

**15-DAY NOTICE ON ESPR AND EPC
LIST OF PUBLIC COMMENTERS**

#	NAME OF ENTITY	DATE REC'D	LATE
1	Airlines for America	3/28/2013	
2	Alliance of Automobile Manufacturers	3/28/2013	
3	American Chemistry Council	3/28/2013	
4	Association of Global Automakers	3/27/2013	
5	Boots Retail USA	3/27/2013	
6	Consumer Specialty Products Association	3/28/2013	



Airlines for America™

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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.

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

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

¹² See ESRP 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,

A handwritten signature in black ink, appearing to read "Tim", with a large, sweeping initial "T" and a smaller "A" following it.

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



AUTO ALLIANCE
DRIVING INNOVATION®

March 28, 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 Additions to the Rulemaking File (R-2011-02/OAL
File No:Z-2012-0717-04)

Dear Ms. Buttle:

On behalf of the Alliance of Automobile Manufacturers (“Alliance”), I am pleased to submit the following comments in response to the latest additions to the Department’s rulemaking file for the Safer Consumer Product regulations (the “Proposed 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 efforts put forth to date, and embraces the goals and vision for safer consumer products embodied in California’s Green Chemistry Statute (the “Statute”).

The Alliance has grave concerns with the piecemeal processing and segmented public review periods for the Proposed Regulations. We have spent considerable time and resources to understand the goals, process and criteria that the Department is creating to implement the Statute, and to ensure that we are providing thoughtful comments that will result in a practical and workable set of regulations. Our task has been made most difficult, if not impossible, with the segmented and piecemeal commenting process. This latest release of nine external scientific peer review reports gives us only 15 days to review. It is simply not sufficient time to retain a scientist consultant to provide expert counsel, determine whether these external opinions are scientifically supported, or how they fit into the context of the entire Proposed Regulation.

Even more troubling, however, is the recent solicitations by the Department encouraging stakeholders to comment on alternatives assessment (AA) guidance being prepared by another state. See *Exhibit A: March 15, 2013 DTSC Solicitation for Comments and Exhibit B: March 5, 2013 DTSC Solicitation for Comments*. Specifically, the Department is requesting that stakeholders concerned about how the State of California will implement AA under the Proposed Regulations should participate and comment on the State of Washington guidance because “DTSC staff have participated in the effort because much of the information may be relevant to the Alternatives Analysis guidance we will be preparing.” *Excerpt from Exhibit A*. The document the Department is requesting review on is entitled, “Guidance for Alternatives Assessment and Risk Reduction” prepared by the Washington State Department of Ecology, under the auspices of the Interstate Chemicals Clearinghouse (IC2), which an association comprised of the environmental agencies of 11 states, including the California Environmental Protection Agency, as well as local and tribal governments, academia, and NGOs. See <http://www.newmoa.org/prevention/ic2/aaguidance.cfm>.

As we have previously commented, the AA is a critical and central compliance component of the Proposed Regulations, and any guidance on how stakeholders are to prepare an AA must be included in the Proposed Regulations so that industry can understand how Department intends to regulate it, what requirements it is planning on imposing, and the criteria and standards by which Department will judge compliance. The California Administrative Procedure Act (“APA”), Cal. Gov. Code §11346 *et seq.*, establishes basic minimum procedures agencies must follow when adopting new regulations. The minimum procedures include providing to the public a copy of the express terms of the regulations and an initial statement of reasons for proposing the regulations. *Cal. Gov. Code §11346.2*. Agencies must also give the public at least 45 days to comment on proposed regulations and initial statement of reasons. *Cal. Gov. Code §11346.4*. By releasing segments of the complex and ambitious regulations for public review in short, isolated spurts, the Department effectively deprives the public of an opportunity to understand and provide meaningful input on the totality of the Department’s plan to implement the Statute, depriving the public of due process of law.

We again urge the Department to follow the APA in adopting guidance to implement the Statute. The Alliance submitted extensive comments on all prior versions of draft regulations, and hereby incorporates each of its previous comments by reference in this letter. This latest 15 day request for comment severely compounds the due process problems from this segmented rulemaking. From the segmentation of the definitions of hazard traits in a separate rulemaking conducted by the Office of Environmental Health Hazard Assessment, the isolated revised Initial Statement of Reasons, the two separated and short scientific peer review comment periods, and the request to comment on guidance being prepared by the State of Washington, stakeholders were presented with bits and pieces of information in a manner that precluded meaningful comment on this ambitious and far-reaching regulation.

The Alliance seeks to have a meaningful opportunity to provide thoughtful comments to the Department’s Proposed Regulations. Throughout the regulatory development process, the Alliance has consistently advocated for revisions that will render the Proposed Regulations more

Ms. Buttle, DTSC

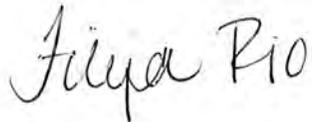
March 28, 2013

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effective, efficient and expedient, while maximizing the potential for environmental benefits envisioned by the Statute.

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

Sincerely,

A handwritten signature in cursive script that reads "Filipa Rio".

Filipa Rio
Director, Environmental Affairs

Attachments

Exhibit A: March 15, 2013 DTSC Solicitation for Comments

Exhibit B: March 5, 2013 DTSC Solicitation for Comments

From: Joelson, James@DTSC [<mailto:James.Joelson@dtsc.ca.gov>] **On Behalf Of** events@DTSC
Sent: Friday, March 15, 2013 10:02 AM
To: events@DTSC
Subject: Opportunity to comment on the IC2 Guidance for Alternatives Assessment and Risk Reduction

Greetings,

This repeat note is to encourage comments to the IC2 Guidance for Alternatives Assessment and Risk Reduction. DTSC staff have participated in the effort because much of the information may be relevant to the Alternatives Analysis guidance we will be preparing. Given that, your comments will help us in developing the SCP guidance. Please do not frame comments to the IC2 draft based on the California requirements, but focus on the methods and tools and approach as it generally applies to alternative assessment.

The following message is being forwarded to participants of the DTSC Alternatives Assessment Workshop, held in October 2012, to help keep you informed of current developments in AA:

The Interstate Chemicals Clearinghouse and participating member states have released a draft copy of the Guidance for Alternatives Assessment and Risk Reduction. The document is available for download at: <http://www.newmoa.org/prevention/ic2/aaguidance.cfm>. The document can be downloaded either as a complete document or separately as the guidance and supporting documents.

The public and interested stakeholders are invited to review the draft guidance and provide input. The public comment period will end on April 19, 2013. If you have questions, please contact either Dr. Alex Stone, Guidance Team lead at (360) 407-6758 or via email at alex.stone@ecy.wa.gov or Linda Glasier, Stakeholder Coordinator at (360) 407-7355 or via email at linda.glasier@ecy.wa.gov.

From: Joelson, James@DTSC [<mailto:James.Joelson@dtsc.ca.gov>] **On Behalf Of** events@DTSC
Sent: Tuesday, March 05, 2013 11:38 AM
To: events@DTSC
Subject: Download a draft copy of the Guidance for Alternatives Assessment and Risk Reduction

Greetings,

The following message is being forwarded to participants of the DTSC Alternatives Assessment Workshop, held in October 2012, to help keep you informed of current developments in AA:

The Interstate Chemicals Clearinghouse and participating member states have released a draft copy of the Guidance for Alternatives Assessment and Risk Reduction. The document is available for download at: <http://www.newmoa.org/prevention/ic2/aaguidance.cfm>. The document can be downloaded either as a complete document or separately as the guidance and supporting documents.

The public and interested stakeholders are invited to review the draft guidance and provide input. The public comment period will end on April 19, 2013. If you have questions, please contact either Dr. Alex Stone, Guidance Team lead at (360) 407-6758 or via email at alex.stone@ecy.wa.gov or Linda Glasier, Stakeholder Coordinator at (360) 407-7355 or via email at linda.glasier@ecy.wa.gov.



March 28, 2013

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

Re: American Chemistry Council Comments on External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products Regulation as Revised 15-Day Public Notice and Comment Period (R-2011-02)

Dear Ms. Von Burg:

The American Chemistry Council¹ (ACC) welcomes the opportunity to provide comments on the revised External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products Post-Hearing Changes (R-2011-02). As noted in our previous peer review comments, dated January 4, 2013 (attached), ACC is encouraged that the Department of Toxic Substances Control (DTSC) submitted scientific portions of the proposed rule to external scientific peer reviewers.

ACC would like to reiterate that although we are pleased that DTSC has proceeded to implement scientific peer review as required by HSC §57004, the peer reviewers' reports are not indicative of a holistic approach to an external scientific peer review of the proposed revised Safer Consumer Products Regulation.

As articulated in HSC §57004, California specifies that agencies must enter into an agreement with certain institutions (National Academy of Sciences, the University of California, the California State University or other appropriate body) when initiating a peer review process of scientific portions of proposed regulations. However, the statute is not clear as to the specific criteria that are to be used to first identify potential peer reviewers, the process to select the final

¹ The business of chemistry is a \$760 billion enterprise and a key element of the Nation's economy. It is one of the Nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy – designed to address major public policy issues, and health and environmental research and product testing.



peer reviewers and what role DTSC and Cal/EPA should play in these processes. For transparency purposes, and to assure a balance of expertise and perspectives, ACC requests that DTSC disclose the criteria used to identify and select peer reviewers, including the processes used to address any conflicts of interest or bias.

In addition, ACC requests clarification as to why DTSC's scientific peer review did not address 1) the scientific portions of the proposed regulations pertaining to ascertainment of data reliability and study quality and the processes for integrating results across studies, and 2) the scientific portions of the proposed regulations pertaining to evaluation of aggregate and cumulative risk.

Regulatory determinations will require Cal/EPA to implement scientific procedures, such as those employed by the U.S. Environmental Protection Agency (U.S. EPA)² and Food and Drug Administration³ or the European Chemicals Agency (ECHA)⁴ to evaluate studies to determine the quality, reliability and adequacy of scientific information. In addition, where multiple studies exist, particularly if results across studies significantly differ, or where results from exposure modeling contrasts with exposure monitoring studies, Cal/EPA will need to integrate such results using a scientific process for determining the overall weight-of-the-evidence for a particular metric, effect or outcome. It is inexplicable for both DTSC and OEHHA to continue to ignore the importance of these scientific evaluation processes for determining the overall weight of the scientific evidence, which clearly is an integral part of the scientific evaluation procedures of the proposed regulatory process.⁵ Thus, this process is a scientific evaluation procedure which is well within the scope of the proposed regulatory process, therefore is subject to HSC §57004, and should be addressed as such by DTSC.

Secondly, both aggregate and cumulative risk are scientific evaluation procedures and therefore fall within the scope of HSC §57004. Aggregate and cumulative risk determination procedures require scientific evaluation of hazards, scientific evaluation of exposures and scientific methods to combine risks spatially and temporally across routes and media (aggregate and cumulative) and across chemicals (cumulative). Clearly, DTSC's exclusion from peer review of these scientific portions of the proposed regulations falls short of full compliance with HSC §57004.

Independent scientific peer review provides important feedback that needs to be evaluated and addressed when preparing the final rule. ACC is hopeful that DTSC, as required by HSC

² <http://www.epa.gov/hpv/pubs/general/datadfin.htm>.

³ Rulis AM and Levitt JA. (2009). FDA'S food ingredient approval process: Safety assurance based on scientific assessment. *Regulatory Toxicology and Pharmacology*. 53: 20-31.

⁴ ECHA REACH Guidance on information requirements and chemical safety assessment; http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1259066690. Volume 3: Chapter R.4 Evaluation of available information.

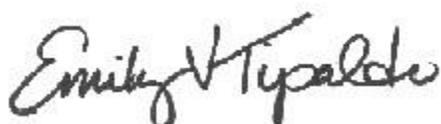
⁵ Comments of the ACC on Proposed Safer Consumer Product Regulation (July 27, 2012 (R-2011-02)) October, 11, 2012, p.2.



§57004, will explain the basis for arriving at determinations in the adoption of the final rule, particularly the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.⁶

If you have any questions or concerns regarding the comments, please contact me at Emily_Tipaldo@americanchemistry.com or 202-249-6127.

Sincerely,



Emily Tipaldo
Manager, Regulatory and Technical Affairs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA (SectyRodriquez@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)
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
(Mike.Rossi@gov.ca.gov)
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
(Cliff.Rechtschaffen@gov.ca.gov)
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor
(Martha.Guzman-Aceves@gov.ca.gov)

⁶ California Health and Safety Code Section 57004(d)(2).



March 27, 2013

SUBMITTED VIA EMAIL TO GCREGS@DTSC.CA.GOV

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

RE: Comments on the Safer Consumer Product Program's External Scientific Peer Review Reports and the Environmental Policy Council's Resolution; Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04

Dear Ms. Buttle:

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 External Scientific Peer Review of the Safer Consumer Product (SCP) regulations released on March 13, 2013 and the Environmental Policy Council's Resolution of February 28, 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.

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 America Subaru of America, Inc., ADVICS North America, Inc., Delphi Corporation, Denso International America, Inc., and Robert Bosch Corporation. We work with industry leaders, legislators, and regulators in the United States to create public policies that improve motor vehicle safety, encourage technological innovation, and protect our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. For more information, visit www.globalautomakers.org.

Global Automakers has been actively engaged in the development of the Safer Consumer Products 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 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.

We appreciate that DTSC has convened another round of external scientific peer review for the newly revised SCP regulations released on January 29, 2013 and are providing detailed comments and recommendations in the Attachment 1. We are also providing comments regarding the California Environmental Policy Council's determination regarding multi-media evaluation in Attachment 2.

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

**ATTACHMENT 1: External Scientific Peer Review Reports of
DTSC's Revised Safer Consumer Products Regulations**

**Comments Submitted by
*The Association of Global Automakers, Inc.***

We appreciate that DTSC has convened another round of scientific peer review for the newly revised SCP regulations released on January 29, 2013.¹ We believe that a number of the reviewers have raised significant issues with the integrity and soundness of the scientific knowledge, methods and practices proposed in the regulations. We have addressed them each in the detailed comments that follow and urge that DTSC adopt the recommendations that we have put forward.

Peer Review Topic 1: "The use of the chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Candidate Chemicals list."²

Global Automakers is pleased to see that there is consensus on the bifurcation of the lists used by DTSC as the starting point for the selection of Chemicals of Concern (COCs). Making a clear and purposeful distinction between Candidate Chemicals (CCs) and COCs is critical to ensure that the public understands that the CC list is not a list of chemicals that have been shown to cause adverse effects when used in consumer products. As pointed out in the External Scientific Peer Review (ESPR) Report submitted by John Applegate, "it is clearer that chemicals only become Chemicals of Concern when they are associated with a product, and thus with *exposure* from a product".

A number of reviewers have identified concerns about the list(s) that both they and the public have raised during the development of these regulations. They continue to be concerned about the magnitude of the lists and the substantial burden this will place on DTSC and the regulated community in trying to winnow those lists down to a focused, risk based and high priority set of COCs; Global Automakers shares these concerns. A second and no less serious concern that has been identified in the Peer Review Report submitted by Dr. George Gray is that "the focus on existing lists does not address the seeming contradiction of using certain hazard traits to develop the list while not acknowledging that many chemicals may not have been tested for the trait". DTSC has made clear that they want the SCP regulations to be forward-looking. The focus on these existing lists, rather than a forward-looking approach that focuses on new chemicals and new technologies will undoubtedly result in regrettable substitutions that will need to be addressed further down the road. As summed up by Dr. Gray, "A list

¹ We have not been able to locate the original document transmitted to the Peer Reviewers in the regulatory file and suggest that this document should be added along with the ESPR Reports. As a result, we reference the "Notice" as included in the comments submitted by Dr. Norman Christensen.

² Comment submitted by Christensen includes original memo from: Wong, Jeff, "Notice To Proceed With Scientific Peer Review For Safer Consumer Product Regulations, Attachment 2: Scientific Factors: Peer Review Topics. Attachment 2 contains the topics that DTSC is requesting the peer reviewers to comment on," dated January 30, 2012.
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/CONSOLIDATED-LIST-OF-ESPR-REPORTS-2.pdf>, pages 14-18.

built from lists of chemicals with existing toxicologic or policy concerns will fundamentally encourage the use of new and less tested materials.” As one of the two peer reviewers with extensive experience in managing a regulatory science program, we would encourage DTSC to carefully consider his comments on this topic. Global Automakers continues to recommend that DTSC:

- (1) Focus on a smaller set of chemicals and endpoints
- (2) Remove from consideration chemicals that are under review by international or federal regulatory authorities
- (3) Provide exemptions for chemicals in products where there is no exposure pathway
- (4) Provide exemptions for chemicals that are present unintentionally
- (5) Refrain from recommending untested alternatives as viable replacement chemicals

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

Global Automakers shares the concerns identified by a number of the peer reviewers that replacing the term “ability to” with the term “potential to” creates yet another degree of uncertainty in the priority setting process. As pointed out by Mr. Applegate, “The challenge confronting the rule makers, therefore, is how to assure that the term ‘potential’ means something more substantial than mere speculation, without depriving ‘potential’ of the expansiveness necessary to fulfill the preventive legislative mandate.” Dr. Gray shares that same concern and further states that “the change of the criterion from ‘ability to’ to ‘potential’ decreases the precision with which priority products can be identified... and increases the possibility of arbitrary judgments...” The change from “ability to” to “potential to” fundamentally alters the criteria and lowers an already low threshold to one that can arguably be met by any of the CC or COC listed chemicals, considering that any chemical can “potentially” be toxic, even water, depending on dosage.. Any of the COC or CC chemicals could be assumed to have the potential to contribute to or cause adverse effects given the nature of the lists. By altering this key criterion, DTSC has de facto eliminated one of the priority setting screens.

Global Automakers strongly recommends that DTSC reconsider this change and return to the more scientifically rigorous finding of “ability to contribute to or cause adverse public health and environmental impacts”, proposed in the July 2012 Version of the SCP Regulations.

³ *Ibid*, 17.

Peer Review Topic 3: “The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical.”⁴

As recognized by a number of the reviewers, the effect of adopting the practical quantitation level (PQL) as the Alternatives Analysis Threshold (AAT) for COCs is to greatly limit the scope of the previously proposed AAT exemption and to put in place a constantly shifting target. The PQL for any specific chemical will become lower as technology advances. In addition, this proposed approach ignores the concepts of both hazard and exposure and critical scientific parameters such as the toxicity or the exposure potential of the compound. Global Automakers similarly commented on the PQL in our comments on the January 2012 Revised SCP Regulations, which we submitted on February 28, 2013. Reviewers such as Dr. Gray, who have had experience administering regulatory chemical control programs recognize the lack of scientific integrity with this proposed approach and have recommended that DTSC utilize a more risk based approach to the AAT.

Global Automakers urges DTSC to weigh the input from these reviewers heavily. Dr. Gray, in his position as Assistant Administrator of the Office of Research and Development (ORD) at the U.S. Environmental Protection Agency (EPA) has first-hand experience in managing a national level priority setting and risk assessment program. To dismiss that experience and his valuable input to this process would be a mistake. If DTSC can enhance the likelihood of success of this program by building on the successes and bypassing the mistakes of similar regulatory schemes then we urge you to do that. We recommend that DTSC adopt the AAT of 0.1% proposed in earlier versions of the SCP regulations.

Peer Review Topic 4: “The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.”⁵

Global Automakers continues to support a more quantitative approach to determine adverse impacts or effects. As currently proposed, the regulations allow for so much flexibility on DTSC’s determinations that there is no transparency in the process and no opportunity for replication. It is quite likely that determinations made by DTSC will become “staff dependent” and that outcomes will be unpredictable and non-replicable. A number of reviewers have raised these same concerns, and Global Automakers urges DTSC to reconsider the qualitative aspects of the priority setting approach and to the extent possible, build in quantitative criteria.

⁴ *Ibid*, 18.

⁵ *Ibid*, 18.

Conclusion

Global Automakers believes that the peer reviewers have provided DTSC with valuable feedback and suggestions for fine-tuning the SCP regulations. These reviewers have technical expertise on many of the topics on which they have commented. Global Automakers recommends that DTSC carefully consider the peer reviewers' comments, and we recommend that DTSC adopt the recommendations that we have put forward in today's comment.

**ATTACHMENT 2: The Environmental Policy Council's Resolution
Regarding the Need for a Multi-Media Life Cycle Evaluation for the
Safer Consumer Product Regulation**

**Comments Submitted by
*The Association of Global Automakers, Inc.***

California Health and Safety Code Section 25252.5 requires the Department of Toxic Substances Control (DTSC) to coordinate the preparation of a multi-media lifecycle evaluation of the Safer Consumer Product (SPC) regulations and submit it to the California Environmental Policy Council (EPC) for review. Only if the EPC, following an initial evaluation of the proposed regulations, conclusively determines that the proposed regulations will not have any significant adverse impact on public health or the environment can DTSC be exempted from this requirement. Preparation of a multi-media lifecycle evaluation and its review by EPC is a critical component part of the guiding statute, AB 1879. The statutory requirement demonstrates the Legislature's intent that this complex regulatory program be evaluated closely by the Council, particularly in terms of unintended impacts.

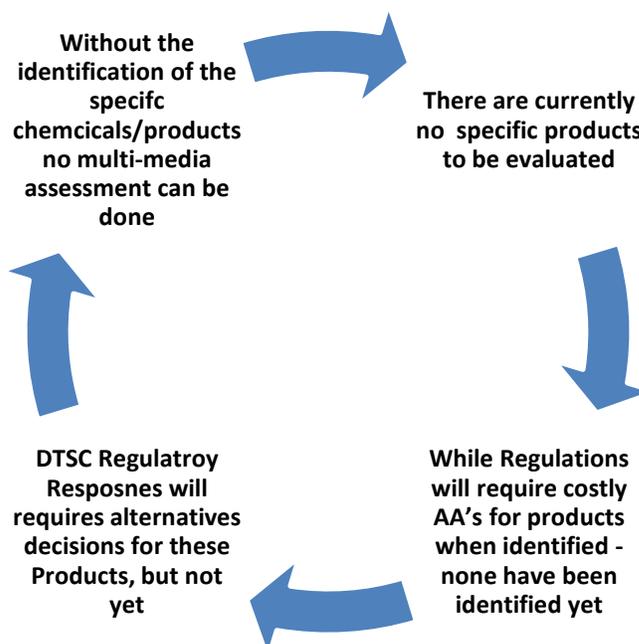
On February 28, 2013, the EPC issued a resolution determining that the SPC regulations being issued by DTSC "will not have any significant adverse impact on public health or the environment" (State of California, California Environmental Protection Agency, Environmental Policy Council, Resolution, February 28, 2013). The EPC issued this determination immediately after a public hearing where multiple presenters shared their concerns and asked the EPC to require the multi-media assessment. The consequence of this determination is that DTSC will not be required to perform a multi-media lifecycle evaluation of the regulations. Global Automakers is concerned about the specifics of this determination, as well as the precedent that the EPC has set in exempting this type of regulatory action from the multi-media assessment requirement.

The EPC has determined that the SCP regulations only (1) 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; (2) 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 the chemical of concern; and (3) specify the range of regulatory responses that DTSC may take following the completion of the alternative analysis. EPC has further determined that "DTSC's adoption of the proposed regulations will not affect any specific chemicals or products, and therefore will not result in any direct physical impacts to public health or the environment" (State of California, California Environmental Protection Agency, Environmental Policy Council, Resolution, February 28, 2013).

Both DTSC in its presentation of the proposed regulatory scheme to the EPC and the EPC in its determination, have followed a circular logic paradigm that purports that (1) prior to implementing the regulations and selecting the Priority Products that will be required to undergo the rigorous and costly Alternative Assessment (AA) process, there are no specific products to be evaluated; (2) while the regulations will require that manufacturers, importers, assemblers and retailers perform costly and

potentially uninformed AAs for products once they are identified, no products have yet been identified; (3) DTSC Regulatory Responses will require manufacturers, etc. of those products to switch to alternatives, potentially making uninformed substitution decisions, but none have been made yet; and (4) without the identification of the specific chemicals/products that DTSC will target, no multi-media assessment can be done. This logic is depicted in Figure 1 below. This line of reasoning is faulty and presumes that DTSC could not anticipate and assess the impacts of uninformed substitutions, such as, the lack of availability of viable alternatives and the lack of availability of replacement parts to repair complex durable goods for continued safe consumer use, as well as other predictable outcomes. It is clear that DTSC has a large universe of chemicals in mind – in fact they have proposed a list of over 1200 chemicals that would immediately become Candidate Chemicals (CC) upon promulgation of this rule. There is an immediate impact from that very listing which is to steer consumer product manufacturers away from those chemicals and towards potentially newer and untested alternatives. It is also clear that DTSC intends to identify five (5) products and potentially hundreds of Chemicals of Concern (COCs) shortly after promulgation of this rulemaking. It is disingenuous to disregard this clear and predictable outcome and to assume that DTSC does not already know with reasonable certainty what those chemical / product combinations will be.

Figure 1. Decision Logic for Exempting DTCS from the Multi-Media Assessment Requirement



For a regulatory program as broad and complex as the one being proposed by DTSC, a comprehensive multi-media evaluation is a necessary safeguard to ensure that the regulations do not result in unexpected and significant adverse impacts. This evaluation must “be based on the best available

scientific data, written comments submitted by interested persons, and information collected by [DTSC] in preparation for adopting the regulations..." Cal. Health & Safety Code § 25252.5(b).

During the course of the development of these regulations, DTSC has received hundreds of comments that have cautioned against some of the unintended consequences of these regulations. DTSC should have presented these comments to the EPC, and the EPC, in turn, should have given them serious consideration before reaching their determination. In addition, comments were also submitted directly to the EPC prior to its determination, which should have been addressed by DTSC and EPC as part of the determination.¹

If the EPC truly believes that it is not possible for DTSC to address some of the very clear potentials for adverse impacts at this point in the rulemaking process, then at a minimum, the EPC should clearly stipulate that once chemical and product combinations have been identified, the DTSC must come back through the process with the required multi-media assessment for each chemical and product combination.

In its February 28, 2013 Resolution, the EPC included a statement that directs:

WHEREAS, if DTSC, in finalizing its Safer Consumer Products regulations, fundamentally alters the regulations in such a manner that the regulations directly affect specific consumer products, DTSC shall resubmit its regulations to the Council.

Global Automakers requests that EPC clarify this provision of the Resolution to ensure that when DTSC develops its first and any subsequent Priority Product list, that DTSC will then be required to perform a multi-media lifecycle analysis based on the full SCP regulations applicable to the products listed.

¹ The Association of Global Automakers submitted comments to the CEPC on the need for multimedia life cycle evaluation for the SCP regulations through our coalition, The Durable Goods Coalition, on February 27, 2013. The Durable Goods Coalition recommended that DTSC should prepare and submit a multimedia life cycle evaluation to CEPC, as required under AB 1879. We incorporate these comments by reference in today's comment.

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March 27, 2013

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

RE: Comments on External Scientific Peer Review Reports

Reference Number: R-2011-02

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

Boots Retail USA appreciates the opportunity to provide comments on the External Scientific Peer Review Reports concerning the Post-Hearing Changes made to the Proposed Regulations:

The External Scientific Peer Review Reports underscore the need for established science-based procedures for decision-making, such as those used by the Environmental Protection Agency (EPA) and the European Chemicals Agency (ECHA)

In our comments of February 27, 2013, on the Post Hearing Changes made to the Proposed Regulations, we noted the need to incorporate the same science-based procedures that supported the regulatory decisions to include the chemicals that are now in the proposed Candidate Chemicals List. We noted further that the terminology used in the Proposed Regulations opens the door to non-scientific – hence potentially arbitrary and capricious - decision-making concerning changes to the Candidate Chemicals List and the establishment of and changes to the Priority Products List.

We note that the Reports of several external peer reviewers underscore our concerns. In comments made on the proposed evaluation criteria in Article 3 for prioritizing product-chemical combinations as potential Priority Products:

- Deborah H Bennett, Ph.D, at the University of California, Davis, states, “There appears to be no definition for significant or widespread and I feel this *criteria can be interpreted in a variable manner* by the regulating body and the regulated entity.”
- George M. Gray, Ph.D. at George Washington University, in his comments notes, “In my view the change of the criterion from “ability to” to “potential” ... *increases the possibility of arbitrary judgments* about what evidence constitutes “potential”.”

Ansis M. Helmanis, Esq.
Special Counsel

In comments submitted concerning the use of the terms “adverse” impacts and “adverse effects” as used throughout the Proposed Regulations:

- William H. Farland, Ph.D., at Colorado State University, reiterates, “Finally, as discussed in my previous review, the discussion of *what constitutes “adverse” continues to need further clarification.*”
- George M. Gray, Ph.D. at George Washington University, concurs, “The *term “adverse” is a confusing mix* of qualitative, quantitative, and theoretical effects *with no concrete standard that must be met.*”

The concerns expressed in the above mentioned comments by these external peer reviewers are grounded in the fact that the regulatory framework in the Proposed Regulations has no established equivalent in the internationally recognized science-based procedures that govern the decisions made concerning chemical-based hazards by regulatory agencies such as the EPA and Europe’s ECHA.

The confusion as to terminology and process in the Proposed Regulations resulting from the lack of established and recognized scientific evaluation procedures threatens the well-intentioned efforts of the DTSC to protect the public from potential chemical-based hazards and risks to users, consumers and third parties, including the environment.

Sincerely,

Ansis M. Helmanis

cc: Steve Lloyd, CEO, Boots Retail USA



Representing Household & Institutional Products

Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

March 28, 2013

Via E-Mail: GCRegs@dtsc.ca.gov

Ms. Jackie Buttle, Acting Regulations Coordinator
Regulations Section
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P.O. Box 806
Sacramento, CA 95812-0806

Re: External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products (Z-2012-0717-04)

Dear Ms. Buttle:

The Consumer Specialty Products Association (CSPA)¹ appreciates the opportunity to review and provide comments on the External Scientific Peer Review Reports for the Scientific Basis of the Safer Consumer Products Regulation. CSPA and our member companies have been actively engaged in the advancement of California's green chemistry program over the past five years, from the announcement of the Green Chemistry Initiative, through the adoption of the 2008 legislation (SB 509 and AB 1879) which provides the statutory basis for this regulation, and through the years-long regulatory development process.

CSPA members are committed to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. As stated in previous submissions regarding the Safer Consumer Products Regulation, CSPA and our members support the broad goals of the Green Chemistry Initiative and look forward to continuing 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 welcome this opportunity to review and comment on the expert peer review of the scientific basis for the regulation. Given the numerous aspects that make the Safer Consumer Products

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.

regulation unworkable in terms of its stated purposes in light of the resource limitations of the Department of Toxic Substances Control (DTSC), the public, and industry noted in our previous submissions, we welcome the external peer review of the regulation as we echo a number of concerns we raised with the external scientific peer review period, including:

- Improper external peer review process;
- Inadequate guidance by DTSC to the external peer reviewers for appropriate consideration of the “scientific basis” and “scientific portions” of regulation per California Health & Safety Code Section 57004;
- Incomplete disposition by DTSC of the external scientific peer reviewer comments per requirements of California Health & Safety Code Section 57004; and
- Appearance of bias or conflict of interest.

We also call attention to a contravention of Administrative Procedures Act requirements: There has been numerous comment periods on documents related to this rulemaking. At times the public comment periods have overlapped. The Department sent a request for peer review on January 30, 2013 with a review deadline of March 4, 2013. This comment period coincided with the public comment period on the Safer Consumer Products regulation, which prevented an opportunity for the public to review the external scientific peer review comments prior to commenting on the regulation or for the DTSC external peer reviewers to review the public comments.

In addition, it should be noted that as part of the rulemaking process, DTSC is statutorily required to accept any or all portions of the findings of the scientific peer review or explain any aspect of which there is disagreement with the findings of the scientific peer review. There remain a number of areas upon which the peer reviewers are diametrically opposed and to date this action has not occurred.

With respect to the charge questions, we question the benefit of regurgitating essentially the same charge questions asked to the peer reviewers in the first external peer science review and feel that their skills and aptitudes could have been better utilized.

One particularly vexing remaining issue for CSPA is the Alternatives Analysis Threshold and the Practical Quantitation Level (PQL): the Department should find it very troubling that the reviewers hold such disparate views about the intelligence, benefit, practicality and cost involved in applying the PQL. The Department should reconsider this provision.

Below are specific comments and concerns raised by the peer reviewers we think are worthy of additional response or other consideration by DTSC as part of the peer review process.

Applegate peer review comments:

- CSPA agrees with the reviewer’s assessment that “The change in terminology from "Chemicals of Concern" to "Candidate Chemicals” provides a clarification and an

adjustment of the CCSPAR structure, even though it does not appear to change the basic operation of the regulations.”²

- Reviewer previously noted significant concern with listing process in that:

“What is missing in § 69503(b), as elsewhere in the CCSPAR (SCJ), is a statement of a clear standard for placement on the list or not. The regulations come closest to a precise in the threshold (exemption) procedure (§ 69503.6), but the overall regulatory strategy is to emphasize casting a wide net, multi-step processes, exhaustive enumeration of relevant factors, and professional judgment.”

We believe this concern regarding effective use of departmental resources must be addressed.

- CSPA recommends that DTSC carefully consider the reviewer’s comment “the CCSPAR process will be an enormous undertaking at best, and this will require greater departmental resources.”³

Ashford peer review comments:

- Reviewer previously raised the concern that “the substitution criteria should not be restricted to chemical substitutes,” and recommends “safer technological or administrative approach that delivers a comparable, but safer functional purpose.” In the current comments, the reviewer raised the same concern, “requires that non-chemical alternatives are to be included in the alternatives analysis and the regulatory responses required of the manufacturer of the COCs.”⁴ CSPA continues to believe the regulation provides the regulated entity the discretion to consider any option in the Alternatives Analysis process.

Bennett peer review comments:

- Reviewer raised a concern that “I am somewhat concerned with the language in 69503.2,a,2, specifically potential for one or more exposures can contribute to or cause significant or widespread adverse impacts. There appears to be no definition for significant or widespread and I feel this criteria can be interpreted in a variable manner by the regulating body and the regulated entity.”⁵ CSPA agrees with this concern and requests that the regulation be clarified accordingly.
- Reviewer again raised a scientific issue noting that the regulation does not clearly define “products” and needs improved guidance. This area of ambiguity has been raised in CSPA’s previous comments⁶.

² http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/12-5-Applegate_review-02-20-13.pdf, page 1.

³ http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/12-5-Applegate_review-02-20-13.pdf, page 5.

⁴ http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/12-75-Ashford_review-03-04-13-1.pdf, page 2.

⁵ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/17-5-Bennett-review-03-08-13.pdf>, page 1.

⁶ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Combined-SCP-Comments.pdf>, CSPA Comments, § 69503 General, page 531.

- Reviewer again raised a significant scientific issue that “chemical with multiple routes of exposure would result in higher priority over a product with a single route of exposure.” The reviewer correctly notes that the magnitude of exposure is much more important consideration than the number of exposure pathways and recommends modification of the regulation.

Gray peer review comments:

- Reviewer again raised the appropriate scientific issue that the Chemicals of Concern list will be too large and that the prioritization criteria are too broad to improve the specificity of the list. As noted, “Public concerns, and expectations, will be heightened when the presence of this large number of potential chemicals of concern is identified. Yet the priority setting and listing process will begin with only five priority products.”⁷ CSPA agrees generally with this assessment and remains concerned about the scientific rigor of the determination of the as yet unpublished Chemicals of Concern list. CSPA is also very concerned that the identification of the initial five priority products will be determined by non-scientific considerations which would undermine confidence in the overall process.
- Reviewer expressed significant concern with the over-reliance on specific hazard traits for identification and *de minimis* determinations due to differences in dose response and unevenness in toxicology databases. CSPA agrees with this recommendation to utilize potency and levels of human or environmental exposure as a better means of prioritizing the Chemicals of Concern list.
- Reviewer again raises the valid concern that a data-rich chemical could be replaced by a data-poor chemical inviting the possibility of regrettable substitutions. He again emphasizes that “existing lists does not address the seeming contradiction of using certain hazard traits to develop the list while not acknowledging that many chemicals may not have been tested for the trait.”⁸ CSPA echoes these concerns.
- Reviewer again raises the significant scientific issue that reliance on biomonitoring lists is an inefficient means of prioritizing the Chemicals of Concern list and further emphasizes that “prioritization factor can be scientifically supported.”⁹ CSPA agrees with the concern.
- Reviewer previously noted that “the Alternatives Analysis Threshold exemption is an important administrative tool for focusing effort and resources,” while noting a significant number of scientific and technical issues requiring “more specificity to ensure consistency and fairness in their application.” The reviewer is very concerned about the latest modification, and that “it is focused only on detection and has no role for the relative toxicity of a compound. In my view, an NSL-like approach, identifying a significant risk threshold, would be more scientifically sound.”¹⁰ CSPA agrees with these concerns.

⁷ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/45-5-GRAY-Review-3-4-13.pdf>, page 2.

⁸ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/45-5-GRAY-Review-3-4-13.pdf>, page 4.

⁹ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/45-5-GRAY-Review-3-4-13.pdf>, page 6.

¹⁰ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/45-5-GRAY-Review-3-4-13.pdf>, page 7.

Hattis peer review comments:

- The reviewer raises the same concern as others in that “it does beg the question of how broad the definition of a ‘product’ is?” The question was compounded by the reviewer’s attempt at receiving clarification from DTSC and the lack of meaningful response.¹¹ CSPA agrees with these concerns.

Locke peer review comments:

- This scientific peer reviewer commented in the first round of peer review. It appears the reviewer did not comment in the second round of peer review. CSPA requests the absence of comments by this scientific peer reviewer be explained.

Renn peer review comments:

- The reviewer raises a very troubling and potentially discriminatory concern in the recommendation that “it would be wise to allow for more public review if a chemical is pursuing the alternative analysis threshold route.”¹² CSPA strongly disagrees with the reviewer’s assertion. CSPA raised a significant number of concerns with the replacement of alternative analysis threshold level with Practical Quantitation Limit in our previous comments.¹³ In addition, the responsible entity is required to document the alternative analysis threshold level in significant detail and the addition of public review would discriminate against a responsible entity meeting the statutory requirements while potentially exposing confidential business information and/or trade secret. It would also likely slow down the process without any inherent benefit to the public.

Sass peer review comments:

- In our previous comments, we raised significant concerns about apparent bias and lack of impartiality of this reviewer and we reiterate these concerns. As noted in comments, “Tri-TAC, representing California wastewater treatment facilities, submitted comments on the proposed safer consumer products regulations, recommending among other things that the 303(d) list of impaired waters be included as a means of identifying candidate chemicals.”¹⁴ This does not reflect the scientific opinion of the reviewer, which is what the reviewer should have provided; instead it reflects the comments of an interested party and allows for the perception of bias by the reviewer. This concern, coupled with our concern about the scientific validity of using the 303(d) list in this manner, leads us to recommend that the 303(d) list be removed.
- We agree with the reviewer’s statement, “First, what constitutes a “significant” or “widespread” adverse impact is not well-defined. Second, if the phrase “significant or widespread adverse impacts” is to be used to determine priority products, it should apply to the chemical, not the product-chemical combination, since the adverse environmental or health impacts attributable to a single product-chemical combination may be

¹¹ http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/47-5-Hattis_review_2-18-13.pdf, page 5-7.

¹² http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/69-5-Renn_review_03-03-13.pdf, page 4.

¹³ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/CONSOLIDATED-LIST-OF-COMMENTS-3.pdf>, page 18, 20-23 or page 319, 321-324 of consolidated comments.

¹⁴ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/73-5-SASS-review-2-28-13-1.pdf>, page 2.

impossible to determine, although the chemical has documented significant and/or widespread adverse impacts.”¹⁵

- CSPA is deeply troubled by the reviewer’s statement, “If there is reasonable grounds to believe that a COC may be present in a product, even as a contaminant, and if there is a potential that the product-chemical combination may present a risk even at levels below the PQL, than a threshold exemption should not be issued.”¹⁶ How would a responsible entity show in a scientifically defensible manner that a chemical of concern is not present below a level that is not quantifiable or detectable? This flies in the face of practicality and appears to show a profound misunderstanding of basic analytical methodology.

Summary and Conclusions

As noted in the latest peer reviewer comments, there are a significant number of scientific issues raised that have not been adequately addressed by the existing draft of the regulation. It is clear that DTSC has not disposed of the external peer review in a manner consistent with External Scientific Peer Review Guidelines:

The board, department, or office may accept the findings of the external peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the findings of the external scientific peer review entity, it shall explain, and include as a part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.¹⁷

This is abundantly clear by simply noting the reviewers’ concerns with the “list of lists” approach, some of which are diametrically opposed to one another. It is unclear if the scientific issues discussed in our previous comments or in this peer review will be addressed prior to the next release of the regulation.

We support the external peer review process and when conducted properly the reviewers’ feedback strengthens the process. The reviewers undoubtedly expended great effort in the course of their review and, as of yet, it is unfortunate that their efforts have not been utilized in a practical and meaningful manner. Consequently, in order to fully utilize the external peer review process per California Health & Safety Code Section 57004, CSPA requests that DTSC:

- Address the numerous scientific issues identified within the external peer review comments;
- Address the numerous concerns we have expressed about the propriety of the external peer review process;
- Address the incomplete disposition by DTSC of the external scientific peer reviewer comments;

¹⁵ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/73-5-SASS-review-2-28-13-1.pdf>, page 2.

¹⁶ <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/73-5-SASS-review-2-28-13-1.pdf>, page 3 .

¹⁷ California Environmental Protection Agency (Cal/EPA) External Scientific Peer Review Guidelines, <http://www.calepa.ca.gov/publications/Reports/PEERRVW.PDF>

- Improve the inadequate guidance by DTSC to the external peer reviewers to ensure appropriate consideration of the “scientific basis” and “scientific portions” of regulation;
- Recognize and act on the concerns raised above and in our previous comments regarding the appearance of bias or conflict of interest by members of the peer review board, and
- Request that DTSC empanel and complete an additional external peer review in the event of any “significant” revision to the regulation.

CSPA appreciates the opportunity to comment on the Safer Consumer Product Regulation External Peer Review and remains supportive of the principles of Green Chemistry and programs that are consistent with those principles. We continue to believe further work must be done to make this regulatory process science-based, economically and technically feasible, and workable for both DTSC and the regulated community.

Respectfully submitted,



Steven Bennett, Ph.D.
Senior Director of Scientific Affairs and Sustainability



Kristin Power
Director, State Affairs – West Region

cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency
Gina Solomon, Deputy Secretary for Science and Health,
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Michael E. Rossi, Senior Advisor for Jobs and Business Development,
Office of the Governor
CSPA Scientific Affairs Committee Green Chemistry Task Force
CSPA State Government Affairs Advisory Committee
Laurie Nelson, Randlett/Nelson/Madden