Responses to Peer Review Points

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This document is my peer review of "Division 4.5, Title 22, California Code Of Regulations Chapter 55. Safer Consumer Products—Text of the Proposed Regulations" and the accompanying "Initial Statement Of Reasons, Safer Consumer Products, Department Reference Number: R-2011-02 Office of Administrative Law Notice File Number: Z-" Below I have first provided my specific responses to the four points suggested in the inquiry to me. Then I provide comments on more general issues, and finally there is a section directed to specific parts of the text of the regulations and the statement of reasons document. The peer review points are given in normal type and my responses are provided in bold face.

Attachment 2 Scientific Factors Peer Review Points

The statute mandate for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following points that constitute the scientific basis of the proposed regulatory action. An explanatory statement is provided for each issue to focus the review. In each point, section 25252 of the Health and Safety Code provides the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

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. ~~(See Attachment 4 and 4-A)~~

SEE ATTACHMENT 4 – JULY 18, 2012 TEXT OF PROPOSED

REGULATIONS ARTICLE 2, SECTION 69502.2

AND ATTACHMENT 6 OF THE ACCOMPANYING INITIAL STATEMENT OF REASONS

~~The overarching criterion in identifying a Chemical of Concern (CoC) is that the chemical exhibits a hazard trait or an environmental or toxicological endpoint as identified in Chapter 54. Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data, Title 22, California Code of Regulations. The important terms to consider are (1) "chemical," (2) "hazard trait," and (3) the substances named on the identified lists in section 69502.2(a). A substance on the identified lists must be a chemical and exhibit a hazard trait. The intent of incorporating the identified lists is to begin the Safer Consumer Products program with an initial CoC list that utilizes the work conducted by other governmental agencies, "authoritative organizations" (as defined in section 69401.2(b), Chapter 54, Title 22), and studies that meet the definition of "reliable information" or "reliable information demonstrating the occurrence, or potential occurrence, or exposures to a chemical."~~

~~Using the lists developed by others streamlines efforts to develop a CoC list as well as develops a robust list of chemicals that will send signals to the marketplace to avoid regrettable substitutions when manufacturers voluntarily replace CoCs in products, especially as DTSC will start out with a small number of Priority Products.~~

~~Subsection (a)(1) identifies lists that government agencies, or "authoritative organizations," developed to require regulatory action on a chemical to safeguard the public or the environment. The chemical lists are derived from California, state, country, and international governmental agencies and organizations sources. Some of these lists include "nonchemicals," such as nutrients, soil, or bacteria; however, it is the intent of DTSC to curate the informational CoC list to remove "nonchemicals," and chemicals that are excluded by law (e.g., pesticides).~~

~~Subsection (a)(2) identifies chemical lists that were found by authoritative organizations to have human or environmental exposure and includes chemicals that are found in the environment or receptors, including humans, through environmental monitoring or biomonitoring data and reports. The authoritative organizations generated these lists include voluntary agreements with stakeholders to advise voluntary chemical action to reduce or eliminate these chemicals due to their potential exposures to public and environment.~~

~~This subsection intends to include emerging chemicals of concern where the chemical may be prevalent or persistent, but have incomplete toxicity information. The weight of evidence based on reliable information demonstrating the exposure or potential exposure is used to substantiate the need for the chemical listed as a CoC. For example PBDEs were found to be persistent in studies conducted by the DTSC's Environmental Chemistry Laboratory in the early 2000's, but scientific studies were insufficient to definitively identify a hazard trait. Years later, additional scientific studies showed that some forms of PDBEs cause kidney toxicity and warranted chemical action.~~

~~Subsection (a)(3) include chemicals that exhibit a hazard trait based on the definition of reliable information, even though they may be generated by under the auspices of "authoritative organizations." These chemicals are important to include in the initial CoC list because they are used by governmental agencies are a source of "reliable information" to identify hazard traits and assess hazards in environmental media or consumer products. These chemicals exhibit hazard traits such as carcinogenicity and neurotoxicity that are important to stakeholders and the intent of the AB1879 (2008).~~

The initial list of Chemicals of Concern is reasonably assembled from sets of chemicals evaluated for important types of toxic effects by other governmental entities. This is a quite sensible starting point, as it makes use of extensive work done by previous expert evaluators. DTSC does not need to "reinvent the wheel".

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.

SEE ATTACHMENT 4 – JULY 18, 2012 TEXT OF PROPOSED REGULATIONS ARTICLE 3, SECTION 69503.2

AND ATTACHMENT 6 OF THE ACCOMPANYING INITIAL STATEMENT OF REASONS

~~Article 2 produces a list of CoCs. Article 3 incorporates prioritization of a CoC and a product that contains a CoC in an interactive fashion to identify Priority Products that would undergo an Alternatives Analysis. The process of identifying a potential Priority Product may start with the CoC or the product depending on the information available. In either case, both the adverse impacts of the CoC and potential exposure of the CoC in the product are considered before the CoC/product combination are proposed and finalized as Priority Products.~~

~~For instance the CoC list could be culled and those that exhibit considerable adverse effects, especially to sensitive subpopulations, may be targeted for information on their volume in commerce, and use in manufacturing. Research could then proceed on to the types of products that use these "CoCs of higher concern" to determine exposure potential in consumer products.~~

~~Conversely, using the potential exposure criteria, product research may show certain types of product categories have a high likelihood of exposure routes. Further research and information requests to manufacturers, albeit voluntary, into ingredients may indicate the presence of CoC(s) in the product category which would warrant listing~~

~~as a Priority Product.~~

~~In both instances, the interplay of CoC and product is considered – adverse effect of the CoC and exposure potential of the CoC based on product's life cycle. These potential Priority Products would undergo an evaluation of the "Key Prioritization Criteria" in section 69503.2(b), to determine which of these candidates for Priority Products should be given "higher priority" and undergo the public listing process in section 69503.3. Please note that the Key Prioritization Criteria are different for assembled and formulated products.~~

The articulated prioritization criteria are based on sound reasoning, as far as they go. However there are several key issues that are not squarely faced and will need to be developed further as the system evolves:

- **The initial unit of analysis/prioritization seems to be the chemical itself. However it is clear that the same chemical in different uses may have very different likelihood of being transferred to a person. For example a calculation I did some time ago based on human breathing rates and typical house ventilation rates indicates that about 6% of a typical chemicals emitted to indoor residential air will be inhaled by a person before being lost from the house. Doing the same type of calculation for outdoor emissions using typical results from air dispersion modeling suggests that the intake fraction for outdoor emissions is about 1000 times less than this. In the light of this substantial disparity there is reason for DTSC to consider chemical X use combinations as the unit of analysis for eventual prioritization. There are disadvantages to this—chemicals authorized for one use may be actually used in other ways. However exposure pathways and intake fractions may be very different across different uses of the same chemical, making it difficult to assess a chemical without making implicit or explicit assumptions related to use types.**

- **Second there is no articulation, as far as I can see, of the ways that priorities will be influenced by differences in the types of toxic or ecological effects that a chemical may produce. This is quite a complex issue that depends in part on the presence or absence of nonlinearities in dose response for the effects, and how the exposures are distributed among either human or non-human receptor organisms. DTSC has recognized this by choosing at this stage to express its priorities as "narrative" criteria rather than a fully articulated set of analytical processes. It is a reasonable first step to first do prioritization rankings within specific types of adverse effects (e.g. carcinogenesis, fetal growth inhibition), and then allocate efforts among different kinds of effects according to the capacity of DTSC staff with expertise in**

evaluating chemicals producing those effects.

- **Third, there is no identification of the need for consistency across chemicals and chemical uses in the uncertainty metric that will be used for priority ranking. Will chemicals be ranked by some "conservative" sets of assumptions (e.g. assumptions expected to overestimate exposure and risk of harm most of the time), or will assessors aim, for example, for "expected value" (arithmetic mean) estimates of exposures and population risks? If "conservative" assumptions will be used, because, for example most existing cancer potency values reflect them, how will DTSC seek to create a consistent degree of "conservatism" across chemicals that act on the body in different ways and reach humans via different exposure pathways? . Without guidance on this, it is likely that comparisons will be made that are inconsistent with respect to the uncertainties of different types that are involved with different bases for quantifying different effects. It is likely that without guidance the relatively "conservative" Superfund type assumptions will tend to be used. However these are not designed to be equally "conservative" for different cases or different kinds of effects. Absent more detailed guidance, it is likely that the comparisons will not be as informative as they might be about the real comparative consequences of using different chemical formulations in the same products, and imperfect or downright counterproductive choices may be made in many cases.**

~~3. Application of a de minimis level by adding the concentrations of CoCs that have the same hazard trait or environmental or toxicological endpoint, referred as "cumulative concentration," in the proposed regulations is scientifically understood and adequately protects public health and the environment.~~

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

SEE ATTACHMENT 4 – JULY 18, 2012 TEXT OF PROPOSED REGULATIONS ARTICLE 3, SECTION 69503.5

_AND ATTACHMENT 6 OF THE ACCOMPANYING INITIAL

STATEMENT OF REASONS

Section 69503.5 specifies eight types of information that may be used in specifying an Alternatives Analysis Threshold Exemption for a listed Priority Product containing a Chemical of Concern:

"(A) The inherent potency of the Chemical of Concern;□(B) The ability of the Chemical of Concern to bioaccumulate;□(C) The unintended presence of the Chemical of Concern in organs, tissues, or fluids; (D) The presence or absence of a threshold dose-response;□(E) The ability of the Chemical of Concern to contribute to or cause disproportionate adverse impacts on sensitive subpopulations and/or environmentally sensitive habitats;□(F) The degree to which the severity of adverse impacts associated with the Chemical of Concern is affected by aggregate exposures to the Chemical of Concern, if the Chemical of Concern is found in multiple common and frequently used products; (G) The degree to which the severity of adverse impacts associated with the Chemical of Concern is affected by cumulative exposures to other Chemicals of Concern that are the basis for the product being listed as a Priority Product and that exhibit the same hazard trait and/or environmental or toxicological endpoint(s); and/or (H) Any relevant regulatory action threshold established by a government agency.

These are all reasonable and helpful to an analysis of risk. However I think it would be helpful to add one or two considerations relevant to the expected "intake fraction" (Ilacqua et al. 2007; Humbert et al. 2011) (Huijbregts et al. 2005) (that is, the fraction of the chemical expected to be inhaled, ingested or otherwise taken in by a human) for the use of chemicals of concern in the types of application expected for the product under analysis. For example, if a paint is used indoors in a residence, then the paint solvent will be emitted indoors; and, if people are present in the same space, will therefore have about a thousand times greater intake fraction on average than if the same paint were used outdoors. Other considerations specific to chemicals, such as volatility/partial pressure as a function of temperature, may also be relevant to the <u>rate</u> at which chemicals are emitted and transferred to people. Because detoxification capacity for specific chemicals can be limited; transfer of chemicals to people at a greater rate per unit time may sometimes be more hazardous than transfer of the same total amount at a smaller rate. Overall, if these exposure related factors are omitted from the list, as they currently seem to be, then I am afraid that the prioritization that results and the analyses that are done to determine the "Alternatives Analysis Threshold Exemptions" may neglect some important information affecting risk from specific types of products in specific use applications.

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.

SEE ATTACHMENT 4 – JULY 18, 2012 FOR CONTEXTUAL USE OF "ADVERSE" TEXT OF PROPOSED REGULATIONS ARTICLE 5

AND ATTACHMENT 6 OF THE ACCOMPANYING INITIAL STATEMENT OF REASONS FOR RATIONALE

~~Sections 69301.2(a)(2)-(8)~~ Sections 69301.2(a)(3)-(10) provides a number of definitions for adverse impacts. These terms are used in the regulatory language to consider when identifying CoCs, prioritizing Priority Products, conducting Alternative Analysis, and assigning Regulatory Responses. The definitions are used within their regulatory context to determine "adverse." When information or data is available, a qualitative or quantitative determination can be made to substantiate and describe the "adverse" impacts and to explain them during the public process prior to listing the CoCs and Priority Products.

During the Alternatives Analysis, it is intended to provide guidance specific to the Priority Product to describe the expectations of DTSC to address "adverse" impacts, which will lead to the appropriate Regulatory Response after the Alternative is chosen. The various uses of "adverse" as they apply to Alternatives Analysis within the highlighted regulations in Attachment 4 adequately convey the intent of what adverse means in regulations. The regulations with the AA guidance that will be developed to provide DTSC's expectations for "adverse" impacts in the Alternative Analysis will be used to help with compliance.

I think in practice the approach of more specifically defining "adverse" in the context of different analyses will cause little difficulty. Even in cases where an effect (such as fetal growth restriction) may not be the endpoint of ultimate interest, but an indicator of chemical effect that predicts the effect(s) of interest, there will be little harm in using it to create indices of relative potency which will guide the private sector in the direction of developing safer consumer products.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and area asked to contemplate the following questions:

- (a) In reading the supporting documentation in Attachment 4 and proposed implementation language, are there any additional scientific issues that are part of the scientific basis of the proposed rule not described above? If so, please comment with respect to the statute language given above.

- (b) Taken as a whole, is the scientific portion of the proposed rule based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed actions may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statue requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewers have the opportunity to comment on all aspects of the scientific basis of the proposed DTSC action. At the same time, reviewers also should recognize that DTSC has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed rule. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that relevant to the central regulatory elements being proposed

I will respond to this by first identifying and discussing a few overarching issues that are not developed fully in the previous comments. Then I will give notes on specific parts of the regulation text or statement of reasons where I have particular comments.

Issues:

1. **Concentrations of concern that are the basis of exemptions from further scrutiny are defined in terms of concentrations of specific chemicals in the marketed product. There is a need to take precautions against the possibility that manufacturers or other responsible parties will qualify for exemption by simply marketing their**

product in a more dilute form. For example, a dangerous swimming pool disinfectant might be exempted by providing the chemical in a 10x smaller concentration with instructions to use a 10x larger amount of the product to disinfect a swimming pool. To combat this possibility, exemption threshold concentrations for a particular products should be defined together with the equivalent of a "serving size" in nutrition—perhaps a "use size". When a particular product has a particular "use size" the exemption threshold concentration may be appropriately lowered if the product use size is increased relative to competing products.

2. **The definition of an "alternative" in the "alternatives analysis" might be slightly expanded to include a technology substitution that would make the product type being considered unnecessary. For example, wrinkle free men's business suits not requiring dry cleaning might be a reasonable substitute in this sense for dry cleaning chemicals.**
3. **In alternatives analyses, there will be a need to counteract the tendency for analysts working for responsible parties to assume that a particular chemical structurally related to known toxicants has zero activity of a particular type if the chemical has not been specifically tested. There is a long and sad history of this. I recall that when 2,4,5-trichlorophenoxy acetic acid (245-T) was first phased out of home pesticide formulations because of teratogenicity findings, the initial response was to simply substitute 2,4,5-trichlorophenoxy propionic acid for which there were no comparable studies. This will happen repeatedly unless counteracted by mandated presumptions for chemicals with clear structural similarities to regulated chemicals of concern. Therefore the statement on p 78 of the statement of reasons that DTSC may evaluate chemicals in some cases with the aid of structure-activity models is very welcome and should be pursued.**
4. **The "statement of reasons" provides no analysis of the expected cost or benefit of the regulations pending identification of priority product categories. This is a cop-out to some extent. It might be possible to place some bounds on economic impacts by considering as examples what might be required for some highly likely candidate chemical applications—e.g., perhaps swimming pool and hot tub disinfectants; laundry detergents; household surface cleaners; and paints and similar products used to create surface layers for indoor and outdoor surfaces; glues and similar products that cause different surfaces to adhere to one another. It is also possible to derive at least some preliminary assessments of the analytical effort likely to be required in the private sector by referencing the effort that has gone into the assessment of existing and new sites where hazardous waste has been disposed (e.g. under Superfund and RCRA). In my judgment, the effort required for these newly proposed regulations will be comparable in scale to the analytical effort required under those previous pieces of legislation combined.**
5.

Detailed comments on particular text in the regulation text.

p. 13

(56) "Safer alternative" means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts.

This begs the question of how effects of different types will be put on a common scale for comparison

Detailed comments on particular text in the statement of reasons:

p. 81-2

The inclusion of emphasis on exposure factors is also very important and welcome

It perhaps could be further improved by citing literature on "intake fraction" (Ilacqua et al., 2007, Ries et al., 2009, Humbert et al., 2011) (Marshall and Behrentz, 2005) (Huijbregts et al., 2005) (Bennett et al., 2002a, Bennett et al., 2002b, Li and Hao, 2003, Margni et al., 2004)

p. 107
The first paragraph here, although standard, is unacceptably vague. What incidence of what severity of effect is meant by "no appreciable risk to human health". And at what level of confidence should this be judged. A "straw man" benchmark that I have suggested in the past is that the chemical should pose less than a 1/100,000 risk of mild adverse effects with 95% confidence (Hattis et al., 2002). The 1/100,000 incidence was originally patterned after the California Proposition 65 requirement of carcinogen notification.

p. 114, petition process

This is very important as it allows DTSC to leverage the resources that environmental groups and other non-governmental organizations may make available to help implement the goals of the legislation.

p. 119

Appropriate guidance to the private sector in performing AAs is essential. It would be good if DTSC could foreshadow in these regulations some of the likely content of this guidance. In particular, some guidance is needed on uncertainty analysis and the probabilistic basis for comparisons among alternatives. Is the AA supposed to compare expected values, 95%tile high estimates, median or central estimates, or what? A further key issue is that the comparisons among alternatives must have the same probabilistic basis. It is no good comparing a mean estimate for one chemical and a 99th percentile upper confidence limit estimate for an alternative chemical or vice versa.

p. 145—description of methods for alternative analyses

I would suggest going just a little bit further by saying that the description of the methods and data on which the analysis is based should be complete enough that the analysis can be reproduced by other competent analysts.

p. 154, regulatory responses

This is good as far as it goes. There should be some admission, however, that sometimes there will be tradeoffs between different kinds of effects (e.g. fetal growth retardation vs carcinogenesis). In such cases the DTSC must use its best judgment to choose options that, on the whole, produce effects that it considers less significant in endangering public health. P. 155 has a welcome admission that tradeoffs among different types of values are inevitable, and an overall "cost benefit" framework will be applied at the agency's discretion.

p. 162

Prohibition of continued sale of dangerous products into the stream of commerce in California appears to be the most extreme sanction contemplated here. However in very rare cases where DTSC deems there to be an "imminent hazard" there may be a need for a further step: recall of product already sold. If legally permissible, I think this should be added as a possible further type of extraordinary regulatory response.

At a less extreme level, DTSC may find it helpful to counteract possible evasion by regulated parties in the form of stockpiling a soon-to-be prohibited product at some intermediate stage in the marketing of a chemical product. For example, a manufacturer might provide a substantial inventory of product to a wholesaler for later distribution to retail outlets.

p. 186—requirements for educational institutions to certify assessors:

The areas included here are very good. I particularly like the inclusion of (E) Professional Ethics

references

Bennett DH, Margni MD, McKone TE, Jolliet O (2002a) Intake fraction for multimedia pollutants: a tool for life cycle analysis and comparative risk assessment. Risk Anal 22:905-918.

Bennett DH, McKone TE, Evans JS, Nazaroff WW, Margni MD, Jolliet O, Smith KR (2002b) Defining intake fraction. Environ Sci Technol 36:207A-211A.

Hattis D, Baird S, Goble R (2002) A straw man proposal for a quantitative definition of the RfD. Drug Chem Toxicol 25:403-436.

Huijbregts MA, Geelen LM, Hertwich EG, McKone TE, van de Meent D (2005) A comparison between the multimedia fate and exposure models CalTOX and uniform system for evaluation of substances adapted for life-cycle assessment based on the population intake fraction of toxic pollutants. Environ Toxicol Chem 24:486-493.

Humbert S, Marshall JD, Shaked S, Spadaro JV, Nishioka Y, Preiss P, McKone TE, Horvath A, Jolliet O (2011) Intake fraction for particulate matter: recommendations for life cycle impact assessment. Environ Sci Technol 45:4808-4816.

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Li J, Hao J (2003) Application of intake fraction to population exposure estimates in Hunan Province of China. J Environ Sci Health A Tox Hazard Subst Environ Eng 38:1041-1054.

Margni M, Pennington DW, Amman C, Jolliet O (2004) Evaluating multimedia/multipathway model intake fraction estimates using POP emission and monitoring data. Environ Pollut 128:263-277.

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Ries FJ, Marshall JD, Brauer M (2009) Intake fraction of urban wood smoke. Environ Sci Technol 43:4701-4706.