones. For example, the Chemical Safety Board's recent interim report about the Chevron refinery fire uses a variation of the U.K. Health and Safety at Work Act's "as far as reasonably possible". The phrase has a specific legal meaning (see Edwards vs. The National Coal Board, 1949). It also is used in legislation around the world to deal with the economic feasibility of dealing with hazards. At the very least, DTSC needs to ensure that "economically feasible" goes past the company's bottom line and accounts for externalized costs that are part of what these regulations are designed to reduce.

On the point about review of petitions, we have one addition to CHANGE's comments. Opponents of comprehensive chemical lists -- the chemical industry in general -- already are on the offensive. Their actions include the recent court case involving the state Chamber of Commerce and styrene industry taking on Prop 65's use of IARC 2B lists, the styrene and formaldehyde industries' efforts to remove their substances from listing by the National Toxicology Program's 12th Report on Carcinogens, and the proposed bills in the California legislature that seek to undermine Prop 65. This regulation should not give them another avenue to hide information about hazards.

Please let me know if you have questions.

Sincerely

Dorothy Wigmore, MS
Occupational Health Specialist
Worksafe