Department of Toxic Substances Control

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TO: Scientific Peer Reviewer

FROM: Jeff Wong, Ph.D.
Office of Pollution Prevention and Green Technology
Department of Toxic Substances Control

DATE: January 30, 2012

SUBJECT: NOTICE TO PROCEED WITH SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

Thank you for your participation as a scientific peer reviewer for the California Safer Consumer Product Alternative Regulations. Attached you will find:

- Attachment 1: Summary of Proposed Regulations and Changes. Attachment 1 provides a brief background that has led the Department of Toxic Substances Control (DTSC) to propose regulations for Safer Consumer Products regulations and the revisions that were made.

- Attachment 2: Scientific Factors: Peer Review Topics. Attachment 2 contains the topics that DTSC is requesting the peer reviewers to comment on.

- Attachment 3: Revised Proposed Regulations for Safer Consumer Products. Attachment 3 contains the revised proposed regulations that are the subject of this peer review request, which can also be found at: http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf

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

Please complete your review by **March 4, 2013** and send your written comments to Daphne Molin at daphne.molin@dtsc.ca.gov. If you require clarification of this communication, please contact Dr. Jeff Wong at jeff.wong@dtsc.ca.govor (916) 322-0504 or Daphne Molin at daphne.molin@dtsc.ca.gov or (916) 445-6130.

Attachment 1
Summary of Proposed and Revised Regulations

Background

On July 27, 2012, DTSC entered the rulemaking process for The Safer Consumer Products Regulations to fulfill the mandate of AB 1879, which became Chapter 559 (stats. of 2008). This law directs DTSC to adopt regulations to establish a process to reach an aspirational goal that encourages the manufacture of safer consumer products through innovation and the use of safer or less hazardous chemicals. DTSC is proposing a four step regulatory process that:

(1) Yields an informational list of chemicals that have been identified by an authoritative organization or reliable information to exhibit a hazard trait or shown by reliable information to demonstrate the occurrence of the chemical in the public or environment. These chemicals are referred to as Candidate Chemicals after they have been identified, subjected to stakeholder input, and finalized by DTSC.

(2) Allows DTSC to evaluate product-chemical combinations and nominate products for the proposed Priority Products list and finalize the list following public review and stakeholder input.

(3) Requires manufacturers to examine their Priority Products and their potential alternative products through an Alternatives Analysis and identify the selected alternative product, if any. Copies of the completed Alternatives Analysis Reports, excluding trade secret information, will be made publically available.

(4) Designates Regulatory Response options for DTSC to impose on to manufacturers based on their product selection in the Alternatives Analysis process.

In the July proposal, a product that would be listed as a Priority Product and that meets the criteria for an alternatives analysis threshold exemption was exempt from the requirement to perform an Alternatives Analysis if a responsible entity for the product submits an Alternatives Analysis Threshold Exemption Notification to DTSC. Peer reviewers were asked to review and provide comment on the scientific nature of four topics points. The previous request can be found at:
http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Revised-Request-Memo.pdf

After considering public comments, Departmental resources, and various practical and policy issues, DTSC revised the proposed regulations and asks the reviewers to review the revised proposed regulation, and comment on the scientific nature of the same four points (Attachment 2). To provide the peer reviewer the context of these revised regulations, please refer to the Summary of Significant Changes in January 2013 Revised Proposed Regulations at:
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Summary-of-Changes.pdf

Attachment 2
Scientific Factors: Peer Review Topics

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

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

Topics:

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

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

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

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

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

Christensen response: These changes are consistent with our scientific understanding of the potential impacts of these chemicals on the human and ecosystem health.

Attachment 2
Scientific Factors: Peer Review Topics

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

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

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

Christensen response: These changes are important and founded in sound science. Replacing "a significant ability" with "potential" is especially important. "Significant ability" is an imprecise phrase open to a variety of interpretations. "Potential" is much clearer and consistent with the intent to protect human and ecosystem health.

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

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

Attachment 2
Scientific Factors: Peer Review Topics

Christensen response: The Practical Quantification Limit is scientifically sound. Furthermore, it is logical that that Alternative Analysis Threshold would apply only to contaminant chemicals and not to chemicals intentionally added to a product.

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

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

Christensen response: These changes seem appropriate. The terms "impact" and "effect" are often used as synonyms and the difference between them is subtle (impact perhaps being a generally negative effect).