

Peer Review of Proposed Regulations, R-2011-02

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The following represent my opinions on the Text of Proposed Regulations regarding Safer Consumer Product Alternatives (Chapter 55). They are based on my careful reading of the text of the proposed regulations, with particular attention to the portions dealing with Chemicals of Concern and Product Prioritization and Alternatives Analysis. The following refers to the Scientific Factors upon which I was asked to comment.

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.

The Department of Toxic Substances Control (DTSC) was mandated under AB 1879 to adopt regulations to establish a “process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.” The DTSC’s criteria for defining Chemicals of Concern is straight forward, thorough and scientifically sound. Each of the criteria is based in solid peer-reviewed science. We can be confident that these criteria are sufficient to produce an initial Chemicals of Concern list. Similarly, the process for making additions to the Chemicals of Concern list is clear and science-based.

As I indicated in my evaluation of an earlier draft of the proposed regulations, the DTSC’s inclusion of chemical and physical properties, chemical volume in commerce, and adverse impacts to sensitive subpopulations, potential for exposure in a consumer product, and adverse impact to the environment is not only consistent with this mandate, but necessary to meet it. The specific metrics for evaluating chemicals against each of these prioritization criteria are quite complete. I reiterate my earlier concern that, for the majority of chemicals, quantitative data exist for only a small subset of these criteria and metrics. This is not a flaw in the proposed regulations, but is rather a statement of the need for more data.

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 criteria for identifying and prioritizing products containing Chemicals of Concern are clear, comprehensive and based on sound science. The framework of focusing on the potential for adverse public health or environmental impact during the product life cycle, potential to

impact particular groups of individuals, species or ecosystems, and the mode and volume of product use is logical and scientifically sound.

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 principles underpinning the department's Alternative Analysis Thresholds are clear and will ensure that approval of alternative chemicals is based on the best available science and technologies. The current wording removes the ambiguity associated with the *de minimis* concept used in earlier drafts. The threshold is not to be interpreted as a risk/no risk determination.

The array of factors influencing AA threshold determinations includes consideration of the source of chemicals of concern and minimum detectable concentrations. The emphasis on "detection" as a minimum threshold rather than "quantitation" is consistent with our understanding that chemicals may have adverse impacts on health or ecosystems at concentrations below levels of quantitative measurement. The list of other considerations (Inherent potency, bioaccumulation potential, body burden, existence of a threshold dose, variation among populations in susceptibility, product use and cumulative effects) is quite complete.

The two-stage process ensures that there is first identification of product requirements and a thorough audit and presentation of potential chemical alternatives, then a very detailed evaluation of the properties of existing and potential alternatives. The criteria for suitable Alternative Analyses are clear, as are the necessary qualifications for entities carrying out AAs.

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.

"Adverse" is carefully defined and applied consistently throughout the proposed regulations. Furthermore, when scientific information is available, a qualitative or quantitative determination of adverse impact can generally be made. As I discussed above, scientific information may be in short supply with regard to some criteria. However, the proposed regulations provide sufficient latitude in such situation to protect the interests of both the public and "responsible entities."

The Big Picture

My comments on the earlier draft of these regulations (R-2010-05) pertain here. Overall, I find these regulations to be consistent with accepted scientific principles and process. Priorities are set based on a quantitative assessment of risk (exposure probability and potential consequence of exposure to the public, sensitive groups and the environment). The emphasis on evaluation of full life cycle is important. The criteria for exemptions are clear, as

are the processes for evaluating and granting them. The emphasis on green chemistry principles in the regulatory process is also consistent with the science and best practices overall.

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