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PEER REVIEW REPORT FOR
CALIFORNIA SAFER CONSUMER PRODUCT ALTERNATIVE REGULATION
***as revised* JANUARY 2013**

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Thank you for the opportunity to conduct a peer review of the California Safer Consumer Product Alternative Regulations (CCSPAR), as revised following hearings. My comments respond to the revised regulations dated January 29, 2013. The review follows the four specific Peer Review Topics identified in the attachment to the January 30, 2013, memorandum to peer reviewers from Dr. Jeff Wong.

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 Candidate Chemicals list.

(a) The revised regulations include no substantial changes in the criteria for selection of lists and chemicals, and they are appropriate.

(b) The two newly added lists are also appropriate for the purpose of identifying Candidate Chemicals.

(c) As I indicated in my previous comments, the approach of using existing lists makes a great deal of sense, because using lists rapidly generates a comprehensive list of chemicals and avoids duplication of effort. The lists are compiled by reliable and authoritative governmental organizations. The ability to add or subtract from the list is also important, as new information will develop and the CCSPAR process will undoubtedly develop over time.

The change in terminology from "Chemicals of Concern" to "Candidate Chemicals" provides a clarification and an adjustment of the CCSPAR structure, even though it does not appear to change the basic operation of the regulations. "Candidate Chemicals" is probably a more accurate name for chemicals derived from existing lists, because the lists are a preliminary step in the overall analysis. The Candidate Chemicals approach also emphasizes the risk-based nature of the overall CCSPAR process to the extent that it requires consideration of both hazard (toxicity) and exposure. AB 1879, which is the basis for the CCSPAR, clearly indicates that both hazard and exposure are to be considered in evaluating products. *See* §§ 25252(a), 25253(a). Within a risk-based structure, the list of

chemicals, without more, indicates a "candidate," and using the new nomenclature, it is clearer that chemicals only become Chemicals of Concern when they are associated with a product, and thus with *exposure* from a product. *See* § 69503.5(b)(2)(B) and article 3 generally.

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.

(a) The memorandum to peer reviewers indicates that this topic is intended to raise the question whether the revised CCSPAR, having focused the regulations more sharply on the chemical-product combination, retains the breadth to cover the range of products and dangers envisioned by the AB 1879 legislation. The issue is not, it seems to me, definitions and exclusions from the meaning of "product" or "consumer product," though there has been some clarification of repair, replacement, and the like, which seem appropriate.

Rather, the topic focuses on the use of the term "potential" to modify both exposures and impacts/effects. As a preliminary matter, the idea of regulating potential harm, as opposed to actually realized harm, should not be controversial in this setting. It is the essence of preventive regulation, and prevention (as opposed to reparation or compensation) is the *raison d'etre* of most environmental, health, and safety regulation, including CCSPAR. The challenge confronting the rulemakers, therefore, is how to assure that the term "potential" means something more substantial than mere speculation, without depriving "potential" of the expansiveness necessary to fulfill the preventive legislative mandate.

The CCSPAR seems to address this in two ways. First, the revised CCSPAR adds a new definition of "potential" as "reasonably foreseeable based on reliable information." § 69501.1(a)(51)(A).[1] This is a relatively narrow definition, as it requires some degree of both [1] foreseeability and [2] quality of information. Both of these limitations carry legal baggage:

> [1] "Reasonably foreseeable" is not defined in the regulation, but it is the subject of an enormous amount of litigation and commentary in tort law, particularly in the famously knotty problem of proximate cause. The function of proximate cause in tort law is to narrow the hugely broad concept of cause in fact ("but-for" cause), so the use of the standard formula for proximate cause (reasonably foreseeable) is sensible enough here. It also makes structural sense, inasmuch as the regulations start with a broad term ("potential") and then narrow it through the definition.

[1] The definition of "potential" does not apply in two very specific cases, but this does not change the analysis here.

However, there is a danger that foreseeability will itself become a point of contention and legal wrangling. This could be quite disruptive to an already heavily burdened regulatory system.

[2] "Reliable information" is extensively defined in the regulations. § 69501.1(a)(58)-(59). The meaning of "reliable information" is perfectly sensible in its own terms. However, as with "reasonably foreseeable," there is a possibility that DTSC action will be delayed by challenges to "potential" based on this term. That is, a great deal of time could be spent resolving the scope issue, long before the heart of the CCSPAR – the alternatives analysis – comes into play.

Second, "potential" also seems to be limited by the way that it is used in article 3. The key section reads as follows:

> Key Prioritization Principles. Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria:
>
> (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
>
> (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse effects.

§§ 69503.2(a); *see also* §§ 69503.2(b), 69503.3(a)(1). In this language, potential exposure seems to be qualified by the capacity of the exposure to [1] "contribute to or cause" [2] "significant or widespread" impacts or effects.

[1] The term "contribute to or cause" (or vice versa) is common in federal environmental law statutes, and it is intended to be expansive. In particular, the phrase permits (or requires) regulatory action to go forward despite the existence of scientific uncertainty. *See, e.g., Massachusetts v. EPA*, 549 U.S. 497, 506 n.7, 534-35 (2007) (interpreting the Clean Air Act, 42 U.S.C. §§ 7521(a)(1)). *See also* 42 U.S.C. § 7408(a)(1)(A) (listing of air pollutants). In other words, "contribute to or cause" should not be interpreted to require a particular level of certainty in connecting the exposure and the effect or impact. Nevertheless, since "potential" is also used in this section, it might suggest that a particular impact or effect must also be "reasonably foreseeable" from the level of exposure caused by a product. I do not think that this interpretation was intended, but the section could be read to imply a level of certainty that would be difficult to demonstrate.

[2] Likewise, while the nature and scope of impacts and effects are very comprehensively defined (as in the initial proposed regulations), the term "significant or widespread" is undefined. Presumably it is meant to mean something like "more than de minimis," but *how much* more is left open to debate. This could add unproductive complexity to the department's analysis to justify the list of Priority Products.

The foregoing is admittedly a fairly laborious analysis of the language in the regulations – perhaps too laborious. I do not suggest that the regulations are misguided in

introducing "potential" to assure that the regulations are sufficiently preventive, and then trying to place some boundaries around the naturally expansive term "potential." There is also sense in using familiar terms like "reasonably foreseeable" and "reliable information." Nevertheless, the definitions and the way that "potential" is used in the regulations could be more limiting to the coverage of the CCSPAR than intended. Furthermore, both the terms themselves and the way that "potential" is used invite an affected party to bring in a large body of law and to parse the statutory language minutely at a very early stage in the proceedings, before the real work of the CCSPAR alternatives analysis has begun. Given the resource challenges that DTSC faces in implementing the CCSPAR, this must be considered carefully.

(b) Given the breadth of the CCSPAR, it is useful that the regulations repeatedly emphasize that other adequate regulatory regimes are an appropriate reason for DTSC *not* to act under CCSPAR. *See* §§ 69503.2(b)(2), 69501.1(b)(3). These anti-duplication provisions are good additions in the revised regulations.

(c) Section § 69503.2(b)(3) adds a new provision that permits DTSC to "consider whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible." Presumably the purpose of this new section is to allow the inclusion of a chemical-product combination as a Priority Product if there is such an alternative, or to allow exclusion if no such alternative exists. This makes sense, but within the structure of the CCSPAR it is not clear how this provision in article 3 is related to the formal Alternatives Analysis in article 5. Does it preempt or substitute for the Alternatives Analysis in some cases? Is it a preliminary alternatives analysis that will be repeated more fully later in the process?

It is possible that the answer is the unusually narrow meaning of "economically feasible." "Economically feasible" is defined as an alternative that "does not significantly reduce the manufacturer's operating margin." § 69501.1(a)(29). The more common understanding of "feasible" is much broader. For example, as described in the well known *Cotton Dust* case, "feasible" includes anything which is "capable of being done." *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 508-509 (1981). That is, a feasibility-based standard requires the manufacturer to stretch to the limits of what it can do, and so in the case of economically feasible, to the limits of what it can afford. The new CCSPAR definition would seem to treat as infeasible nearly anything that costs money (unless the whole cost can be passed along to the consumer, I suppose). So, given this narrow meaning, is § 69503.2(b)(3) to be understood to allow exclusion or inclusion only where the alternative or lack of alternative is extremely obvious and does not require the analysis in article 5? In any event, the relationship between the chapter 3 and chapter 5 provisions should be clarified.

3. The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products are scientifically understood and practical.

(a) The revised regulations limit the use of the Alternatives Analysis Threshold (AAT) – which is in effect the exception process for Priority Products – to the Practical Quantitation Limit (PQL) of a *contaminant* in a product. § 69501.1(a)(12). PQLs, in turn, refer to the lowest measurable quantity of the contaminant. § 69501.1(a)(52). The effect of this change is greatly to limit the scope of the prior AAT exceptions process. Assuming that limitation is intended, the rationale is presumably that, especially in such comprehensive regulatory regime, DTSC should be focusing its limited resources only on those contaminants which it can readily measure. This is sensible, just as it is sensible to treat intentionally added chemicals differently. § 69501.1(a)(26). As a practical matter, intentionally added chemicals are likely to be easier than contaminants to control, delete, or substitute in products.

(b) The fuller description of this question in the Scope of Work also notes the new requirement that the list of Priority Products is subject to the California APA. § 69503.4(a). It is not immediately obvious why the question to reviewers links the AAT-PQL process to the APA change, except that the narrowing of AAT-PQL means that little will be excluded from the Priority Product list, and so more Priority Products will be subject to APA procedures. (At least, that is how I read it.) It is hard to object to using a regular administrative process to promulgate and seek comment on administrative action, but – as above – the CCSPAR process will be an enormous undertaking at best, and this will require greater departmental resources.

4. The definitions of the various "adverse" impacts and general usage of the terms "adverse" impacts and "adverse effects" are 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.

(a) I observed in my report on the initial draft of the regulations that the term "adverse" is very broad, and it comprehensively covers the impacts and effects that AB 1879 and the CCSPAR seeks to prevent. For emissions and discharges, the adverse aspect is the emission itself, which has the potential to cause adverse effects or impacts (*e.g.,* § 69501.1(a)(9)(E) (water)). For adverse effects and impacts, the definitions focus on the harm that can be caused by exposure to the chemical in question (*e.g.,* § 69501.1(a)(7) (soil)). Between them, they cover the causes and effects comprehensively, and the recent changes in the definitions do not appear to change the broad scope at all.

(b) The question also states that a qualitative or quantitative determination of adverseness can be made, and that either is adequately protective if reliable information is available. I agree with this statement. Qualitative information must frequently be relied upon when quantitative information is absent, limited, or of questionable reliability – and this situation is common, if not typical, among toxics.

The acceptance of both quantitative and qualitative information is implied rather than expressly stated in the CCSPAR. (The actual words "quantitative" and "qualitative" are

only used in the regulations incidentally and in relation to Alternatives Analysis.) While the definition of "reliable information" as it relates to exposure mainly points to quantified information (such as monitoring data, § 69501.1(a)(58)), the general definition of "reliable information" is quite clearly *not* limited to quantitative information. § 69501.1(a)(57). Since the general definition is the one that would be used on the more uncertain toxicity side of the risk equation, this provides some assurance that quantification will not be a severe obstacle to protective regulation. Another indication of the validity of qualitative information is the acceptance of structural and mechanistic similarities as evidence of toxicity. § 69503.3(a)(3). Such similarities are indeed useful evidence, but one can rarely make a quantitative leap from one structure to another without data concerning both chemicals. Thus, to accept similarities *themselves* as evidence implies the acceptability of qualitative information.

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Thank you again for the opportunity to review the revised California Safer Consumer Product Alternative Regulations. I will be happy to clarify any of the foregoing comments or address other issues, should that be of assistance.