

Responses to Peer Review Points

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This document is my peer review of the updated “**TEXT OF PROPOSED REGULATIONS – POST-HEARING CHANGES January 2013**” for the DTSC regulations (Division 4.5, Title 22, California Code of Regulations). Below I have first provided my specific responses to the four points suggested in the inquiry to me. Then I provide comments on more general issues, and finally there is a section directed to specific parts of the text of the regulations and the statement of reasons document. The peer review points are given in normal type and my responses are provided in bold face.

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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.

Topics:

Review Issue 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

Response: The addition of these two new sources of candidate chemicals seems well founded. They each provide an additional useful perspective on additional chemicals for which there is some basis for concern to the extent they are used in consumer products.

This having been said, I have some residual concern with the definition of a “chemical” as used in the strike-through version of the new regulations:

““Chemical” means either of the following:

1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity; or
2. A chemical ingredient, which means a substance comprising one or more substances described in subparagraph 1.”

Some pesticides, (e.g. toxaphene, now eliminated from use) have no single structure but are defined as the product of a chemical reaction (for toxaphene, the reaction of chlorine with camphene, which produces about 200 different individual chemical entities). I think that DTSC will want to be sure that it is clear that such a reaction product based on a mixture with no particular defined chemical structure is covered by the regulations as a “chemical”.

Review Issue 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.

Response: These clarifications are helpful, as far as they go. However there is still much to be defined in determining how DTSC will actually set its priorities in designating particular chemicals with particular hazard traits in particular products. It is clear from the choice to define the priority setting goal in the form of a narrative standard that DTSC does not want to lock itself in to a specific formula. However it seems clear that different formulae will be used for different hazard traits and that in at least in the cases of some hazard traits the formula will look something like:

Priority score = (potency) X (fraction used in a particular product type expected to reach people [or other type of vulnerable receptor, depending on the hazard trait] X (use volume)

In this equation

- “potency” can be defined as the reciprocal of the dose found to cause a standardized response (e.g. 1/LD50 for an acutely lethal toxicant in a standard species; 1/ED10 for carcinogenesis over background)
- the second term is the “intake fraction” (fraction ingested, inhaled, or otherwise absorbed by people of that used for the purpose)
- “use volume” is the annual quantity estimated to be used in a particular product type in California

Some variation of this type of scoring is likely to be needed among different hazard traits.

It should be emphasized that in an initial analysis, these relative priority scores should be calculated within sets of chemicals expected to exhibit specific hazard traits. Combining the information for different hazard traits is a step that can be left to later analysis. It is also important to understand that the DTSC need not have definitive evidence on the specific numerical values of each of the three components of this equation—the analysts will often need to develop estimates for specific chemicals based on analogies and utilizing adjustments to approximately put somewhat different types of data on comparable scales for ordering.

With this kind of elaboration, I think the priority-setting schema can be considered well founded in available risk assessment theory and available data.

Review Issue 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.

Response: Defining the Alternatives Analysis Threshold in this way essentially removes the issue of the degree of hazard posed by analytically detectable amounts of a Chemical of Concern. This is probably reasonable and will cause no great difficulty if the basic formulae for prioritization are well structured and well implemented.

Some fairly serious priority-based weaning of candidates for attention is indicated by the new provision in the rules to limit the initial set of product-chemical combinations for attention to five. This is reasonable to focus the efforts of the department. However it does beg the question of how broad the definition of a "product" is. If the definition is as broad as, say, "paint" then it could include hundreds of different formulations made by different companies. Alternatively, is a "product" a specific paint formulation made by a particular manufacturer, perhaps limited to a specific color and place of intended use (e.g. "red indoor residential paint")?

In response to an inquiry for clarification, a DTSC worker directed attention to the following passages in the regulations and the “statement of reasons” document:

“1. Revised Regulations Section 69503.5 (b):

(b) List Contents. The Department shall specify in the proposed and final Priority Products lists the following for each listed product-chemical combination:

(1)(A) A description of the product-chemical combination that is sufficient for a responsible entity to determine whether one or more of its products is a Priority Product.

(B) If the product-chemical combination is a component of one or more assembled products, a description of the known assembled product(s) in which the component is used shall be included.

2. ISOR (keep in mind the ISOR may not entirely line up with the revised regulations)-

www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf

Section 69503.4(a)(2)(B)

DTSC intends to be as specific as possible when products with multiple parts or components are identified as Priority Products to name the specific component or homogeneous material that is basis for the listing, and, thus, subject to the Alternatives Analysis. DTSC may, of course, name an entire multi-component product as a Priority Product when it is appropriate to do so.

3. ISOR-

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>

Section 69503.3(f) specifies that by January 1, 2014, DTSC must issue a Priority Product Work Plan covering next three years.

This is intended to provide a level of certainty and predictability to responsible entities and other stakeholders regarding the types of products that will be considered for evaluation prior to releasing a proposed Priority Product List. The work plan will include product

categories, which may illustrate for example a level of detail comparable to the Family (i.e., Cleaning Products) or Class (i.e., Laundry) hierarchy level identified using the Global Product Classification (GPC) Standards

[<http://www.gsl.org/gdsn/gpc>] and a general explanation, which may include exposure concerns, such as access to sensitive subpopulations. The work plan will plot a course for DTSC for three years.”

Response continued: Saying that DTSC will be “as specific as possible”, it seems to me, still begs the question of how DTSC will balance the benefits and limitations of defining products relatively broadly or narrowly. A broad definition of a product type will increase the potential benefits of devoting one of the five precious initial chemical-product slots to a particular case. On the other hand the broader the definition of a product, the greater the complexity of the analysis needed to identify reasonably functionally equivalent “alternatives”. The indoor paint example is illustrative. A manufacturer of a specific red pigment might argue that there is no practical alternative to its product if one wishes to achieve a very specific red hue. On the other hand, if one broadens the category to include a wide range of available colors and textures, then many paint formulations and even wallpaper in some cases could be considered as technically feasible alternatives if the “product” were defined as “indoor wall or ceiling covering”. I would suggest that a couple of added paragraphs on this issue could usefully help guide DTSC staff to wiser choices in defining product categories.

Review Issue 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.

Response: These minor clarifications do not seem to pose significant problems.

Other Issues Posed by the Current Draft

(Page numbers refer to the 106 page revised text of the regulations with strikeouts and additions).

***P 12 ,line 22-- (29) “Economically feasible” means that an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.**

Without further elaboration of what is meant by “significantly” this provision might be used to argue infeasibility for changes that decrease the manufacturer’s operating

margin by 1-5%. This should be specified more clearly lest extensive litigation result.

“Functionally acceptable” means that an alternative product meets both of the following requirements:

(A) The product complies with all applicable legal requirements; and

(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

This definition seems good to me.

p. 13-- “Importer” means a person who imports a consumer product into the United States product 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.

I am concerned that the last sentence in this definition could cause problems. Imagine that a maker of plywood or particle board imports an adhesive known to contain and emit formaldehyde. If “the product” is the adhesive, then the importer could argue that he just used the adhesive in his workplace to make the plywood or particle board but did not sell or distribute the adhesive itself. This would allow such a person/firm perhaps to get around the fact that consumers could be extensively exposed to emissions from the plywood or particle board manufactured with the adhesive. This, it seems to me, should be a prime candidate for regulation by DTSC, but may escape regulation unless the language is changed to make it clear that a product (e.g. plywood or particle board) that incorporates the imported material that causes such emissions and consumer exposures is subject to controls.

p. 65, line 1—“ (C) Economic impacts.

1. The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:

a. Public health and environmental costs; and

b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.”

The suggestion that alternatives analyses include monetization of impacts might be qualified by some caveat like (where reasonably feasible) or some such. This is to avoid hanging up the process in very difficult issues such as how much a fish in the wild is worth, or how much an uncertain mild health response is worth.