

**To:** Jeff Wong, Ph.D.  
Office of the Chief Scientist  
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**From:** William H. Farland, Ph.D., ATS  
Scientific Peer Reviewer



**Date:** October 10, 2010

**Subject:** Scientific Peer Review for Safer Consumer Product Alternative Regulations

Thank you for the opportunity to serve as a scientific peer reviewer on the above referenced subject. I have completed my review which is structured around the scientific factors 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. There are, however, two areas that I have identified that could be addressed to improve the approaches that are presented. First, the use of a long list of factors to bring chemicals into consideration will raise the question of how to evaluate chemicals with incomplete data sets (virtually all chemicals). Since the absence of data does not equal the absence of risk, all chemicals could be argued to be candidates for "Chemicals Under Consideration." This issue is not a new one and it has plagued approaches to chemicals regulation in the U.S. Progress has been made with the use of defined data sets, e.g. SIDS or their equivalent, for high production volume chemicals in Europe and the U.S. At the very least, the issue should be identified upfront and acknowledged as a significant shortcoming to this approach to comprehensive chemicals regulation. Second, while the proposed regulation provides a reasonable approach to evaluate priority chemicals and products and their alternatives, more attention should be given to the process for comparison. Simply doing a side-by-side comparison of hazard, exposure and life cycle will likely not lead to obvious choices for safer alternatives. Approaches for carrying out the comparison and weighing differences could be provided. This addition would significantly improve the utility of these proposed regulations, in my opinion.

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: Use of chemical properties, toxicological information, volume of the chemical in commerce, and adverse impact to sensitive subpopulations, public, and the environment to develop supporting rationale and prepare Chemicals Under Consideration and Chemicals of Concern (COC) (now called Priority Chemical) lists.**

**General Comment:** While the comment is made frequently within the regulatory documents under review that the various factors discussed are not exhaustive, they are comprehensive and, individually, are scientifically sound. In essence, this is a laundry list that serves the purpose to identify a large number of factors that could bring a chemical into consideration. In the absence of any kind of hierarchy, quantitative guidance or threshold values, this list does little to triage the universe of chemicals to be considered as priorities. Virtually no chemical will have information to address all of these factors. This sets up the situation that allows the argument, based on the premise that the absence of information does not equal the absence of risk, that any chemical should be a "Chemical under Consideration." Although difficult to impossible to implement for all existing chemicals, the solution to this problem is defining and obtaining a minimum data set in order to make the decision to list the chemical as "under consideration." In the absence of this approach, providing a list of "Chemicals under Consideration" based on a list of scientifically-based factors but only considering available data adds little to the establishment of a comprehensive "process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern." This issue is not a new one and it has plagued approaches to chemicals regulation in the U.S. Progress has been made with the use of defined data sets, e.g. SIDS or their equivalent, for high production volume chemicals in Europe and the U.S. At the very least, the issue should be identified upfront and acknowledged as a significant shortcoming to this approach to comprehensive chemicals regulation.

The following are comments specific to the language providing the scientific basis for choosing the above mentioned factors as articulated in the "Initial Statement of Reasons, R-2010-05. Both the document language and my comments are provided for ease of understanding.

### **Chemical and Physical Properties**

**Section 69302.3(a)(1) through (15)** are necessary to allow DTSC to consider chemical and physical properties as potential hazard traits when identifying a Chemical under Consideration. Chemical and physical properties provide DTSC basic information for a chemical and its behavior during its manufacture and use. Chemical and physical properties may also be used, to some extent, as predictive indicators of behavior in the humans, wildlife, ecosystems, and the environment.

The specified properties are not an exhaustive list, but provide common chemical and physical properties that may be used to evaluate a chemical and its potential public health and environmental threats.

DTSC may consider as prioritization factors, to the extent applicable, density, dissociation constant, explosiveness, flammability, flash point, granularity, melting or boiling point, oxidizing properties, partition coefficient, stability in organic solvents and relevant degradation byproducts, surface tension, vapor pressure, viscosity, water solubility, and other physical, chemical, or quantum properties specific to nanomaterials.

**Comment:** While recognizing that this is not an exhaustive list of chemical and physical properties, I would add “molecular weight” and “extent of polymerization and monomer content” to the list. In my experience, these characteristics have been very useful in determining if chemicals need to undergo further review.

### **Adverse Public Health Impacts**

**Section 69302.3(b)(1) through (26)** are necessary to allow DTSC to consider as chemical prioritization factors adverse public health impacts. Section 69302.3(b) specifies that public health impacts will include an evaluation and comparison of impacts resulting from a single, intermittent or frequent use of or contact with the chemical through dermal, oral and inhalation routes of exposure. The hazard traits and toxicological endpoint factors listed in this subsection are not an exhaustive list of the adverse impacts to public health that may be considered by DTSC in the chemical prioritization process.

**Comment:** Add a statement that these hazard traits and toxicological endpoint factors may be based on observations in humans or in other animals which have relevance for human health risk assessment. Also, I see little value in identifying individual organ system or tissue toxicities individually. These could be grouped simply as organ system or systemic toxicity and the category of effects defined.

**Section 69302.3(b)(2)**, identifies bioaccumulation in humans as a chemical prioritization factor. This may be shown by either biomonitoring data or scientifically sound predictive chemical behavior, e.g., mercury behavior, and is a measure of exposure to a chemical. Bioaccumulation occurs when a person absorbs the chemical at a rate greater than that at which the substance is lost.

**Comment:** The statement above is not precise and would not be easily understood by a lay reader. Clarify as follows: This may be shown by either biomonitoring data or scientifically sound predictive models of chemical behavior under physiological conditions, e.g., mercury accumulation in mammals, and is a measure of exposure to a chemical.

**Section 69302.3(b)(7)** identifies the effects of electromagnetic radiation, including ionizing radiation and non-ionizing radiation as a chemical prioritization factor. Electromagnetic radiation may cause damage to organ tissue.

**Comment:** Add a statement that such effects can be caused by radioactive or radiomimetic chemicals. In addition, radiosensitizers which enhance the potential for these effects should also be mentioned.

**Section 69302.3(b)(8)** identifies endocrine toxicity as a chemical prioritization factor. Endocrine toxicity may result in an adverse effect (i.e., disruption) following exposure to a chemical on the structure or function of the endocrine system, which produces hormones that control a number of functions in humans. Endocrine disruption may produce adverse developmental, reproductive, neurological, and immune effects in humans.

**Comment:** Is disruption an adverse effect or does it lead to an adverse effect? Rewrite the second sentence above to read : Endocrine disruption following exposure to a chemical may

result in an adverse effect (i.e., endocrine toxicity) on the structure or function of the endocrine system, which produces hormones that control a number of functions in humans.

**Section 69302.3(b)(9)** identifies epigenetic toxicity as a chemical prioritization factor. Epigenetic effects are changes in an organism that are caused by exposure to a chemical without changing the underlying gene sequence; that is, non-genetic factors cause the organism's genes to behave (or "express themselves") differently.

**Comment:** "Epigenetic effects" may not be a basis for concern but epigenetic effect-based toxicity may be. I would add a sentence for clarification to complete this statement: Alteration of the expression of genetic information at the transcriptional, translational, or posttranslational levels has the potential to contribute to various diseases and be the basis for a toxic response.

**Section 69302.3(b)(12)** identifies hepatotoxicity as a chemical prioritization factor. Hepatotoxicity affects the structure or functions of the liver, gall bladder, and gastrointestinal tract and may cause liver damage, hepatitis, vascular changes, gall bladder disease, and inflammation of the gastrointestinal epithelium.

**Comment:** This definition of hepatotoxicity seems overly broad. I am not aware of a definition of hepatotoxicity in common use that includes inflammation of the gastrointestinal epithelium. I would include this effect under general organ or tissue system toxicity, not hepatotoxicity.

**Section 69302.3(b)(20)** identifies chemical persistence as a chemical prioritization factor. The ability of a chemical to remain in organic tissue and exist for a long period of time prior to its release or elimination in humans may also be known as biopersistence.

**Comment:** Chemical persistence should not be included in discussions of public health impacts. "Biopersistence" is an appropriate factor. The description should include being refractory to metabolism. I would replace "release" above with "metabolism" and replace "may also be" with "is". Therefore, the sentence would read: Section 69302.3(b)(20) identifies biopersistence as a chemical prioritization factor. The ability of a chemical to remain in organic tissue and exist for a long period of time prior to its metabolism or elimination in humans is known as biopersistence.

**Section 69302.3(b)(26)** is necessary to clarify and make more specific the types of "potential effects on sensitive subpopulations, including infants and children", as identified in Health and Safety Code section 25252, that DTSC will consider when identifying a Chemical under Consideration. Section 69301.2 further defines sensitive subpopulations and includes, but is not limited to, pregnant women and the elderly.

**Comment:** In addition to pregnant women and the elderly, sensitive subpopulations should be further defined to contain individuals with pre-existing diseases which make them more sensitive to the effects of chemical exposures. This concept is widely accepted by the toxicological community and is used by the U.S. EPA in describing sensitive subpopulations.

### **Adverse Ecological Impacts**

**Section 69302.3(c)(1) through (7)** are necessary to allow DTSC to consider as chemical prioritization factors adverse ecological impacts. Ecology is intertwined with human survival; adverse impacts to the ecological system will impact public health. For example, chemicals that

affect plants or animals may affect public health through ingestion of the chemical; chemicals that affect plant survival may adversely impact the delicate balance of nature that may ultimately affect the balance of carbon dioxide and oxygen in the air. The factors listed in this subsection are not an exhaustive list, but they provide common ecological factors to consider when prioritizing a chemical as a Chemical under Consideration.

**Comment:** While I don't take issue with the factors identified, the scientific bases for using them as chemical prioritization are not well articulated in the "Initial Statement of Reasons". Society has recognized the inherent value of ecosystems. This should be stressed. There seems to be an attempt to link these effects back to impacts on public health to justify their use in prioritization. While I agree that a coupling of ecological impacts to potential direct and indirect health effects is important, it is also important to value ecological impacts per se as a consideration for prioritization.

### **Adverse Environmental Impacts**

**Section 69302.3(d)(1) through (5)** are necessary to allow DTSC to consider as chemical prioritization factors adverse environmental impacts. Public health is impacted by chemical environmental pollutants. Chemicals may cause environmental contamination through air, water, and soil and the public may be exposed to the chemical through contact with environmental media. The factors listed in this subsection are not an exhaustive list, but provide common environmental factors to consider when prioritizing a chemical as a Chemical under Consideration.

**Comment:** From a logical progression perspective, I would like to see this section precede the discussion of adverse health impacts and adverse ecological impacts. This section relates to the nature and duration of environmental contamination that leads to the adverse impacts mentioned above.

### **Priority Chemicals**

#### **Section 69302.4. Priority Chemicals**

This section, in its entirety, is necessary to specify and describe the prioritization factors that DTSC may use to identify and list Priority Chemicals from the Chemicals under Consideration list. It is possible that as DTSC evaluates a chemical for listing as a Chemical under Consideration, DTSC will simultaneously be evaluating the chemical as a Priority Chemical as well. DTSC will provide the rationale and supporting documentation for listing a chemical as a Priority Chemical, and interested parties will have the opportunity to comment on DTSC's rationale pursuant to section 69302.2.

**Comment:** The discussion of the approach to identifying Priority Chemicals is relatively straight forward and has a sound basis in current risk assessment practice. It describes targets, degree of threat and pathways to exposure as important considerations for identifying Priority Chemicals. Although, in practice, integrating limited information in these areas to reach conclusions for priority setting is not an easy task.

It is interesting to note that Section 69302.4(a)(3) allows availability of DTSC resources to influence the numbers and types of chemicals to be placed on the Priority Chemicals list. Although this factor has a basis in practicality, in my opinion, it has the potential to undermine the scientific considerations for adding chemicals to the list. One could envisage a scientifically-based priority chemical not being added to the list because of lack of available resources. Also in the Initial Statement of Reasons explanation of Section 69302.4(e), it should refer back to the three categories specified in Section 69302.4 (d), not (e).

**Review Topic: Use of consumer product marketing, potential for exposure of the COC (Priority Chemicals) in the consumer product to the public or contamination to the environment, to develop supporting rationale and prepare a list of Products Under Consideration and Priority Products.**

**Comment:** The approach to determining Products Under Consideration and Priority Products parallels the approach used for chemicals. In describing this process, DTSC has correctly highlighted the importance of considering dispersive volume in this approach in order to estimate the amount of the priority chemical entering commerce. This is a first step in understanding potential for threat to public health and the environment. Coupling knowledge of levels of priority chemical in products, dispersive volume and use patterns allows an understanding of potential for population and individual exposure which is critical for listing and for priority Product identification. It is particularly appropriate that sensitive receptors potentially exposed to priority products and their constituents are evaluated. Products provide exposure pathways that might not be identified for the priority chemicals alone.

My above comment regarding the role of available DTSC resources in listing decisions applies equally well to this section on products.

**Review Topic: Use of human health and environmental impacts of the COC in the Alternatives Assessment to develop safer consumer products.**

**General Comment:** This section is focused on the conduct of a comparative assessment of alternative chemicals and products. The concept of the comparison and the assessment of the benefits of the alternatives gets lost in the discussion of the process for the conduct of the assessment. As you can see below, the factors for assessment appear to be appropriate but there is little discussion on how to do the comparison.

#### **Section 69305.5(b) Chemical Hazard Assessment**

**Comment:** The discussion of the use of all of the factors contained in the chemical and product prioritization considerations is appropriate for the conduct of Alternatives Assessment (AA). This Section refers back to properties and factors for consideration articulated in Section 69302.3. As such, comments provided on those properties and factors apply in this context as well. It is unclear why Section 69305.5(b)(4) refers back only to Section 69302.3(d)(1) and not Section 69302.3(d)(1) through(5). All of these would seem to be appropriate for AA and I see no scientific reason not to include them in the Hazard Assessment.

Note: In the Initial Statement of Reasons, Section 69305.5(b), there is an incorrect reference to Section 69305.6(b)(1) through (4) which should read 69305.5(b)(1) through (4).

### **Section 69305.5(c) Exposure Potential Assessment**

**Comment:** Again, the discussion of the factors to be considered in the comparative exposure assessment for the AA is parallel to that used for the chemical and product prioritization process. These appear to be appropriate for the AA as well. Unlike many of the previous sections of the document, cross-referencing is not as extensive and is a bit confusing, even with the Initial statement of Reasons in hand.

Note: In the Initial Statement of Reasons, Section 69305.5(c), there is an incorrect reference to Section 69305.6(c)(1) through (4) which should read 69305.5(c)(1) through (4). Also, in the Initial Statement of Reasons, Section 69305.5(c)(2), there is an incorrect reference to Section 69305.6(c)(2)(A) which should read 69305.5(c)(2)(A).

### **Section 69305.5(d) Multimedia Life Cycle Evaluation**

**Comment:** The description of the use of a multimedia life cycle evaluation contains appropriate factors to conduct the assessment of priority chemicals and products and their alternatives. Again, I have difficulty seeing the focus on the comparative aspects of the assessment. Use of alternatives can change characteristics of a product which will impact environmental fate and transport, exposure and hazard potential. It can also open up more product uses which could affect the above. Conducting comparative life cycle assessments and choosing the safer alternative with regard to public health and /or environmental impacts will be difficult. More of a focus on a comparative process description seems warranted in this section.

**Review Topic:** In reading the supporting documentation in Attachment 4, the excerpts of law that provide DTSC with the aspirational goals to develop regulations that outline a process to prioritize chemicals and consumer products, and proposed implementation language in Attachment 5, are there any additional scientific points that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.

**Comment:** I am satisfied that the treatment of this issue and the characteristics, factors and processes described are sufficient from a scientific standpoint, notwithstanding the comments made above. Given the current state of the science and limitations of available data, the statutory language really is aspirational and the process emanating from them will be, by necessity, difficult to implement until more and better data are obtained on chemicals and products.

**Review Topic:** Taken as a whole, is the scientific portion of the proposed rule (Attachment 5) based upon sound scientific knowledge, methods, and practices?

**Comment:** Yes. The science contained in the proposed rule is based on sound scientific knowledge, methods and practices.