To: Jeff Wong, Ph.D.
Office of the Chief Scientist
Department of Toxic Substances Control

From: William H. Farland, Ph.D., ATS
Scientific Peer Reviewer

Date: March 4, 2013

Subject: Scientific Peer Review for Safer Consumer Products Regulations

Thank you for the opportunity to serve as a scientific peer reviewer on the latest version of the Safer Consumer Products Regulations. I have completed my review which is structured around the scientific issues and peer review points that you provided. My detailed comments are attached.

My detailed comments notwithstanding, I am of the opinion that the proposed rule is based upon sound scientific knowledge, methods and practices. The Regulations continue to rely heavily on the work of others who have constructed lists of potentially hazardous substances which, for the most part, have relied on public processes and scientific peer review in their construction. The addition of lists from authoritative organizations will only strengthen the basis for State decision-making. The use of the term "candidate chemical" for the large number of chemicals that will comprise the "list of lists" is more scientifically defensible than call them "Chemicals of Concern" from the outset. "Concern" needs to be raised in the context of the product-chemical combination. The evaluation criteria for prioritizing the product-chemical combinations are robust and comprehensive. As such, they provide a reasonable basis for identifying all types of consumer products as potential Priority Products. The basis will still require significant scientific judgment but the clarification in the current version of the regulations to define "potential" effects or exposures as "reasonably foreseeable based on reliable information" will help in this context. I believe that the use of the "Practical Quantitation Limit (PQL)" is also an improvement for establishing an Alternatives Analysis Threshold. Finally, as discussed in my previous review, the discussion of what constitutes "adverse" continues to need further clarification. Slight changes to the use of "impact" versus "effect" in the proposed language of the regulation have done nothing to bring about this clarification.

Thank you again for the opportunity to participate in the scientific peer review of these proposed regulations. Feel free to contact me if you have questions regarding the attached detailed comments.

Review Topic: 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.

Comment:

As indicated earlier, it is my opinion that the use of chemical lists developed by "authoritative bodies" in California as well as elsewhere in the US and internationally is a scientifically defensible approach to identifying "Candidate Chemicals". Each of the lists was the product of a rigorous process for determining criteria for inclusion and all have undergone independent peer review at the process level if not at the individual listing step. This point was well made in the "Initial Statement of Reasons" (ISOR) document where individual lists, their processes and scientific integrity are described. While each list will have its own criteria and listing thresholds, in the aggregate, they produce a list of chemicals that embody the hazard traits or chemical characteristics described in the regulation. Originally, the chemicals identified in subsection (a)(2) were identified as Chemicals of Concern (COCs). I believe that the response to comments and the change to call these "Candidate Chemicals" is more consistent with the fact that additional analysis will be required in order to determine whether their presence in a product raises a "concern". Because these chemical lists were originally generated for a specific purpose (monitoring or reducing exposure/contamination), the Department is relying on the authoritative organization's determination regarding chemicals exhibiting a hazard trait to be listed. Further analysis will determine which of the traits may be exhibited under particular product chemical combinations and specific exposure scenarios and therefore, when a chemical may be of concern.

The 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.

It has been determined that 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. For these reasons, I see no problem with adding these lists to the list of lists. I do, however, question why the addition is limited to chemicals classified as Category 1 respiratory sensitizers when the same Regulation (EU Regulation 1272/2008) which has been in force since January, 2009 also includes a list of Category 1 skin sensitizers. Chemicals in this category meet the criteria of either having evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons or if there are positive results from appropriate animal testing. Chapter 54 (Section 69403.2) lists dermatotoxicity as one of the "Other Toxicological Hazard Traits" under Article 3. Sensitization is included as one of the toxicological endpoints in determining

dermatotoxicity. Therefore, it would seem prudent to not limit the addition to the list of respiratory sensitizers from the EU Regulation.

The regulation provides for the opportunity to add or remove chemicals from the list as new information relating to hazard traits becomes available. This opportunity includes a public notice and comment process which allows for broad based scientific input. This may be important for some future listing decisions because of the infrequency of updating of individual lists mentioned in the regulations and the evolution of the testing and assessment process.

Review Topic: 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.

Comment:

The regulation has provided a scientifically sound approach to prioritizing product-chemical combinations to identify consumer products containing Candidate Chemicals as potential Priority Products. To be considered a Priority Product, a product-chemical combination 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. In addition, it will consider waste and end-of-life effects in reaching this conclusion. The decision shall also consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. A further criterion to be considered is "the scope of other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse 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." In this way, if a product is regulated by another entity with respect to the same potential adverse impacts and potential exposure pathways, and potential adverse waste and end-of-life effects, a listing decision is made under the regulation only if there is a determination 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." In addition, the regulation allows consideration as to whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

As stated above, the regulations require consideration of information from both candidate chemicals and consumer products in combination. Evaluating and examining the information

from both, based on the availability of information to inform such judgments, will allow for flexible decision-making regarding which of the products should be listed as Priority Products. Because the decision-making process to designate a product as "high priority" is based on a variety of information and a narrative approach, DTSC has continued to use a narrative approach to describing its priority setting decisions rather than a quantitative weighting scheme. This seems like a sound decision given the typical available information and the differences one would see from product to product. As indicated in section 69503.3, decision-makers will use a wide-range of available information to consider and evaluate the potential adverse impacts and widespread exposure. Given the broad range of characteristics related to adverse impact and exposure parameters specified for evaluation over the lifecycle of the product within the regulation, this approach seems comprehensive, scientifically-sound and should be applicable to a wide range of products.

In expressing its intent in the revised regulations to consider "potential" for adverse impacts or wide-spread exposure rather than using the term "ability to" cause, the DTSC is clearer in its position that the impacts and exposure are "reasonably foreseeable" rather than simply hypothetical, given available information. This is an important distinction in establishing the criteria for listing Priority Products.

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

Comment:

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 listed chemicals solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient.
The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification, including the source of the contaminant COC(s). The notification must identify the PQL(s) for the COC(s) and the methods used to determine the PQL(s). The use of the PQL is standard practice in environmental regulations and laboratory analysis. This level is defined as a point where a signal can be quantified with statistical rigor. EPA has routinely used the PQL to estimate or evaluate the minimum concentration at which most laboratories can be expected to reliably measure a specific chemical contaminant during day-to-day analyses. This approach is scientifically defensible and understandable by the analytic community.

One issue that needs mention is that improved analytical performance (and hence, possible reduction of the PQL) may be suggested by lower detection limits from new methods. The existence of new methods with lower detection limits may not directly translate to improved analytical performance until sufficient experience is gained with the method and adoption is widespread. Since it will be incumbent on the submitter to justify the PQL selected for the COC(s) contained in the Priority Product, changes to PQL's in individual chemical candidates may be seen over time. These will need to be considered at the time of review of the notification.

Review Topic: 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.

Comment:

The regulation is clear in its intent to protect consumers from the hazardous components of consumer products. In this context, avoiding "adverse" impacts/effects is easily understandable. In the scientific or toxicological definition of adverse, it is less clear. I addressed this issue in detail in previous review comments. Certain endpoints from toxicological testing which are used to determine hazard based on animal studies or high level exposures need to be viewed carefully as to whether these constitute "adverse" effects in the context of human hazard. Issues discussed in this regard have to do with what constitutes an "adverse" versus an "adaptive" response to the exposure. While these issues will clearly need to be addressed in order to make a scientifically defensible case for the potential "adverse impacts" of product-chemical combinations, the closest statement I can find in the regulation is that "The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts…" While this statement may be reassuring to some, it is neither indicative of the difficulty nor explicit about role that scientific judgment will need to play in many of these decisions.

Of a less serious nature is the general use of impact and effect interchangeably. There appears to be no convention as to when one term is chosen over the other. In the current draft, impact has been changed to effect in a number of instances but there does not seem an obvious rationale for doing this. In general usage, "impact" is considered a weak alternative to "effect." The definition given for "impact" does not address a difference. Unless a rationale for the use is presented, it might be better to choose one or the other with "effect" being my preference.