

## Scientific peer review for safer consumer product regulations

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### Question 1:

The use of chemical list developed by other sources is an efficient and effective manner for developing a screening list of potential chemicals of concern. Existing list of chemicals can clearly provide chemicals for which there is known toxicity. It is important to also include emerging chemicals for which there might be significant exposure due to their used in consumer products or their persistence in either the indoor or outdoor environments, but for which there may be limited toxicological data. This need is addressed in two ways. First, the lists in 69502.2a1, A-F, I, J and L are all updated by the organization overseeing them. By having so many lists, there is redundancy assuring that at least one organization will be up to date when you toxicological factors are found. Additionally, these lists also focus on a wide range of toxicological endpoints. The sources G-H, K, M, and N all include chemicals that are persistent and bioaccumulative, critical because if adverse health endpoints for these compounds are found at a later date, exposure cannot be reduced significantly as these compounds will continue to remain in the environment. Chemicals that are demonstrated to have widespread exposure through national and state biomonitoring programs are also included.

There are several points that may not made sufficiently clear on the additions to the chemicals of concern list.

69502.2b1A1 - the text in the initial statement of reasons for this section makes clear that DTSC may also evaluate chemicals that are structurally similar to another compound with a known toxicity profile. This is an important point because such chemicals are often found to have adverse toxicological effects as well. However, in the actual proposed regulations, the text is so short that this point cannot be ascertained from the document. It is not clear to me how these two documents will be used in concert and thus this might not be a problem.

69502.2b1A6 - the text in the initial statement of reasons for this section lists a number of approaches that can be used to determine the chemicals impact on the environment. Recalling that many consumer products are used in the indoor environment, I think indoor environmental modeling should be included explicitly on this list. Additionally, as it is my assumption that personal care products are included in the consumer products regulated under this regulation, exposure models to determine the direct dermal exposure would also be appropriate to include explicitly. I note that it does indicate this is a non-exhaustive list of example tools, however, given the potential for much greater exposures for compounds that remain in the indoor environment or that are applied directly to skin, it would be good to include these scenarios. Additionally, the document states that "environmental ... presence may also be estimated ... using measurement". Here, and other places in the document that suggest documenting exposure through environmental measurements should make clear that both indoor and outdoor measurements can be used. Careful reading of the document such as in 69502.2b2 would seem

to indicate that presence in the indoor environment is a marker of exposure. This is appropriate considering the significant fraction of time spent indoors. However, such explicit language should be included more frequently in the document.

69502.2b2 - I was pleased that data indicating presence in the indoor environment was included in this section as a factor to identify a chemical of concern. While evaluating this section, I wanted to determine if Journal papers by academic researchers were considered reliable, as academic researchers are often at the forefront of identifying new chemicals of concern. I note the definition of "reliable information" states "published in a scientifically peer-reviewed pool report or other literature," as peer-reviewed papers are a prevalent source of information, it might be nice to state these to specifically rather than include them in "other literature."

Question two:

The task addressed in this section of the regulation is quite daunting. As noted in the document, regulators often do not know what chemicals are present in what products, making assessment difficult. This was explicitly pointed out in 69503.2a1B3. It is noted that DTSC could "consider using survey techniques to obtain this information." By this, I'm assuming that they mean go out and measure for the compounds in actual products. If this is the case, it might be useful to note that taking composites of various different specific products within a category may be a more cost-effective way to accomplish this goal. This may be too detailed to include in this document but I thought it might be a useful suggestion.

My primary concern related to the product prioritization process is that the regulation explicitly acknowledge two potentially significant exposure scenarios: personal care product use resulting in dermal application and indoor applications of chemicals.

The document should explicitly consider and note direct consumer exposure from the product, such as in the case of personal care products that may be applied directly to skin, or additives to plastics either placed directly in the mouth or used in food packaging where the compound does not interact with the environment, but rather, exposure occurs directly from the product. While there is nothing excluding these exposures from being evaluated, I think the document could be strengthened by more explicitly including this consideration. An example of where this could be directly noted is in section 69503.2b1, as a chemical that is easily absorbed dermally, could result in higher levels of exposure.

Likewise, when environmental fate and transport are considered, the indoor environment is rarely explicitly mentioned. However, consumer products are often used in the home and as a result, a much greater portion of the released compound is taken up by an individual in the population. In both these instances, and the direct consumer exposures from a product, a significant amount of exposure may occur even if the overall production volume of a chemical is low. I want to stress that the document

does not appear to be incorrect, because it appears that these exposures are considered, however, I think it would be much clearer and the prioritization process could be much better focused should more explicit discussion of these pathways that can lead to a high degree of exposure for a small release of chemical into the environment. Specific locations one could mention the indoor environment include: 69503.2a1B2, 69503.2a1B4 (field studies in the environment), 69503.2b1 or mentioning indoor modeling in 69503.2a1B4. I thought that section 69503.2a3 which specified focusing on areas not adequately protected by other regulation was a very effective use of resources, and would potentially lead to an additional focus on the indoor environment. In section 69503.2a3f, the agency may want to consider that a chemical might be more persistent in the indoor environment than the outdoor environment due to a lack of sunshine and thus lack of photodegradation.

This section would be more readable if there was a good definition of “products” upfront in the document or in the glossary. Buried within the “initial statement of reasons,” in section 69503.3f, it mentions that “the work plan will include product categories, which may illustrate for example a level of detail comparable to the family (i.e. cleaning products) or class(i.e. laundry) hierarchy level identified using the global product classification standards. I used this as my working definition of “products” when reading the document,, but would have appreciated clearer guidance.

There was one of potential discrepancy throughout this document. My interpretation of this regulation is that it is to provide safer products to individuals residing in California. However, in many cases, such as in section 69503.2a1, it states “DTSC is required to consider the adverse impacts due to exposures to the chemicals of concern in consumer products during its lifecycle,” with manufacturing often included in that lifecycle. However, nowhere is the manufacturing location apparently considered. I see two potential remedies for this. First, one could specify that one need only include exposures that occur in California, explaining that if manufacturing occurs outside of California it does not need to be included in the analysis. Second, one could note that if manufacturing was done outside of California, exposures would not occur in California, nonetheless in an attempt to improve global environmental health, these exposures should be accounted for in the analysis. Perhaps this is stated somewhere or further explained, however I could not find such an explanation. There is one mention of “the locations of these practices to be assessed” within section 69503.2a1B1a, however it is not terribly informative.

I appreciated the nice descriptions of the sensitive subpopulations that might be included in the analyses. This is important to consider.

In section 69503.2a3c, the agency discusses the frequency, extent, level and duration of exposure for each scenario. These are the critical components of an exposure assessment and will guide the agency well. However, the extent is defined as the number of routes of exposure, rather than focusing on the cumulative exposure. Having two routes of exposure may not be important should the magnitude of exposure through another use result in a higher overall exposure. While it may not be feasible to some exposure over multiple routes, it might be nice to state this as a goal in this section, as well as counting the routes of exposure. In section 69503.2b2, the document states that a chemical with multiple routes of exposure would result in higher priority over a product with a single route of exposure. This

statement definitely needs to be modified to prevent incorrect prioritization as the magnitude of the exposure in a single pathway needs to be determined.

In section 69503.2a3e, well there is little the agency can do about this point, people do not always follow the engineering and administrative controls listed in warning labels. One might want to at least note that the agency is aware that this sometimes occurs.

Question three:

The first part of section 69503.5 is very reasonable, and I feel it is important to consider both the technical and economic feasibility of removing contaminants. However, section 69503.5c3 is either not clearly written or may result in thresholds that are not reasonable, it is unclear which is the case. The introductory section of this text indicates that a threshold different from what would be developed under paragraphs 1 and 2 could be developed following a listed set of criteria. In considering many of the criteria, one would imagine the agency would lower the threshold, while in some, one would imagine the agency would increase the threshold. While the reasons for lowering the threshold are all very valid, it is not clear how that would be weighed against the technical difficulties related to removing things such as unintended contamination or level set below analytical method limits of detection. More guidance should be provided to understand how these two competing factors would be weighted.

Additionally, one section, 69503.5c3E, appears to be incorrect stating if a chemical does not affect sensitive populations there may be justification to modify the threshold. One would anticipate if there were adverse effects to sensitive populations, that may be an instance where one would weigh exposure more heavily than technical and economic feasibility.

One other small note is that in section 69503.5c2A, the agency may want to note that there can be considerable variability in analytical detection limits from one laboratory to another and may want to think about how to account for this factor.

Question Four:

The definitions of the various adverse impacts as listed in the glossary section are very appropriate. The goal of quantifying these adverse effects as part of the alternative analysis is also very appropriate. However, there two potential problems within the alternative analysis section of the document. First, the second stage relies on the life cycle impact assessment using multimedia models. One problem with traditional life cycle impact assessment is that this field does not adequately account for direct consumer product use such as personal care product use as well as exposures that occur in the indoor environment. These are both critical pathways for quantifying the public health impact. If this is being accounted for outside of the multimedia modeling it needs to be specified. The second potential problem is that ultimately, the plan is to determine quantitative values for the adverse public health endpoints, with the stated goal of selecting the alternative that has the lowest impact (69505.5c). There

is considerable data needed to determine risk quantitatively. There will be considerable uncertainty on any quantitative value, thus making determination of the alternative with the lowest adverse effects difficult to ascertain. If uncertainty ranges overlap, it would be difficult to determine the alternative with the lowest adverse impacts, and this should be acknowledged.

One additional comment with in article 5, unrelated to the use of the term adverse, is that it is not entirely clear that the life cycle assessment to be conducted at the second stage of analysis fully matches the stated objective, line 36 of page 117, “the regulations establish a process for evaluating chemical concerns in consumer products, and their potential alternatives, to determine how to best limit exposure or to reduce the level of hazard posed by chemical of concern” which seems to imply a focus on hazard reduction, while the A-M list for the life cycle impact assessment encompasses a much broader range of endpoints.

Additional comments:

Section 69502.2a: “consumers will be more informed about the chemicals of concern that may also be present in the products they purchase and manufacturers and importers and retailers may take voluntary actions on the chemicals in their quest for safer consumer products” - is not entirely clear how consumers will be informed about these chemicals and that may factors will readily volunteer information about the chemicals in their products. Well I would love to see this happen, I'm not entirely convinced about the reality of it. Likewise in the next paragraph, it is stated that manufacturers who wish to restrict products containing certain chemicals will reduce the possibility of regrettable substitutions. Again, while this is an issue of great concern, it is not entirely clear how this regulation will accomplish this goal.

Section 69503.3a: one of the difficulties in this regulation of chemicals that exist in multiple products. It is not entirely clear how elimination of the product with the most significant exposure will have a marked change in the overall exposure to a chemical in multiple products. Is there anything that would encourage manufacturers to consider this chemical in other consumer products?

I wanted to note that under the retailer option of determining the responsible party, it seems that there may be some difficulties with enforcement of this regulation. I am particularly concerned about small retailers that may stock off-brand items for short periods of time. It seems that these could easily slip through the system. No specific changes are requested due to this concern, however it should be noted.