

Review
Safer Consumer Product Alternative Regulations

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Summary

My review of the proposed Safer Consumer Product Alternative Regulations finds both good points and areas of concern. I begin with a general summary, address the specific charge questions and then provide a couple of individual comments. My responses are focused on the areas of my scientific and technical expertise and my understanding of the materials provided. I do not address questions of the scope or applicability of the regulations.

I recognize the considerable effort and process that has gone into the development of these proposed regulations. The expertise of the Department of Toxic Substances Control and the Green Ribbon panel that was assembled is extensive and impressive. I am sure that there is a great deal of thought and discussion that went into the proposed regulations that is difficult to reflect in the documents. My review is based on my understanding, developed through reading the materials supplied.

The goal of identifying impacts of consumer products or their constituents (if they exist) and reducing those impacts is laudable. 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 appropriate¹.

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 me this means evaluating the

¹ 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]

risks of a current material or product objectively and accurately. It also means being able to compare the risks of the product as currently formulated with the risks of an alternative formulation. I am not confident that the proposed regulations meet these goals.

Some of my concerns arise from a lack of clarity about how specific steps of the regulatory process will occur. Much of this comes from confusing terminology. The proposed regulations emphasize a goal of reduced impacts (page 8), which are generally considered to mean the risk of, or actual, adverse public health outcomes (like death or disease) or environmental damage. To understand potential impacts, and evaluate alternatives, requires a risk-based approach. Yet the word risk does not appear in the description of the proposed regulations (Department Reference Number R-2010-05), except in reference to a GAO report, and other less well-defined words are used instead. For example, “threat” is frequently used but its meaning is not clear. If it is interpreted to mean “hazard” in the general risk assessment paradigm, it is insufficient for decision-making. At the same time other discussion of the evaluation of “threats” posed to human or environmental health seem to point toward a risk-based approach. For example, in developing the list of “Priority Chemicals” DTSC says it will “consider both the potential for exposure to the chemical and the potential harm resulting from potential exposures.” Perhaps the proposed regulations would be best served by replacing the term “threat” with the better defined and better understood term “risk.”

Without an evaluation of exposure and the unique dose-response (or concentration-response) relationship for each chemical we cannot be sure that chemicals of concern have been appropriately identified and that alternative assessment really identifies lower risk options. Exposure considerations must go beyond volume in commerce or types of use to actually consider the properties of the chemical and the potential exposures that consumers or the environment actually face. The risk-based approach must also confront the scientific uncertainty inherent in evaluations of potential hazard and strive for best estimates of risk to ensure sound comparisons.

The proposed regulations appear to me to continue a focus on existing lists of potentially hazardous materials and may foster a biased focus on “the same old chemicals,” compounds with significant databases and long-standing policy concern. To combat this information and attention asymmetry it would be useful to use existing tools, or develop new tools, to develop provisional hazard and risk values for all chemicals. This would facilitate sound identification of chemicals of concern and alternatives assessment and the provisional nature would stimulate the development of data to refine our knowledge. Unless a way is found to ensure parity in the attention given to different chemicals we are in danger of moving from the frying pan into the fire.

Finally, there is little specificity on the approaches that will be developed to guide Alternatives Assessment (AA). This is a key part of the process and will require

hard thinking about identifying and characterizing risks for comparisons. The inevitable tradeoffs that will occur between alternatives must be confronted. It is highly unlikely that any one alternative considered in an AA will be superior on all health and environmental dimensions, let alone those of feasibility or performance. A hazard-based system like the Green Screen for Safer Chemicals provides, in my opinion, insufficient information for these decisions. Weighing a potential kidney toxicant against a highly flammable compound or a greenhouse gas or a material that requires greater energy use to perform its function requires quantitative predictions of the actual outcomes that might occur, not just a listing of potential hazards.

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 basis for developing the proposed regulatory text that is the focus of this peer review.

1. 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) lists.

One of the stated goals of the bills these regulations are implementing is "acceleration of the quest for safer products." By definition this activity requires the comparison of the risks of current products and the new products or processes that may replace them. If the risks are not accurately assessed we will not know if the products currently in use are safe or if the replacement products truly reduce risk to the consumer and the environment.

The proposed regulations appropriately take a life-cycle approach to evaluating the potential health or environmental risks of current products and their redesigned or reformulated replacements. The goal of identifying the chemicals and products that pose the greatest public health and environmental risk is approached through the prioritization of chemicals of concern (COC) into a list of "priority chemicals." This information will be used to identify "priority products" to undergo a defined series of alternative assessment steps. In some cases, I believe, this will be a quite

straightforward process but in others there will be real challenges to comparing chemicals and confidently identifying “safer” products.

I have several scientific and analytic concerns about the proposed approach to COCs and its ability to ensure sound assessment of both current products and chemicals and potential alternatives.

- The approach seems to be strongly oriented toward a hazard-based approach, utilizing lists of chemicals with certain identified “hazard traits.” If prioritization is focused on hazard (e.g., prioritization by lists (p12)) without consideration of relative toxicity it is not clear that identification of COCs will be appropriate and comparison of alternatives is essentially impossible.
- There seem to be a strong focus on certain hazard traits. It is not clear to me why, for example, kidney toxicity is less of a priority than other endpoints. There is also mixing of outcomes and mechanisms. Endocrine disruption, for instance, is a mechanism of toxicity not an “impact.”
- It is not clear how exposure to be handled – 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. This is discussed under Section 69302.1(a)(2) but how it is to be determined that a compound has “no exposure pathway that might pose a threat to public health or the environment in California...” without the use of quantitative risk assessment is not clear to me. Some judgment will need to be made about what is a “threat” (i.e., what specific level of risk – as in the implementation of NSRLs for Proposition 65) and what exposure pathways might exceed that level. In my view this can only be done on a quantitative basis.
- “Potential exposure” (used in developing the list of COCs) is a very vague term that doesn’t seem to discriminate between levels that might be of real concern and those that would not.

2. Use of consumer product marketing, potential for exposure of the COC 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.

- The lifecycle approach to thinking about opportunities for exposure is to be commended.
- I recognize the need for some way to consider exposure in a priority-setting scheme. However, marketing data or presence in products would be considered

very low on a hierarchy of exposure data². The variability in products, in uses and in matrices means that these surrogates would be very, very crude stand-ins for human or environmental exposures.

- I would urge the consideration of approaches like “intake fraction³,” developed especially for lifecycle analysis and comparative risk assessment as a more rigorous method for identifying exposures of concern.
- Identification of “Products of Concern” and “Priority Products” must reflect the actual exposure potential of a particular use of a chemical. Even low level marketing or use can give rise to substantial exposures in dispersive applications while widespread use may have little opportunity for exposure if the chemical is sealed, bound to a matrix or otherwise unavailable. The goal here should be identification of the highest risk uses.

3. Use of human health and environmental impacts of the COC in the Alternatives Assessment to develop safer consumer products.

- It is critical that the Alternatives Assessment phase appropriately consider the potential risk of the COC/Priority chemicals and those that may be used as replacements. A focus on hazard, rather than risk, may bias this comparison.

A critical concern is the information asymmetry likely to occur between listed COCs and PCs and the potential alternatives. Given that all substances have the potential to cause toxic effects, it is often less scrutinized chemicals that are not on lists and are looked to as possible alternatives. To address this, the regulatory scheme should use a method for developing “provisional” health and environmental profiles of all chemicals that would provide judgments on potential hazards and identify specific risk levels. There are a wide range of tools and relationships that have been developed in this area⁴.

² National Research Council (1991) *Environmental Epidemiology: Public Health and Hazardous Waste*. National Academies Press, Washington, DC

³ Bennett, D.H., McKone, T.E., Evans, J.S., Nazaroff, W.W., Margni, M.D., Jolliet, O., and Smith, K.R. (2002) Defining Intake Fraction. *Environmental Science and Technology* **36**:207A-211A; Bennett, D.H., Margni, M.D., McKone, T.E. and Jolliet, O. (2002) Intake Fraction for Multimedia Pollutants: A Tool for Life Cycle Analysis and Comparative Risk Assessment. *Risk Analysis* **22**:905-918

⁴ For example: Layton, D.W., Mallon, B.J., Rosenblatt, D.H., and M.J. Small (1987) Deriving allowable daily intakes for systemic toxicants lacking chronic toxicity data. *Regulatory Toxicology and Pharmacology* **7**:96-112; P. Crettaz, D. Pennington, L. Rhomberg, K. Brand and O. Jolliet, Assessing human health response in life cycle assessment using ED10s and DALYs: Part I – cancer effects, *Risk Anal.* **22** (5) (2002), pp. 931–946; C.J. Moudgal, R. Venkatapathy, H. Choudhury, R.M. Bruce and J.C. Lipscomb, Application of QSTRs in the selection of a surrogate toxicity value for a chemical of concern, *Environ. Sci. Technol.* **37** (22) (2003), pp. 5228–5235; C.C. Travis, A.W. Saulsbury and S.A. Pack, Prediction of cancer potency using a battery of mutation and toxicity data, *Mutagenesis*. **5** (1990), pp. 213–219; L. Zeise, R. Wilson and E.A. Crouch, Use of acute toxicity to estimate carcinogenic risk, *Risk Anal.* **4** (3) (1984), pp. 187–199; Venkatapathya, R., Wang, C.Y., Bruce, R.M.

This could encourage additional testing in a cost (and animal) effective manner. For example, a QSAR model could be used to estimate a *daphnia* LD₅₀ that would be the basis of alternative assessment for acute environmental toxicity. Similar evaluations could be used for other endpoints. Provisional assessments could then be modified on the basis of suitable data developed by proponents of the chemical. This approach would provide risk-based information for alternative assessment of less tested chemicals on scientific (although uncertain) grounds. It would encourage efficient testing in that only evaluations seen as unacceptable by chemical proponents would be tested.

- It is unclear how the AA process envisions confronting the inevitable tradeoffs that will occur as alternatives are compared. A compound thought to be less toxic (or not on a list of concern) may require greater energy use to perform a function or may be a Green House Gas (GHG) or contributor to tropospheric ozone formation. The proposed regulations are silent about both the existence of these tradeoffs, let alone those associated with performance, and how they might be addressed.
- It is also important to focus on the very real scientific uncertainty in the characterization of the risk of COCs and their alternatives. One way to illustrate this is to compare the different “levels of no significant concern” issued by different organizations. In the table below I compare the evaluations by CA EPA and the World Health Organization (WHO) for three compounds on the CA Proposition 65⁵ List of Chemicals Known to the State to Cause Cancer or Reproductive Effects. Each would be presumed to be at least a COC and perhaps a Priority Chemicals because of its presence on the list.

Each evaluating organization musters considerable technical expertise to assess all available information. The CA values are No Significant Risk Levels (NSRLs) calculated for the implementation of Proposition 65. The WHO numbers are Tolerable Daily Intakes to guide decisions about drinking water quality. In each case, the two organizations agree that there is evidence that the chemicals are animal carcinogens although they are not known human carcinogens. The two organizations make different science policy judgments about how to quantify the risks, however, and the range of values provides an insight into the very real scientific uncertainty associated with judging how “toxic” these chemicals are (or how desirable a substitute they might be). Clearly a thirty fold (let alone a three hundred fold) difference in the view of what level of exposure is potentially of concern could make a very large difference in a judgment about whether a chemical is of concern or not (or is a suitable alternative or not).

and Moudgal, C. (2009) Development of quantitative structure–activity relationship (QSAR) models to predict the carcinogenic potency of chemicals: I. Alternative toxicity measures as an estimator of carcinogenic potency. *Toxicology and Applied Pharmacology* 234: 209-221

⁵ Safe Drinking Water and Toxic Enforcement Act of 1986

Compound	CA NSRL (ug/day)	WHO TDI ⁶ (µg/day) ⁷	Fold Range
Carbon Tetrachloride	5	98	19.6
1,4 Dioxane	30	1120	37.3
Para-Dichlorobenzene	20	7490	374

The fact that the CA NSRLs are lower in each case may indicate greater conservatism or precaution in the science policy choices made in the assessment process. The use of conservative approaches, especially when they are differentially conservative, has the very real potential of misleading comparisons of alternatives. Scholars have long identified this concern about risk assessment science policy choices in cases where risks are compared⁸. Sound comparisons require central or best estimates of risk with characterization of uncertainty to enable risk-reducing decisions.

Individual Comments

- Description of “toxic-free” products (p7) is scientifically inappropriate. All substances, natural and man-made have the capacity to cause toxicity at the appropriate level of exposure.
- Similarly, the idea that “..none of the alternatives being considered contain a chemical that exhibit a hazard trait” (p17) makes no toxicologic sense
- Are there any provisions for evaluating compounds or products with public health benefits? It seems any evaluation or AA would need to factor in performance.

⁶ WHO Chemical Hazards In Drinking Water
(http://www.who.int/water_sanitation_health/dwq/chemicals/en/)

⁷ Converted from value in µg/kg/day by multiplying by 70 kg

⁸ For example: Nichols, A.L., and Zeckhauser, R.J. (1988) The Perils of Prudence: How Conservative Risk Assessments Distort Regulation. *Regulatory Toxicology and Pharmacology* **8**: 61-75; Zeckhauser, R.J. and Viscusi, W.K. (1990) Risk Within Reason. *Science* **248**:559-564