

Review  
Safer Consumer Product Alternative Regulations

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I appreciate the opportunity to review the revised Safer Consumer Product Alternative Regulations. Considerable progress has been made due to the expertise of the Department of Toxic Substances Control and the Green Ribbon panel and other advisors who have contributed to this effort. My review is based on my understanding, developed through reading the materials supplied. This review reflects my opinions and not necessarily those of George Washington University.

I look at the proposed regulations as a risk analyst and toxicologist with a public health perspective. My overarching interest is ensuring that a system that helps decide what materials in products are of concern and how those should be addressed truly leads to decisions that reduce risk. To this end I begin with a brief statement of my view of alternative assessment so that my approach and views, which clearly influence the way I review the documents, are clear. I then address each of the charge questions in turn and then provide a few specific comments.

**My View**

California is to be commended for taking on the challenge of finding safer chemicals for products and processes. The careful analysis of alternatives when a potential impact is identified in a product is an important step in ensuring risk reduction. A focus on life-cycle thinking is appropriate and can help avoid unintended consequences in choosing alternatives. The focus on all populations, including those that may be more vulnerable, is important and appropriate<sup>1</sup>.

Doing alternatives assessment right and really ensuring that choices reduce risk is very difficult. Two critical, but often overlooked, factors complicate alternatives assessments. First, our traditional approach to chemical assessment can easily confuse and mislead the effort. Second, even if we could appropriately assess the risks of alternative chemicals well, choosing between alternatives means weighing incommensurate outcomes.

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<sup>1</sup> Recognizing that current risk assessment processes are often already focused on potentially vulnerable populations. For example, the US Environmental Protection Agency Defines its Reference Dose (often called the RfD) as “an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (**including sensitive subgroups**) that is likely to be without an appreciable risk of deleterious effects during a lifetime.” [emphasis added]

Traditional chemical assessments have made what are often characterized as “health protective” choices in the face of the inevitable uncertainty associated with the generalizations and extrapolations necessary in using data from surrogate species or different conditions of exposure to assess risk. Critical to alternatives assessment is the recognition that these “protective” science policy judgments can scramble priorities because the degree of precaution differs arbitrarily across chemicals. Simply put, the assumptions are more scientifically appropriate for some chemicals than others.

Take the example of carbon tetrachloride, sure to be a Chemical of Concern (CoC) under the California Safer Consumer Product Alternative Regulations because of its presence on many lists of carcinogens. Both CA OEHHA and US EPA interpret the toxicologic database to suggest that carbon tetrachloride is a cancer risk at any level of exposure. That judgment is in line with the science policy directions of both organizations. But the scientific appropriateness of this assumption is not shared uniformly. The World Health Organization’s International Program on Chemical Safety judges carbon tetrachloride to be a carcinogen with a threshold for its effects with no risk at all at low exposures<sup>2</sup>. Should carbon tetrachloride be a CoC or a desirable alternative for other, more dangerous, solvents?

The key point is that comparing alternatives means that we want have the best and most scientifically appropriate interpretation of risk, not one that is “health protective.” Good alternatives assessment means there is not a thumb on the scale when we are weighing the risks of different chemicals. Alternatives assessment needs to push the evolution of risk assessment tools to generate best estimates of risk, including attendant uncertainty, to ensure good choices.

Successful alternatives assessment also involves weighing competing outcomes<sup>3</sup>. All chemicals have the potential for toxicity at some level of exposure. Attributes of the chemical (like vapor pressure) or its use will determine if adverse health or environmental effects are likely. But chemicals have other characteristics we may want to avoid like flammability, corrosivity or acting as a greenhouse gas. Factors like performance, availability and cost complicate things further. When alternative chemicals vary on many attributes an inherent value judgment must be made regarding the relative concern for each outcome. Because this is not a strictly scientific exercise we must recognize that different individuals will have different views of the relative importance of risk to public health versus worker health versus

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<sup>2</sup> WHO International Program on Chemical Safety Environmental Health Criteria 280 Carbon Tetrachloride, Section 10.1.3 "There is little evidence to suggest that carbon tetrachloride is genotoxic. A quantitative assessment for threshold effects...was therefore employed"

<sup>3</sup> Gray, G.M., and Hartwell, J.K. (1995) The Chemical Substitution Tree: A Framework to Evaluate Risk in Chemical Substitution Decisions. *Pollution Prevention Review* 5:7-17

ecological effects. Sometimes we may find an alternative that is better in every way than the CoC but these situations are likely to be rare. Alternatives assessment must be transparent about how different attributes are considered and weighed against each other. The use of tools like multicriteria decision theory<sup>4</sup> can advance the credibility of these decisions.

### **Charge**

*The statute mandate 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 points that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review. In each point, 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.*

#### **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 Chemicals of Concern (CoC) list.**

- Developing a scientifically appropriate and defensible CoC list is clearly necessary and challenging. To identify key candidates for Alternatives Analysis (AA) the goal would be chemicals most likely to pose a significant risk to workers or consumers.

I am concerned that the effort to cast a very wide net (expected by DTSC to be ~ 3000 compounds) by combining lists of chemicals developed for other purposes to determine CoCs will fail to appropriately focus this effort. It is virtually certain that the list will be too large. If everything is a Chemical of Concern then nothing will be a chemical of concern. I believe the prioritization criteria listed in Article 3 are too broad to help without significantly more specificity.

- 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

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<sup>4</sup> Kiker, G.A. et al. (2009) Application of Multicriteria Decision Analysis in Environmental Decision Making. *Integrated Environmental Assessment and Management* 1:95-108

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.

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<sup>5</sup>.

The potency and levels of human or environmental exposure would be a more focused means of identifying CoCs.

- The use of chemicals that have been put on biomonitoring lists by California or the CDC seems tautologous (§69502.2 (a)(2)(F&G)). Presumably, these chemicals are monitored because they are of concern. Would there be a minimum number of positive samples required to be a CoC? I find it hard to imagine that possible exposure is an efficient way to identify potential CoCs.

**2. Use of the initial product prioritization criteria in the chemical and product prioritization process in Article 3 are sufficient to identify all types of consumer products with CoCs as potential Priority Products. Use of the key prioritization criteria considers those critical factors which identify the potential Priority Products during the initial phase as high priority.**

- The goal of appropriately prioritizing products is necessary and admirable. Including potentially important factors like aggregate and/or cumulative effects and sensitive populations is a worthy goal. However, for most compounds the ability to rigorously address these concerns is very difficult. Important scientific issues like the boundaries for cumulative risk assessments (*e.g.*, are natural products or pharmaceuticals included when looking at product risks?) make use of these tools challenging today. I recognize the aim of a flexible approach to AA

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<sup>5</sup> Olson, H., *et al.* (2000) Concordance of the toxicity of pharmaceuticals in humans and in animals. *Regulatory Toxicology and Pharmacology* **32**(1):56-67

but specifying tools with little agreement on their application may be a recipe for confusion and contention.

- It is unclear to me how “Reliable information concerning public...exposure to the Chemical(s) of concern...” can be used to set priorities. For many compounds there are numerous sources and opportunities for exposure. For example, many compounds that are likely to be on the CoC list, because they are on the Proposition 65 list, are also found in foods. There clearly is reliable information that people are exposed (see Table below<sup>6</sup>). Others are found cigarette smoke, automobile exhaust or have natural sources. How will exposure be apportioned to consumer products?

Proposition 65 chemicals and some foods in which they are naturally occurring

<b>Aniline</b>	<b>Mercury</b>	<b>Methanol</b>
Carrot	Ginger	Orange
Garlic	Rice	Cauliflower
Cabbage,	Coconut	Onion
Apple	Parsley	Pineapple
Celery	Spinach	Tomato
Kale		Black currant
Tea		
Corn		

- The identification of the opportunity for public health or environmental risk reduction as a prioritization factor (§69503.2 (b)) is very sensible. However, using these criteria will require combining both hazard and exposure in a way that is not specified. How widely a product is used in a poor surrogate for exposure because it is obvious that there will be situations in which a chemical of concern is present in a product in a way that will have little or no human or environmental exposure potential and cases with serious exposure potential.

**3. The principles outlined in the proposed regulations that will allow the department to develop Alternatives Analysis Threshold based on best available technologies is scientifically understood**

- The Alternatives Analysis Threshold Exemption is an important administrative tool for focusing effort and resources

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<sup>6</sup> Sources: Dr. Duke's Phytochemical and Ethnobotanical Databases (<http://www.ars-grin.gov/duke>); Duke, James A (2000) Handbook of Phytochemical Constituents of GRAS Herbs and Other Economic Plants: Herbal Reference Library

- The attributes considered in establishing thresholds are a mix of scientific factors (*e.g.*, naturally occurring, potency, bioaccumulation potential) and judgments about the “appropriateness” of the chemical (*e.g.*, ease or difficulty of removing from the product, detectability, unintended presence of the CoC in organs tissues or fluids). Others are technical but have little general agreement about how they should be implemented such as evaluation of aggregate or cumulative exposures. For example, the definition of cumulative risk (called cumulative exposure in the document) “exhibit the same hazard trait and/or environmental or toxicological endpoint(s)” is congruent with the definition in one recent National Academy of Sciences report<sup>7</sup> but at odds with that in another<sup>8</sup> (which requires identical modes of action for cumulative risk). These attributes need more specificity to ensure consistency and fairness in their application

**4. The definitions of the various “adverse” impacts and general usage of the term “adverse” impacts is used throughout the regulations. Within the context of the definitional and general use of the term “adverse” impacts in the regulations and when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment.**

- These comments are based on my reading of §69501.1 (a) (3)-(10), in which “adverse effects” of various sorts are defined. I was unable to locate Chapter 54 with more detailed descriptions
- In my view, as a toxicologist and risk analyst, adverse effects are actual outcomes like those defined in §69401.2 (“... a biochemical change, functional impairment, or pathologic lesion that negatively affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge”).
- Adverse air quality impacts as defined (emissions of listed contaminants (§69501.1 (a)(3)) are not adverse impacts. They may result in adverse impacts
- Adverse ecological impacts (§69501.1 (a)(4)) are well defined except for an intimation that bioaccumulation might be considered an adverse effect. Bioaccumulation without consequences is not an adverse effect.

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<sup>7</sup> National Research Council (2008) *Phthalates and Cumulative Risk Assessment: The Tasks Ahead*. National Academies Press, Washington, D.C.

<sup>8</sup> National Research Council (2009) *Science and Decisions: Advancing Risk Assessment*. National Academies Press, Washington, D.C.

- Public health impacts are reasonably defined subject to my concerns about the concordance of hazard traits between test species and humans that is discussed above. However, exceedance of a standard is not an adverse effect. The values used in setting standards (e.g., RfDs) have some degree of conservatism embedded (although the amount is not known). There may be public health consequences above a standard but it is not certain.

### **Other Points**

- The flexibility allowed in the conduct of AAs is appropriate and necessary. A great deal of learning and experimentation will occur with early AAs and methods and approaches will need to constantly evolve. Too prescriptive an approach will stifle innovation and the ability to adjust to new scientific knowledge.
- §69501.1 (53) (B) The use of biomonitoring data to demonstrate exposure to a COC seems problematic. There will clearly be sources of exposure (*e.g.*, smoking, diet) that will have nothing to do with consumer products. This information is also unlikely to be useful for identifying and prioritizing CoCs and products.
- §69501.1 (53) (D) 1 It is important to remember that RfDs and other risk values are based on average daily intake over a lifetime. A point concentration at a single location or point in time is not necessarily “associated with adverse public health or environmental impacts.”

There are several places where the specifications for AA are too vague.

- §69505.3 How one would determine that an “alternative chemical poses equal or greater adverse public health and/or environmental impacts than the CoC” is not specified at all. The multiattribute nature of the potential impacts and our ability to estimate those impacts quantitatively make this a very important judgment.
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- §69505.4 It appears there is an attempt to recognize the need for weighing various attributes of alternative chemicals (section (b)(6)) but there is no guidance on how this is to be done. Because reasonable people can disagree about the appropriate weight to put on different factors this step would need considerably more specificity and a requirement for complete transparency.