

SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

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Thank you for this opportunity to peer review California's green chemistry safer products proposed regulations. The revised scope of work, dated 18 July 2012, requests a determination for 4 specific points that constitute the scientific basis of the proposed regulations. These are set out in Attachment 2 "Scientific Factors – Peer Review Points." In summary, you have asked for a determination regarding:

- The use of chemical lists used to produce the initial Chemicals of Concern (CoC) list [section 69502.2]
- The use of initial product prioritization criteria to identify consumer products containing CoCs as potential Priority Products [section 69503.2]
- The principles that will be used to develop the Alternative Analysis Threshold [section 69503.5], and
- The definitions of various "adverse" impacts and general usage of the term "adverse" impacts, as it is used throughout the regulations, but especially in sections 69501.1(a)(3) – (10).

In addition, you have asked reviewers to contemplate certain "big picture" questions, such as:

- Are there additional scientific issues that are part of the scientific basis of the proposed rule that are not covered? And
- Taken as a whole, is the scientific portion of the rule grounded in sound scientific knowledge, methodology and practice?

My detailed comments are set out below. *Please note that I am submitting this peer review on my own behalf and that the views expressed in this review do not necessarily represent the views of my employer, Johns Hopkins University and the Johns Hopkins Bloomberg School of Public Health.*

**I. Conceptual Overview and Review of Key Principles**

Attachment 1 (Revised 18 July 2012) contains an informative digest and policy statement overview of these proposed regulations. This attachment references a

University of California, Berkeley 2006 report on green chemistry. This report identified in its findings three “gaps;”

Data gap – a lack of information on which chemicals are safe, which are toxic, and which are in consumer products. An unequal marketplace is created by this lack of access to chemical data.

Safety gap – a lack of tools available to governmental agencies, which cannot appropriately prioritize chemical hazards nor easily remove hazardous products from the market.

Technology gap – an absence of regulatory incentive and market motivation to move toward a green chemistry marketplace, and a lack of investment in the tools that are necessary to build a green chemistry infrastructure.

In part to fill these gaps, and protect public health and the environment, California’s EPA launched a green chemistry initiative in 2007 that is built on six policy recommendations. These recommendations were intended to lead to development of a new consumer products economy that will produce and market toxic-free, sustainable products. Two of these recommendations – to create an on-line toxics clearinghouse on products that will provide data to the market and public, and an accelerated quest for safer products, which creates a systematic, science-based process to evaluate chemicals of concern and identify safer alternatives to ensure product safety – were captured in Assembly bill 1879 and Senate bill 509, and signed into law.

The proposed regulations that are subject to this peer review are intended to implement the second of these two recommendations (accelerate the quest for safer products). The specific objectives of the proposed regulations are to establish a process to identify and prioritize chemicals, or chemical ingredients, that are “chemicals of concern (CoC);” establish a process for evaluating CoCs in consumer products, as well as potential alternatives; and specify regulatory responses that can be taken at the end of an alternatives analysis.

## **II. Specific Peer Review Areas**

With this background in mind, I would like to turn to a discussion of the specific determinations I was asked to address as part of this peer review.

### **A. The use of chemical lists used to produce the initial Chemicals of Concern (CoC) list [section 69502.2]**

According to the proposed regulations, a CoC is defined as “a chemical identified as a Chemical of Concern under section 69502.2(a) or a chemical listed by the Department under section 69502.2(b).” Section 69502.2(a) has a two-part test for identifying CoCs.

First, it identifies CoCs as chemicals that exhibit a hazard trait or an environmental and toxicological endpoint. Both of these terms are defined in chapter 54 of the California Code (see sections 69501.1(a)(29) & (32)).

If either (or both) of these criteria is met, a chemical will be a CoC if it meets one or both of a series of other criteria. First, the chemical is on one of the 13 lists found at section 69502.2(a)(1)(A) – (N). Second, the Department<sup>1</sup> can identify additional chemicals that exhibit hazard traits or environmental and toxicological endpoints by considering a series of factors about the chemical, based on reliable information. These factors include potential adverse public health or environmental endpoints, physical and chemical properties, environmental fate, and ability to degrade into another CoC.

The list of lists, contained in 69502.2(a)(1)(A) through (N), is appropriate for the purposes of this regulation. Each of these lists has been peer reviewed in some manner by the authoritative organizations that prepared them. In addition, the process outlined in this section, which begins by reviewing the chemicals in these lists, is science-based and reasonable. The proposed regulations correctly adopt a narrative, rather than a prescriptive, approach which is also reasonable given the scientific needs of the statute and its unique requirements. Based on the language of the proposed regulations, I assume that the Department will also review the chemicals on these lists before any chemical is characterized as a CoC, and that this review will confirm that the chemical either exhibits a hazard trait, or an environmental or toxicological endpoint. From a scientific perspective, it does not seem necessary at this time to establish a rigid set of rules for classifying CoCs. These rules will likely emerge, if needed, as the regulations are implemented and the Department and the regulated community gain more experience in determining CoCs.

B. The use of initial product prioritization criteria to identify consumer products containing CoCs as potential Priority Products [section 69503.2]

According to the proposed regulations, once a list of CoCs is created, the Department can evaluate products containing these CoCs to determine if they are “Priority Products” that might require further action. Priority Products are those consumer products that contain a CoC, or multiple CoCs, above a certain threshold. The factors and other provisions in this section frame the process to identify and prioritize products that contains CoCs.

The prioritization factors are set out in section 69503.2(a)(1). These factors are descriptive and general, relying heavily upon the Department’s assessment of the product to adversely impact public health and the environment. The Department will review and evaluate the CoC’s hazard traits, aggregate effects, cumulative effects,

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<sup>1</sup> Department = Department of Toxic Substances Control (see section 69501.1(a)(25))

physical and physicochemical properties, and other factors. It will also give priority to products that meet both criteria in section 69503.2(b). These are (1) the product contains CoCs that have a significant ability to cause, or contribute to, adverse public health or environmental impacts or (2) the product has a significant ability to create exposure to the public and/or aquatic, avian, or terrestrial animal or plant organisms to the CoCs in the product so as to contribute to or cause adverse public health or environmental impacts.

In section 65903.2, the Department has proposed a narrative methodology for classifying priority products. The prioritization factors set out in this section and the process to apply them is largely descriptive. This descriptive narrative approach is science-based and makes sense given the nature of the statute and its intent.

This section would benefit from the addition of provisions that expand the information that is available to make these determinations. It consistently refers to the use of “available information,” which does not seem to extend beyond information that is publicly accessible. To enhance the scientific bases of the decision-making described in this section, it would be useful to seek data from the public and members of the business community. Perhaps a data call in provision should be added to this section.

Section 69503.2(a)(1)(B) should be expanded to include information about accidents or overexposures. The purpose of this section is to assess possible exposure scenarios to Priority Products, with a focus on “reasonable product use.” While this is an important starting point, it is also appropriate and scientifically necessary to include accidents and over-exposures, even if these resulted from unintended or improper use of the products. From a scientific perspective, it is essential to construct an exposure distribution, and understanding the “tail” of this distribution (ie., overexposed persons) has scientific value in exposure assessment and analysis. Such information should be available from federal or state agencies, or the companies themselves.

C. The principles that will be used to develop the Alternative Analysis Threshold [section 69503.5]

This section is very important because it will allow the establishment of “thresholds” for that trigger alternative analyses of Priority Products. Priority Products containing CoCs that are below these thresholds will not be required to undergo an alternatives analysis. In other words, products that contain CoCs and have been classified as Priority Products can avoid undergoing an alternatives analysis if they are excluded under this section.

It is necessary first to affirm that, according to the proposed regulations, the default threshold for all CoCs is that compound’s minimum concentration that can be detected

with available laboratory analytical methodology<sup>2</sup>. (See section 69503.5(2)(B).) From a scientific perspective, this has superficial appeal. However, as applied it could be counterproductive and actually defeat the incorporation of the best science into the regulations.

The Department will be evaluating numerous CoCs in many Priority Products, and it is not clear that there are suitable laboratory analytical methodologies for CoCs under these diverse scenarios. Furthermore, some of the available methodologies may be relatively insensitive and thus not be able to detect the CoC at a public health or environmentally relevant level, even though it is known to be incorporated in the Priority Product. A better approach would be for the Department to evaluate first whether available laboratory analytical methods for CoCs are sensitive enough to detect CoCs at or below levels that have the potential to create a public health or environmental risk. If the answer to that question is no, then the Department should NOT set the detection level as the CoC's threshold. Another descriptive method should be developed, based perhaps on modeling and fate and transport of the CoC as it is released from the Priority Product into the environment. This approach can be incorporated into the current draft of the regulations by changing the provision at line 5, page 32 of the Text of the Proposed Regulations (Appendix 4) to read:

“(3) Notwithstanding paragraphs (1) and (2)(A), the Department may specify .... {strike out (A), thereby including (B) in this paragraph.}

This section also states that in the event that a Priority Product contains multiple CoCs that exhibit the same hazard trait or environmental or toxicological endpoint, the Department can specify a single alternatives analysis threshold that applies to the total concentration of the CoCs in the Priority Product. This approach is acceptable for 2 or more chemicals whose effects are known or suspected to be additive. However, there are combinations of chemicals whose joint affect might be multiplicative (or more than additive). Moreover, the CoCs might have a common toxicological endpoint, but different potencies. In such cases, the regulations should have flexibility to accommodate a non-additive way of combining these multiple CoCs. In addition, this section of the regulation should also cover situations in which a Priority Product has two or more CoCs that do not exhibit the same hazard trait or endpoint (eg., a compound that can cause both reproductive effects and cancer).

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<sup>2</sup> A discussion of how the Department determines a detection limit is contained in Attachment 6.

D. The definitions of various “adverse” impacts and general usage of the term “adverse” impacts, as it is used throughout the regulations, but especially in sections 69501.1(a)(3) – (10)

The proposed regulations contain several definitions, set out in sections 69501.1(a)(3) to (10), that focus on adverse impact and the meaning of the term “adverse” as used throughout the regulations. I will concentrate my comments on the term as it applies to public health, which is my area of expertise.

Based on my review of the proposed regulations, it appears that the adverse public health impacts are appropriately covered and are addressed in a scientifically appropriate manner. In addition to the definitions of adverse impacts listed in section 69501.1 (a)(3) to (10), section 69401.2 (a) (Article 1 of chapter 54) contains a definition for “adverse effect” that is scientifically valuable and captures the idea that an adverse effect can be pathway based. According to a 2007 National Academy of Sciences/National Research Council report, regulatory toxicity testing should be moving toward an approach based on pathways and perturbations.<sup>3</sup>

This definition states:

“‘Adverse effect’ for toxicological hazards and endpoints means 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 effect’ for environmental hazard traits and endpoints means a change that negatively affects an ecosystem, community, assemblage, population, species, or individual level of biological organization.”

This definition should also be incorporated into the definitions of “adverse public health impacts,” “adverse environmental impacts,” and adverse ecological effects.”

**E. “Big Picture” and Other Items**

The peer review instructions invite comments on other parts of the proposed regulations. In furtherance of that objective, it is recommended that the Department rewrite and improve the definition of “sensitive subpopulations.”

As it is now written, the definition of “sensitive subpopulations” lacks certain important, scientifically based concepts and should be redrafted. First, the term “pregnant women” should be replaced with the term “women of childbearing age.” A healthy pregnancy is dependent to a large extent on the health of women before conception, as well as after conception. Second, the definition should be expanded to incorporate environmental

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<sup>3</sup> National Research Council, Toxicity Testing in the Twenty-First Century: A Vision and a Strategy (2007), ([http://www.nap.edu/catalog.php?record\\_id=11970](http://www.nap.edu/catalog.php?record_id=11970))

justice communities that are differentially susceptible, or differentially exposed to CoC's, or more likely to be exposed to CoCs because they are bigger users of certain Priority Products.

### **III. Conclusion and Summary – Determinations**

Attachment 2 states that the responsibility of peer reviewers is to “determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practice.” The Department asks peer reviewers of these regulations to make this determination for 4 specific points. Based on my review of the proposed regulations, and the additional explanatory materials that I received from the Department, I conclude that, with the exceptions I have set out above, for each of these 4 points the Department has based these portions of the regulations upon sound scientific knowledge, methods and practice.