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SCIENTIFIC PEER REVIEW FOR SAFER CONSUMER PRODUCT REGULATIONS

Thank you for this opportunity to provide external scientific peer review of specified issues of the Safer Consumer Products Proposed Regulations, as revised January 2013. I used the following two documents for my review:

The Revised Proposed Regulations for Safer Consumer Products (January 2013):
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf

The unofficial version, without underline and strikeout, of the Revised Proposed Regulations:
http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text-NU.pdf

The Statement of Work described for the scientific peer review is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices for the following four topics. I have presented my responses to each of the four topics below. Overall I find the proposed regulations to be scientifically sound, with some significant improvements to strengthen them since the last draft.

Topic 1. Does the chemicals list developed by the sources named in the regulations accurately identify chemicals with hazardous traits that have public health and environmental concerns and so may be used to produce an initial Candidate Chemicals list? The revised regulations now include two additional lists: the chemicals classified as Category 1 respiratory sensitizers by the EU; and, chemicals identified as priority pollutants in CA under the federal CWA has been expanded to include section 303(d) (impaired waters list) chemicals in addition to 303 (c) chemicals.

The addition of the pollutants from the 303(d) list of the Clean Water Act is a significant improvement to the proposed regulations. This list includes any contaminant that contributes to an impaired water designation. It can include contaminants affecting California waters specifically, and those which have environmental impacts but may not necessarily affect human health. These can include metals, pesticides, and organics such as poly-chlorinated biphenyls (PCBs) and de-icing fluids. Metals such as copper from consumer products including marine antifouling paint, pool and spa algaecides, and vehicle brake pads may impair aquatic environments, but have no or limited human health effects. The incorporation of the 303(d) list into § 69502.2 (Candidate Chemicals Identification) will address

consumer product contaminants like copper that are recognized by the State of California a threat to environmental quality. For example, SB 346 requires that the use of copper in vehicle brake pads sold in California be reduced, and also includes a provision linking it with the Safer Consumer Products regulations.

Tri-TAC, representing California wastewater treatment facilities, submitted comments on the proposed safer consumer products regulations, recommending among other things that the 303(d) list of impaired waters be included as a means of identifying candidate chemicals. In their comments, Tri-TAC expressed great concern at the "growing tide" of chemical contaminants in the receiving waters that may compromise the ability of wastewater treatment technologies to operate effectively. We essentially have a toilet-to-tap water system, where wastewater from homes, industrial facilities, and land runoff can go through a wastewater treatment plant, be discharged into groundwater, lakes, or reservoirs, and eventually end up as well water or in a public water system and from there to kitchen tap water in homes around the country. Therefore, protecting all waterways is the best way to protect our source water for human consumption, bathing, and swimming, as well as protecting our environment.

The inclusion of this list into § 69502.2 (Candidate Chemicals Identification), along with the chemicals from the 303(c) list of the federal Clean Water Act is a significant improvement, and will provided a more comprehensive scientific listing of contaminants candidate chemicals of concern.

Topic 2: Are the evaluation criteria for prioritizing the product-chemical combinations in Article 3 sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products? Do the revised regulations specify the key prioritization criteria factors necessary to identify potential Priority Products? The revised proposed regulations define "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information. The revised proposed regulations require the Department to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.

After reviewing the text of the January 2013 proposed regulations for Article 3, as well as the changes from the earlier draft it is my opinion that the regulations as currently proposed provide fairly extensive and comprehensive adverse impact and exposure factors by which to identify potential Priority Products. The descriptions of adverse impacts [§ 69503.3(a)] and exposures [§ 69503.3(b)] are comprehensive and will be effective at identifying potential Priority Products. The inclusion of chemicals that are structurally or mechanistically similar to chemicals with known toxicity profiles [§ 69503.3(a)(3)] is an important factor that will allow the State to identify potential Priority Products even where little data is available.

Article 3 specifies that any product-chemical combination identified and listed as a Priority Product (slated for an Alternative Analysis) must meet both the criteria of having a potential for exposure to the Candidate Chemical(s), and the potential for exposure to contribute to or cause significant widespread adverse impacts [§ 69503.2(a)(2)]. While I support this requirement in principle, I have two concerns. First, what constitutes a "significant" or "widespread" adverse impact is not well-defined. Second, if the phrase "significant or widespread adverse impacts" is to be used to determine priority products, it should apply to the chemical, not the product-chemical combination, since the adverse environmental or health impacts attributable to a single product-chemical combination may be impossible to determine, although the chemical has documented significant and/or widespread adverse impacts.

Regarding the first concern, it is not clear to me what either "significant" or "widespread" mean in this context, who will decide, by what criteria, and for whom? Is impairment of one lake significant? Is two lakes? What about impairment of one river that is use for recreation, but not for drinking water? If the product-chemical combination only poses a risk (exposure plus hazard criteria are met) for people with severe asthma, is that significant or widespread? What if the product-chemical combination poses a risk to people with estrogen-sensitive cancer? Is that significant and/or widespread? What if the adverse effect is significant or widespread (or both), but not severe? What if a product-chemical combination causes a severe effect (such as permanent learning disabilities or severe asthma), but to a limited population so it is neither widespread nor statistically significant across the whole population of the state? I suggest either deleting the words, "significant or widespread" altogether, or adding severity, so that the potential for one or more exposures to contribute or cause severe adverse impacts be considered an additional principle for prioritization. Regarding the second concern, I recommend that the prioritization criteria be applied to the chemical, not the product-chemical combination.

I support the addition of the word "potential" at numerous places throughout this section, and the definition of "potential" to mean that the phenomenon described is reasonably foreseeable based on reliable information. This is both precautionary and reasonable, based on information that is "reasonably available" [§ 69503.2(b)]. In fact, without consideration of potential risks (exposures and adverse impacts), the Safer Consumer Products regulations would not serve its purpose of averting harm.

Topic 3: Are the principles that are outlined in the proposed regulations that will allow DTSC to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products scientifically understood and practical? In the revised regulations the Alternatives Analysis Threshold is now defined as a Practical Quantitation Limit (PQL). A threshold exemption will only apply if a Priority Product contains the COC solely as a contaminant (not for intentionally added ingredients) and the concentration of each Chemical of Concern does not exceed the Alternative Analysis Threshold. The DTSC believes it can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

Article 5 (Page 35) discusses the Alternative Analysis. The section on Threshold Notification in Lieu of Alternatives is discussed in § 69505.3 (Page 41) of the proposed regulations. The PQL is defined as the lowest concentration of a chemical that can reliably be measured within specified limits of precision and accuracy using routine laboratory operating procedures (§ 69501.1 Definitions, Page 13). I agree that the principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold as a PQL for a COC that is present in a Priority Product solely as a contaminant, and not intentionally added, is scientifically understood. It may be practical in the majority of cases.

I am concerned about some cases, probably rare, where the contaminant COC may be at trace levels, even below the PQL, but is still potentially harmful. For example, there is evidence that asbestos is a contaminant of NY State talc powder, and is causally associated with mesothelioma, asbestosis, and excess lung cancer in miners of the talc, although it's hard to know how much of it is being used in consumer products. However, there are some cases in the courts today of plaintiffs/consumers with asbestos-related disease who claim that their only known exposure is from historical talc in consumer products. Further complicating matters, the company mining the NY State talc denies that its talc is contaminated with asbestos, although independent scientists have claimed to have detected it. The PQL may be inadequate to detect it at low but dangerous levels, since detection may depend on the extent

of effort expended using high-powered microscopic equipment. In another case, in Libby, Montana there is an epidemic of asbestos-related disease, and there is great concern about environmental exposures as the cause, although the asbestos has not been detected (i.e. levels of ambient exposures are likely below the PQL). This is likely because a bulk analysis of the mineral is very difficult, since trying to separate asbestos fibers from soil and rock samples is problematic even using rigorous analytical methods.

If there is reasonable grounds to believe that a COC may be present in a product, even as a contaminant, and if there is a potential that the product-chemical combination may present a risk even at levels below the PQL, than a threshold exemption should not be issued. DTSC needs to preserve its right to not issue a threshold exemption.

Topic 4: Can a qualitative or quantitative determination of adverse impact or effect be made? Will it be adequately protective of public health and the environment when reliable information is available?

I agree that the proposed regulations adequately describe measures of adverse impact so that a scientifically-defensible determination can be made. The section of Definitions (§ 69501.1) includes specific criteria to recognize adverse ecological impacts, adverse public health impacts, adverse soil quality impacts, adverse water quality impacts and others. In many cases the definitions include exceedances of an enforceable state or federal regulatory standard, descriptions of reduced function, altered properties, deterioration of quality, or endangerment. These determinations of adverse impact or effect should provide a significant measure of protection for health and the environment, when addressed and complied with.