Review

Safer Consumer Products

January, 2013 Revised Proposed Regulation

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I appreciate the opportunity to review the January 2013 Revised Safer Consumer Products Proposed Regulations. This iteration reflects continued thought and advice as the Department of Toxic Substances Control works to implement the requirements of Health and Safety Code section 25252.

My review is based on my understanding, developed through reading the materials supplied. My views come from my background as a risk analyst and toxicologist with a public health perspective. This review reflects my opinions and not necessarily those of George Washington University. I hope these comments will be considered along with my two previous sets of comments.

I begin with a few general comments about the revised regulations and then address the charge questions that were addressed to the peer reviewers.

My primary concern with the way the proposed regulations are structured is the very wide net that is cast in the beginning (the construction of the Candidate Chemicals list and the priority setting process) and the very narrow process of identifying priority products and conducting alternatives analyses (AAs). It is clear that the myriad of lists along with other criteria for identifying Candidate Chemicals will result in an initial list of hundreds or thousands of chemicals. 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. It seems to me that the potential for citizen frustration and dissatisfaction with the process will be very high.

In my view, a more targeted and risk-based approach to identifying candidate chemicals, which would result in a much smaller list, would be a more logical step. As I have noted in previous reviews, a list of candidate chemicals that is too long risks diluting effort, attention and resources. In addition, the presumably large Candidate Chemical list, based on many other lists, will doubtless cover the chemicals for which we have the greatest toxicological information. This will necessarily encourage the identification of new or less well-studied chemicals as potential alternatives in products or processes. Without a means to develop proxy hazard and dose-response information for these compounds we risk starting onto a "risk treadmill," moving from chemical to chemical as new information becomes available. The tools of structural or mechanistic similarity referred to in § 69503.3 would be useful in this situation.

The AA sections seem more reasoned and reflects the challenge of doing AA well. The idea of "potential" effects or exposures is dropped and replaced with "a material contribution to one or more adverse public health impacts" for example. In addition, the multi-criteria nature of AA decisions, with different possible outcomes to different populations is recognized. I would hope that guidance and examples for AA would include some of the very good work ongoing to demonstrate tools for these difficult decisions[1]. I am especially struck by the recognition of the importance of quantitative analysis tools, weighing and comparing multiple attributes and optimizing decisions in contrast to the very simplistic hazard-based approach taken in developing the Candidate Chemicals list.

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[1] I., Sinsheimer P, Malloy T. Integrating Safer Alternatives into Chemical Policy: Regulatory Framework for AB 1879. Los Angeles, CA: UCLA Law and Environmental Health Sustainable Technology & Policy Program; 2009 pages 1–13; Malloy T, Sinsheimer P, Blake A, Linkov I. Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative. Los Angeles, CA: UCLA Sustainable Technology and Policy Program; 2011 pages 1–65.

Charge to Reviewers

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 25252-25257.1 of the Health and Safety Code provide the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

Topics:

1. The initial Candidate Chemicals are chemicals listed by one or more of the sources named in the regulations and have hazard traits that have public health and environmental concerns.

The broad 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: For virtually all practical purposes, this change in terminology does not affect the duties of responsible entities subject to the regulations.

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

As mentioned above, the hazard-based approach to list development is likely to lead to an unwieldy, unfocused and difficult to manage set of Candidate Chemicals

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. This is a shortcoming that that I identified in a previous review:

> *"I am uncomfortable with the strong focus on specific hazard traits in both identifying COCs and in making de minimis determinations for two reasons. First, it is a well-established toxicologic fact that chemicals may have many different adverse effects. These effects may occur at different doses or be found in different test systems or species. Giving special consideration to carcinogens or compounds with "a reference dose or reference concentration has been developed based on neurotoxicity" in the EPA IRIS program, for example, misleads the public and, potentially, those conducting alternative assessments, about the specificity and accuracy of toxicologic values. For example, Xylenes; CASRN 1330-20-7, Toluene; CASRN 108-88-3 and 1,1,1-Trichloroethane all have oral RfD values in the IRIS database based on toxicologic outcomes other than neurotoxicity. Presumably, they would not be identified as having neurotoxicity as a hazard trait. But all three have positive results in toxicologic tests for neurotoxicity at some level of exposure.*
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> *The second concern arises because of the unevenness of the database for many compounds. For example, in IRIS, Acetone (CASRN 67-64-1) has an oral RfD based on nephropathy yet the IRIS file points out "the database lacks chronic, developmental, developmental neurotoxicity, and multigenerational studies and adequate neurotoxicity studies." Here a compound can't even demonstrate one of the hazard traits of concern because it has not been tested. Even if we had complete data we know that the concordance of hazard traits between test species and humans is not very good, even for chemicals used at pharmaceutically active doses in humans[2].*
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> *The potency and levels of human or environmental exposure would be a more focused means of identifying CoCs.*

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[2] Olson, H., *et al*. (2000) Concordance of the toxicity of pharmaceuticals in humans and in animals. *Regulatory Toxicology and Pharmacology* **32**(1):56-67

I continue to be concerned about the fundamental structure of the Candidate Chemical list. A list built from lists of chemicals with existing toxicologic or policy concerns will fundamentally encourage the use of new and less tested materials. If the AA process is robust enough, this may not be a problem. Making the AA process sufficiently robust will be a challenge.

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.*

Given the enormous number of chemicals likely to be on the Candidate Chemical list, the priority setting process must be rigorous and science-based to identify the right chemicals for further scrutiny. I have no confidence that the process in the revised proposed regulations will accomplish this. In my view, the change of the criterion from "ability to" to "potential" decreases the precision with which priority products can be identified. The change makes interpretation difficult (what does it mean to have "potential *exposures which must contribute to or cause significant or widespread adverse impacts"?)* and increases the possibility of arbitrary judgments about what evidence constitutes "potential" in both adverse effects and exposure contexts.

I would urge a return to the "ability to" language and, further, encourage development of guidance to clearly define how these judgments will be made. Some notion of causation along with criteria for evaluating both causation and attribution will be necessary.

I do not believe the use of biomonitoring data to as a prioritization factor can be scientifically supported (Section 69501.1 (a)(58)(B). Because biomonitoring data cannot apportion exposure to different sources and many Candidate Chemicals will have many sources of exposure (see Table) the identification of a chemical in biomonitoring studies does not indicate a product is a source of exposure.

Chemical	Candidate Chemical Hazard List	Non-Product Sources
Acetalehyde	Proposition 65 Carcinogen	Fruits Coffee Cigarette smoke
Benzene	Proposition 65 Carcinogen and Reproductive Toxicant	Eggs Bananas Cigarette smoke Gasoline

3. The principles outlined in the proposed regulations that establish the 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 be an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedure 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.

The new approach to an Alternatives Analysis Threshold makes little sense to me. First, contrary to other regulations like those implementing Proposition 65, 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. Second, it will be very difficult to administer. Constant advances in analytical chemistry mean the PQL will be a shifting target. The need to reexamine and update (and potentially revoke) threshold status will be constant, diverting effort and resources.

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.

It is understandable and appropriate that the revised proposed regulations seek to identify and prioritize chemical uses that cause adverse effects on people or the environment. However, as defined in the 2013 Revised Proposed Regulations the term "adverse" is a confusing mix of qualitative, quantitative and theoretical effects with no concrete standard that must be met. For example, it is completely unclear who makes the designation, and which methods will be used, to identify "cumulative effects," "aggregate effects" or "potential to contribute to or cause adverse impacts" under § 69503.3. As noted above, the use of the term "potential" exacerbates this problem because the word has no generally agreed upon scientific meaning.

In my view the use of loose language in defining "adverse" will lead to either very little prioritization (because every product-chemical combination will have the "potential" for some exposure or adverse effect) or accusations of arbitrary behavior in prioritization because some assertions of "potential" put forward will be accepted and some will not.

Additional comment: § 69503.2 – How will DTSC know there is a "readily available safer alternative…."? This seems to open the potential for lobbying and strategic behavior on the part of competitors or vendors.