November 15, 2010

To: **Corey Yep and Jeff Wong, PhD**
California Department of Toxic Substances Control

From: **Joel A. Tickner, ScD**

Re: **Peer review for Safer Consumer Product Alternative Regulations**

Thank you for the opportunity to peer review the scientific basis of the Department of Toxic Substances Control's (DTSC's) proposed regulations for Safer Consumer Product Alternatives. I am an Associate Professor of Environmental Health in the Department of Community Health and Sustainability at the University of Massachusetts Lowell. I also direct the Chemicals Policy and Science Initiative of the Lowell Center for Sustainable Production. In that capacity I have worked with governments, industry, and non-profits for over 10 years on advancing alternatives assessment practices, tools, and policies. My research group has researched and developed tools for conducting alternatives assessments; has evaluated industry and government based alternatives assessment programs; has conducted alternatives assessments; has convened stakeholders to develop alternatives assessment frameworks and collaborations; and has developed model alternatives assessment policies.

The State of California and DTSC should be commended for its efforts to develop policies to advance the application of safer chemicals and products in the state. The goals for the regulations set forth in AB1879 as translated in Health and Safety Code Sections 25252 and 25253 are laudable: Accelerate the quest for safer products, and thus create a systemic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety. This is to be achieved through three specific goals: (1) establishing a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern; (2) establishing a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard proposed by priority chemicals; and (3) specifying the range of regulatory responses that DTSC may take following the completion of the alternatives analysis. In Section 69301.1, the proposed regulations specify guiding principles, including: (1) green chemistry and lifecycle thinking principles should be applied throughout implementation of the regulations; (2) that adverse impacts on public health from consumer products throughout their lifecycles be significantly reduced or eliminated; (3) that averse public health and environmental impacts of chemicals used in commerce be significantly reduced while stimulating redesign of products and production processes maintaining function and performance; and (4) that prioritization processes for chemicals and products should identify and prioritize those chemicals and products that pose the greatest public health risk.

These peer review comments focus primarily on the scientific basis of the proposed regulations – "to determine whether the scientific portion of the proposed rule is based

upon sound scientific knowledge, methods and practices." In particular, as requested by DTSC, the comments focus on three particular areas of prioritization and assessment:

1. The prioritization of Chemicals Under Consideration and Priority Chemicals. In particular, the use of chemical properties, toxicological information, volume of the chemical in commerce, and adverse impact to sensitive subpopulations, public, and the environment to develop supporting rationale and prepare Chemicals Under Consideration and Priority Chemicals lists.
2. The prioritization of Products under Consideration and Priority Products. In particular, the use of consumer product marketing, potential for exposure of the Priority Chemical in the consumer product to the public or contamination to the environment, to develop supporting rationale and prepare a list of Products under Consideration and Priority Products; and
3. Alternatives assessment process. In particular the use of human health and environmental impacts of the Priority Chemical in the Alternatives Assessment to develop safer consumer products.

The comments also focus on other issues that impact the scientific basis of the regulations, in particular the implementability and validation of the alternatives assessment processes.

Overall Comments

The proposed regulations represent a strong effort to develop a comprehensive system to prioritize chemicals of concern in products and evaluate potential safer alternatives. The proposed regulations could be strengthened through development of a clearer methodology and decision-logic for prioritization of chemicals and products of concern that distinguishes between hazard and exposure factors. This would support more effective implementation by DTSC and the regulated community.

The aspirations and vision of the proposed regulations are to be commended. The proposed regulations could benefit from modifications described below that would enhance implementation while reducing resource burdens. The enabling statute, while containing certain factors to weigh in prioritization and alternatives assessment processes is intentionally vague, leaving wide discretion to the agency to develop regulations and procedures to most effectively implement the law. While prioritization and comparison and choice of alternatives ultimately includes political, economic, social factors, the actual processes by which these two key aspects of the regulations are implemented should be clear to all stakeholders involved. The prioritization processes and alternatives assessment methodologies would be enhanced by building off of existing approaches that would allow compliance with the California regulations to serve in other jurisdictions.

Key Recommendations:

1. Expand the definition of Reliable Information to include authoritative chemical hazard lists or prioritization processes and chemical surrogate data

2. Establish a more detailed definition or criteria for “safer”.
3. Divide the list of “Prioritization Factors” in Section 69302 into “hazard” and “use and exposure” prioritization factors. Include consideration uncertainty or lack of data as a prioritization factor
4. Clarify the methodology for prioritization of Chemicals Under Consideration (CUC) and Priority Chemicals (PC). The process could prioritize CUCs only on the basis of hazard properties whereas PCs could be based additionally on use and exposure properties. CUC prioritization may include “embedded” hazards, those that occur through the production, use and disposal of the chemical (e.g., toxicity of building block chemicals) or could at least be considered in the PC prioritization process or alternatives assessment process. PC prioritization could include consideration of interactive or cumulative effects from multiple exposures.
5. Develop a clearer definition of product for the Product Prioritization Process. Clarify the methodology/or decision-tree for prioritization of Products Under Consideration (PUC) and Priority Products (PP). The PUC prioritization could be based on “functional-uses” of PCs to ensure a broad consideration of alternatives for functional use categories of PCs. PUC prioritization could consider chemical mixture effects.
6. Consider a more streamlined approach for the alternatives assessment process. Tier II A AA could only hazard based. Tier II B AA can consider lifecycle and changes in potential exposures between alternatives. Results could be presented in a graphical – LiDS wheel type – format so as to elucidate trade-offs between alternatives and opportunities for reducing the overall footprint. The Tier II AA Workplan could be eliminated with only a report being required to conserve resources. Further, an effort could be made to use market forces, where possible, and technical assistance to support the transition to safer materials and products.

It would be useful to view the process of list prioritization and alternatives assessment like a funnel whereby the CUC list is the largest, PC slightly smaller, PUC slightly smaller, and PP (where alternatives assessment is required) even smaller. This will allow for market signals on chemicals to avoid as well as focus alternatives assessment efforts. Requirements should be increasingly detailed for the highest concern chemicals in the highest concern products.

I. Chemical Prioritization Process

a. Overview of requirement. Section 25252 of the Health and Safety Code directs DTSC to “adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern. According to the Code, the prioritization process should include (but not be limited to) considerations of: (1) the volume of the chemical in commerce in the state; (2) the potential for exposure to the chemical in a consumer product; and (3) the potential effects on sensitive subpopulations, including infants and children. In developing regulations DTSC is directed to develop criteria by which chemicals and their

alternatives may be evaluated, referencing and using to the maximum extent feasible, available information from other bodies.

b. Scientific review of the requirement. To implement this section, DTSC has established a two step process of chemical prioritization: Chemicals Under Consideration (CUC) and Priority Chemicals (PC). The two list process makes sense to provide market signals to firms of chemicals of potential concern (and possibly subject to regulation) and chemicals that will most certainly be subject to regulation in Products Under Consideration (PUC) or Priority Products (PC). In its statement of reasons DTSC rightly notes that the CUC list serves as a notification that certain chemicals are being considered for listing as PCs and allows for identification of gaps in data. This two list prioritization process is consistent with processes in other states that have passed chemicals prioritization processes, such as Washington. However, the prioritization process under Section 69302 mixes hazard and exposure factors in some places. It would be useful to clarify the methodology for prioritization of different endpoints.

According to the proposed regulations, two criteria are required to be met for a chemical to be included in the prioritization process: the chemical must exhibit a hazard trait; and the chemical must be reasonably expected to be in a product placed in commerce in California. According to the definition of a hazard trait, only chemicals that exhibit a hazard trait, as identified by OEHHA under the Toxic Information Clearinghouse will be considered in the prioritization process and until then DTSC will only prioritize chemicals that are Carcinogens and reproductive toxicants, mutagens, and EPA listed persistent, bioaccumulative and toxic substances. The "prioritization factors" in 69302.3 will be used to prioritize chemicals with the previously listed hazard traits.

My review of the chemical prioritization process under Section 69302 concludes that it could be simplified and streamlined by separating hazard and exposure factors and clarifying the methodology by which different endpoints are prioritized. A more streamlined process for the two level prioritization would be helpful with the first level (Chemicals Under Consideration) being purely hazard based and the second level (Priority Chemicals) including use and exposure considerations.

Prioritization of Chemicals Under Consideration

Section 69302.3 lists more than 75 "prioritization factors" that can be used in determining whether a chemical is listed as a CUC. These factors range from hazard factors, to exposure factors to regulatory factors, to modeling data. While flexibility to be able to identify a broad range of chemicals of potential concern is important, it would be useful to be clearer about how these factors were listed, the severity or level of effect that would lead to listing; and how these factors are weighed in determining whether a chemical is a CUC or later a PC. DTSC notes that it is not required to consider all of the prioritization factors for each chemical, in which case it would be helpful to have greater clarity about how they will be reviewed and prioritized. Further, little scientific data exist for most of these hazard endpoints and almost every chemical will exhibit one of the "prioritization

factors" which complicates the later alternatives assessment processes and exemptions from that process

Primary Recommendation:

The term "prioritization factors" is somewhat confusing when combined with the terminology "hazard traits". The current list represents a set of factors to consider in determining whether a chemical should be listed but does not prioritize types of data, severity of hazard, or hazard or exposure traits. One can prioritize certain types of hazards (ie CMR or PBT chemicals); or prioritize based on exposure and use categories; or prioritize based on strength of evidence and severity of hazard. It would be helpful for DTSC to clarify its process for how chemicals will be prioritized. While chemical listing has some element of judgment involved, such a process would assist the agency in better documenting decisions made.

It would be helpful for DTSC to eliminate the long list of "prioritization factors" and work towards a two step prioritization approach based on specific hazard and exposure/use traits. An example of a listing and prioritization approach is the "Process for Prioritizing Chemicals for Consideration under Proposition 65 by the "State's Qualified Experts (OEHHA, 2004)". For initial CUC prioritization, this approach could be only hazard based, while for PC prioritization the approach could include use and exposure factors. Such an approach and a separation of hazard and exposure/use factors will allow a more rapid prioritization of the CUC list and a more targeted PC list. The goal of these processes would be expediency, using the minimal resources necessary to achieve a defensible, scientifically rigorous review, and providing strong signals of the chemicals and uses of those chemicals of highest concern to promote the transition to safer materials.

The CUC list would be a significantly longer list than the PC list (similar to lists in ME and WA[1]) providing strong market signals of chemicals of concern to the state, while the PC list would be a more focused list of priority concerns for the state based on use and exposure data. The long list of "prioritization factors" would be divided into "hazard" and "use and exposure" factors to be considered in prioritizing CUC's and PC's (to be included in an earlier section of the regulation). While it may make sense to limit listing PC chemicals to chemicals exhibiting CMR and PBT properties for the time being to focus agency resources, it may not make sense to limit the CUC list to this limited number of hazard traits.

In developing such an approach, DTSC may wish to consider:

- Developing a decision-tree or process for weighing information about the level of hazard and strength of evidence for chemicals. While the particular approach – quantitative cut offs for different levels of hazard (high, medium, low) or

[1] See overview of the Washington prioritization process in Stone, A and D. Delistraty. 2010. Sources of Toxicity and Exposure Information to Identify Chemicals of High Concern to Children. Environmental Impact Assessment Review 30: 380-387.

qualitative criteria for ranking as priority, etc – is not as important, a consistent process would be useful. In the case of prioritization and review schemes that have categorical rankings (high, medium, low; 2, 4, 6, 8, etc), DTSC could determine that only chemicals that reach a certain score in a specific hazard category or across all categories would be placed on the list. Further, DTSC, to limit the CUC list to only chemicals used in products sold in California, could have an initial criteria of being contained in a product sold in California. As such, the approach would contain a decision-logic such as: (1) is the chemical used in a product sold in CA; (2) does the chemical exhibit hazard trait a, b, c, …., etc. This decision-logic could be expanded to include use and exposure characteristics to prioritize PCs.

Several decision-tree processes exist in the literature. These include:

- The Globally Harmonized System of Classification and Labeling Summary Tables which provide a decision-tree of levels of hazard that correspond to specific hazard categories. While covering only a limited number of hazard categories, such a process – expanded to other endpoints - would allow for ranking the level of hazard for particular chemicals to prioritize those with the highest hazard rankings.[2]
- The US EPA's Design for Environment Furniture Flame Retardant Alternatives Assessment process. EPA has developed several documents outlining its alternatives assessment methodology. Importantly, in its process EPA ranks a range of hazards by Low, Medium and High based on various quantitative and strength of evidence characteristics (see EPA's draft Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation).[3] In absence of cut offs for a particular hazard ranking, DTSC could use a more qualitative prioritization guidance recommended by EPA's DfE program for interpreting data (this is similar to the Category 1/Category 2 approach being recommended by OEHHA in its Pre-Regulatory Draft on Hazard Traits, Endpoints, and Other Relevant Data- August 2010).

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Experimental Carcinogenicity Data Description
Negative experimental data
Positive cancer bioassay in experimental animals ***or*** chemical class known to produce carcinogenic effects
Positive experimental data in humans (e.g., epidemiology study)
Experimental Non-Cancer Hazard Data Description
No basis for concern identified
Suggestive animal studies for chemical or analog(s) ***or*** chemical class known to produce toxicity

[2] See GHS Classification and Labeling Summary Tables at http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/English/06e_annex2.pdf

[3] See EPA Furniture Flame Retardancy Alternatives Assessment Interpretive Guidance - http://www.epa.gov/dfe/pubs/flameret/altrep-v1/altrep-v1a-app-b.pdf

Evidence of adverse effects in humans ***or*** conclusive evidence of severe effects in animal studies

- The Massachusetts Toxics Use Reduction Institute Science Advisory Board (SAB) reviewed chemicals reported on under the MA Toxics Use Reduction Act to determine which were lower and higher concern. The group used a Delphi approach (and expert group deliberative review) to bin chemicals into the higher and lower tiers reviewing data on a range of hazard endpoints. The approach was particularly important so that worker health concerns and missing data were adequately considered through the group deliberative process.[4]
- Washington's Department of Ecology undertook a three step process to identify high priority chemicals that are of high concern to children (CHCC), which includes both hazard- and exposure-based prioritization. First, Ecology created a list of high priority chemicals that have been identified by a state agency, federal agency, accredited research university, or other authoritative scientific evidence as known to do one or more of the following: (a) harm the normal development of a fetus or child or cause other developmental toxicity; (b) cause cancer, genetic damage, or reproductive harm; (c) disrupt the endocrine system; (d) damage the nervous system, immune system, or organs, or cause other systemic toxicity; (e) be persistent, bioaccumulative, and toxic; or (f) be very persistent and very bioaccumulative. Second, Ecology created a list of chemicals that met criteria for exposure to children, which includes chemicals (a) found through biomonitoring to be present in humans; (b) found through sampling to be present in the home environment; or (c) present in a consumer product. Third, Ecology cross-referenced the two initial lists to identify potential CHCCs that meet criteria for both a high priority chemical (hazard) and potential exposure to children. To further prioritize the list of potential CHCCs, Ecology developed a framework to qualitatively evaluate the evidence for toxicity and potential for exposure for each of the potential CHCCs based upon a weight-of-evidence .approach, which included ranked scoring for toxicity and exposure.[5]
- The Clean Production Action Green Screen (recommended for Tier I alternatives assessments) is a tool that can be used to prioritize chemicals (and their breakdown and byproducts) into categories based on a wide range of hazard criteria.[6]
- The Dutch Quick Scan, a rapid chemical prioritization scheme developed under the Nation's Strategy on Management of Substances (SOMS0), used a hazard screening matrix that prioritized based on severity of various hazard categories (high, medium, and low were categorized by severity of hazard). Chemical manufacturers were required to submit any available

[4] See http://www.turi.org/content/view/full/7275
[5] See in Stone, A and D. Delistraty. 2010. Sources of Toxicity and Exposure Information to Identify Chemicals of High Concern to Children. Environmental Impact Assessment Review 30: 380-387.
[6] See www.cleanproduction.org

data on the chemical – experimental, analogs, etc. – to categorize them. Further, if there were no data on the chemical, the chemical was automatically considered high concern. [7]

  - Other methodologies such as SC Johnson's Green List, Environment Canada's DSL prioritization process, the Danish EINECs review based on structure activity relationships, and the Swedish Chemical Inspectorate's PRIO program provide methodologies for categorizing or prioritizing chemicals.
- DTSC may want to develop a hierarchy of hazard traits to determine which ones carry more weight in the CUC and PC prioritization process so that companies and the public are aware of chemicals that will receive greater scrutiny by the state and for which alternatives should be sought.

The availability and weight of evidence found in the literature may be very different from one chemical to the next. As such, in addition to having a process for weighing, categorizing, and prioritizing the severity of hazard, DTSC may want to consider including some type of uncertainty factor/consideration in the prioritization process. A chemical with limited data for a number of impacts could be listed as a CUC, simply as a result of a determination of "insufficient data to make a determination". This determination is a qualitative one that should be used primarily when evaluating the highest priority hazard endpoints such as carcinogenicity, reproductive toxicity, mutagenicity, or chronic aquatic/human toxicity. It is a determination that could be made if following the data review process, no data are available to indicate the presence or absence of a particular endpoint or if there are significant gaps in information that preclude a determination.

Specific comments on "prioritization factors" in Section 69302.3

- DTSC may want to more efficiently group hazard characteristics into logical groupings such as: physical hazards, human health hazards, ecosystem hazards (which could be subdivided into wildlife, plant based, etc), atmospheric hazards etc. This will allow scientists, Responsible Entities and the public to understand the main concerns associated with the chemical. Categorizing hazard categories as in the GHS might provide one model. Having a wide range of hazards to consider makes sense, but for the vast majority no data will exist at the present time. It may be easier to group – as in the GHS – certain chronic toxicity hazards, for example, into systemic toxicity. At the least, it would be useful for the hazard categories for prioritization to be consistent with and defined by those proposed by OEHHA in their "Green Chemistry Hazard Traits, Endpoints, and other Relevant Data Pre-Regulatory Draft, August 10, 2010. It would be helpful for Responsible Entities and others to understand, particularly for physical properties (e.g, melting point or vapor pressure), what makes a substance a higher or lower concern. *DTSC may wish to consider whether in evaluating hazard*

[7] See http://www.turi.org/library/turi_publications/turi_methods_policy_reports/alternatives_assessment_for_toxics_use_reduction_2005 for an overview of the Quick Scan and other assessment methods

characteristics if these refer only to the final transformed molecule or its "embedded hazards" including building blocks, reaction intermediates, and byproducts. To be consistent with the alternatives assessment provisions in Section 69.305 that ask companies to consider upstream and downstream chemical hazards, the latter may make sense.

- 69.302.3(b) Adverse public health impacts. The consideration of "single, intermittent, or frequent use," should probably apply to all hazard endpoints and hence be at the beginning of the section as a general consideration when evaluating a hazard endpoint – ie – that the listing of a hazard characteristic as one of concern does not depend on route of exposure or type of exposure but rather that the effect has appeared in a study.
- 69.302.3(b)(7) – it is unclear why effects of electromagnetic radiation is here. There are numerous other endpoints that do not relate to chemical hazard. It would be useful for DTSC scientists to review the hazard factors to determine which are chemically related.
- 69.302.3(b)(20) Persistence is double counted in the hazard properties. It would be better to place this characteristic with all factors related to persistence and bioaccumulation in one broad grouping (such as chemical traits or physical properties)
    - (24) Toxicokinetics is not a hazard property but rather an issue of disposition and should not be included in the list (or if it is in the exposure and use factors)
    - (26) Averse effects on sensitive subpopulations should be included in "exposure and use" but not "hazard" factors
- 69.302.3(d)(2) – Air quality impacts. It is unclear why nitrogen oxides, sulfur oxides, toxic air contaminants are included. Does this mean that the chemical would produce such substances during its manufacture or use?
- 69.302.3(e), (f), and (g)– these are "use and exposure" factors and it would be better for them to be considered only in the PC prioritization process. It is unclear what a "microcosm" study is.
- 69.302.3(g)(7) and (8) – these relate to the definition of Reliable Information and should not be considered in "hazard" or "use and exposure" factors
- 69.302.3(h) – these are not scientific factors that should be weighed in hazard prioritization but rather are ones that should be considered at the time of listing or not listing. These should probably not be considered in the CUC prioritization process.

Prioritization of Priority Chemicals

Section 69.302.4 details the process for prioritizing Priority Chemicals. These chemicals are chosen from the CUC list and are determined to be those that are the highest priority in the state. They are to be prioritized based on hazard; distribution in commerce and contained in products by consumers and greatest potential for exposure. Further, the determination of PCs should be based on relative degree of threat, availability of reliable information to substantiate the threat and as this list has regulatory implications, available resources. While most of these factors seem reasonable for listing, the last one,

availability of resources, does not make sense, given that there is little DTSC resource burden based on the PC listing and this might unduly limit market signals about chemicals that should be substituted in products.

Primary Recommendation:

It would be helpful for DTSC to clarify its process for designating CUCs as PCs based on strength of the evidence of hazard; severity of the effect; and use and exposure, particularly to sensitive sub-populations. At PC listing phase, data indicating exposure from specific products is not necessary (which is the focus of the Product Prioritization Process) but rather data indicating use in products in CA and exposure to the chemical in the state (which could be obtained from surrogate measures such as volume of use and knowledge about the chemical's properties). The "use and exposure" prioritization factors (69.302.3(e)(f)and (g) would benefit from being incorporated into Section 69302.4 in the prioritization of PCs, in addition to those included in section 69.302.4(b)(2) and (3*). As noted above, it may be useful for the Department to develop a hierarchy of hazard factors and exposure factors that would be used in PC listing process.* For example, high volume use of the chemical in dispersive products or use of the chemical in a product that used by a vulnerable population would lead to a higher priority. The Department may want to consider developing a matrix to group hazard and use/exposure categories to identify potential PCs. This would allow Responsible Entities and the public to understand which chemicals in which types of uses present the highest concerns. This approach is consistent with the Dutch Quick Scan, where after the hazard classification phase, chemicals were classified into exposure categories based on their uses (use as a surrogate for exposure) leading to a qualitative risk estimate and recommendations for substitution, restrictions, or engineering controls.

Specific comments on "prioritization factors" in Section 69302.3

It is unclear why Sections 69302.4 (c) and (d) are listed in this section regarding prioritization of PCs. This is not a hazard or exposure and use consideration but rather a policy decision regarding which chemicals will be considered first in the prioritization process. This factor should appear in a different section or earlier in the section on Priority Chemicals. Further, DTSC may wish to revisit its rationale for limiting the first PC list to CMRs and PBTs. The science on CMRs and PBTs is certainly not undisputed and just because a chemical is a CMR or PBT does not mean that more effort has been placed into seeking safer alternatives. The choice of focusing on CMRs and PBTs is a scientifically-informed policy decision and should be maintained as such. Government entities, advocates and companies around the world have focused on these endpoints as endpoints of concern and it is perfectly reasonable for DTSC to initially prioritize chemicals based on them. However, there are many chemicals that are not CMRs or PBTs that may be significantly more damaging for health and environment and should not be excluded.

There is no consideration in the PC prioritization process of potential for cumulative or interactive exposures. One consideration of whether to list a chemical as a PC may be

the fact that it is often found with another chemical of potential concern (eg., a solvent and another chemical agent in construction) or exposure is occurring to an already disproportionately exposed community (e.g., community of color surrounded by chemical plants).

II. Product Prioritization Process

a. Overview of requirement. Under section 69303, products containing PCs are prioritized into Products Under Consideration (PUCs) and Priority Products (PPs). PUCs are prioritized on the basis of several key factors: (a) dispersive volume information for each product; (2) potential for the public or environment to be exposed to the PC contained in the product during its useful life; (3) types and extent of consumer uses that could result in public exposure to the PC and adverse health or ecosystem impacts; (4) whether the product is required to be managed as a hazardous waste; (5) whether the specific PC is required to be used in a specific product by law; and (6) whether the PC in the product is addressed throughout its comparable life-cycle through other laws. PPs are determined from the list of PUCs based on an additional set of hazard, exposure and available alternatives factors.

b. Scientific review of requirement. The list of PCs will likely be a relatively small list. However, chemicals may be used in thousands of different products. In the proposed regulations, it would be useful to more clearly define "product". For example, is product an individual SKU for a particular brand, a category (such as thermometer or thermostat), a component, or a broad functional category, such as dye? Further, is product consideration just focused on PCs or any hazard the product as a whole might have? While the state intends to collect data on what chemicals are contained in what products, this process may take a significant amount of time as Responsible Entities communicate with their supply chains (past Tier I suppliers) to get information. Further, there is significant overlap between the PUC and PP prioritization processes that leads to confusion as to the rationale for the two lists. As in the two lists for prioritization of chemicals, the two list approach for prioritization of products makes sense if there is some distinction in the lists and that one is used to create market signals and an understanding of products that may be under scrutiny at a later time and the other carries regulatory responses. Finally, it would be helpful to clarify the method for the Product Prioritization process (eg. Are there some factors that would carry more weight than others).

My review of the Product Prioritization process under 60303 has found that the process represents a somewhat duplicative set of use and exposure considerations for establishing lists of PUCs and PPs. While the use and exposure based criteria make sense to use at this point, it would be useful for DTSC to be clearer about how "product" is defined and how review for one list differs from review for the other. DTSC may wish to clarify its process flow/decision-tree for review and establishment of the lists.

Primary Recommendation: *DTSC may wish to consider using "functional use" rather than specific product type in developing its PUC list.* This would be consistent with the

alternatives assessment methodologies established by the EPA's Design for Environment Program and EPA's Use Cluster Scoring System of the 1990s. In making an initial PUC list based on functional use (ie lead/solder) it would facilitate the market place to develop and compare alternatives more broadly for that use rather than looking only at a specific product. That way, a database of "best in class" alternatives for particular chemicals and functional uses of concern could provide Responsible Entities with information about alternatives for their particular use and facilitate attention to multiple chemicals (a broad range of alternatives to a particular functional use). It could help facilitate industry consortia to find alternatives for particular chemicals/uses that are of concern and present challenges to substitution. It will also provide a more expedient approach for DTCS to prioritize products, as compared to obtaining information from each Responsible Entity on what chemicals are in what specific products. Information on functional uses of chemicals is fairly readily available from multiple sources. An initial PUC listing by chemical and then functional use, would provide signals to the market place of the chemicals and uses that are of highest concern to the state. This focus is consistent with the idea of alternatives assessment or substitution where the focus is on identifying alternatives to replace the "function" or "service" a particular chemical provides.

DTSC may wish to clarify its decision-logic or approach for reviewing and listing PUCs as noted for the earlier processes.

Specific comments on "prioritization factors" in Section 69303.3

The prioritization factors in Section 69303.3 are still applicable even if the state decides to use functional use in the PUC prioritization process. If this change were to be made, a first step would be to identify functional uses for the particular PC and list them. From there, dispersive volume for that functional use would be examined as well as potential for public or environmental exposure from that functional use, uses that might present health or environmental threats. If the state were to adopt a functional use prioritization for PUCs, sections (f) and (g) would be more relevant in the PP prioritization.

A hierarchy of potential exposures/uses of highest concern may be useful in considering the prioritization factors. For example under 69303.3(c) lists almost every possible use of a chemical as being potentially of concern – are there some uses of higher concern than others?

Prioritization of Priority Products

PUCs are prioritized as PPs on the basis of an additional set of factors including: (1) relative degree of threat posed by the product (with priority given to chemicals and products containing them that pose the greatest public health and environmental threat, are most prevalently distributed in commerce and used by consumers, and for which there is greatest possibility of exposures that could cause harm; (2) availability of information to substantiate the threat; and availability of alternatives.

Primary Recommendation. DTSC may wish to clarify its decision-logic/process for determining Priority Products. While such a process will contain a significant element of scientific and policy judgment given the lack of information on chemicals, having clarity about the process of identifying products and prioritizing them is critical. This decision-tree need not be complicated or inflexible, but it could lay out a clear process for designating PCs given the regulatory attention that will be given to them. Including availability of alternatives as a factor in determining whether a chemical is PUC is reasonable and will help stimulate adoption of safer alternatives and lower the standard of "proof" before action should be undertaken. Based on the recommendation for establishing the PUC list prioritizing functional uses, the PP process may wish to begin by identifying products within functional uses of highest concern based on the PUC prioritization process.

Specific comments on "prioritization factors" in Section 69303.4

As noted previously, the prioritization factors in Section 690303.3 (f) and (g) make more sense at PP prioritization rather than the PUC prioritization. Further, *there is a need in the PP or possibly PUC phase for consideration of mixture effects.* Often times a chemical in a product may be combined with another chemical that enhances the original chemical's toxicity or uptake in the body or persistence in the environment or in tissues. As the proposed regulations are focused on safer consumer product alternatives, products or functional uses of chemicals should be prioritized if there is knowledge that are they are or may be combined with other chemicals that will increase exposure or toxicity.

III. Alternatives Assessment Process

a. Overview of Requirement. Section 69305 of the proposed regulations outline a process for alternatives assessment for chemicals of concern and products of concern. The proposals outline a process for "early" alternatives assessment – Tier I AA Reports; a process for certifying alternatives assessments; de minimis exemptions from alternatives assessment processes; and a process for full alternatives assessments – Tier II Reports. The Tier II process has three components: Development of a Tier II AA workplan; Tier II AA evaluation and comparison, including a Chemical Hazard Assessment, An Exposure Assessment, and a Multimedia Lifecycle Assessment; and development of a Tier II AA report.

b. Scientific review of requirement. Section 69305 represents a laudable effort to establish the nation's first product chemicals alternatives assessment process. Its is further commendable that the process consider the entire lifecycle of chemicals and products to minimize overall environmental and health impacts. However, it would be useful for DTSC to consider approaches to simplify the alternatives assessment process to reduce burdens for both the agency and Responsible Entities. The proposed regulations assume that alternatives will be found that will have no hazard traits; however, as noted previously, nearly every chemical will likely have one or more of the myriad of hazard traits listed. As such, prioritizing hazard traits as ones that should be completely avoided

and having some categorization (eg., 1, 2, 3 etc for each hazard trait) for others is critical for Responsible Entities to know if they are moving towards safer products.

AB 1879 and its subsequent Health and Safety Code 25253 are intentionally vague as to the process that DTCS should develop to implement the statute. As such, DTSC has great opportunity to develop a consistent, methodologically sound alternatives assessment process that meets the goal of including "lifecycle assessment tools that take into consideration" various aspects of lifecycle impact. It is perfectly possible to include lifecycle considerations (life cycle thinking) in the AA process without undertaking complex, costly, and highly uncertain lifecycle assessments. The goal is to understand where impacts could occur along product lifecycles and to minimize those impacts without overburdening the process. To gain ideas on streamlining the alternatives assessment process, it is suggested that DTSC review alternatives assessment frameworks, such as the ones developed by the Massachusetts Toxics Use Reduction Institute to fulfill TUR planning requirements and the Five Chemical Alternatives Assessment Study; the EPA's Design for Environment Alternatives Assessment Process; and the Healthy Building Network's Pharos process which is a multi-media lifecycle alternatives evaluation. The Massachusetts TUR process has been successfully used by firms for twenty years in reducing chemical use, waste, and emissions. A defined set of process steps for alternatives assessment with clarity about the factors in the comparative analysis will help augment quality and consistency in AAs. While the comparative analysis of alternatives may differ between firms (and tools to compare alternatives, though DTSC may want to suggest particular tools), having a clear set of process steps will enhance reviewability of AAs.

Finally, it would be helpful for DTSC to clarify whether the alternatives assessment is a "product" alternatives assessment (ie comparing priority product with other products) or a "Priority Chemical in Priority Product" alternatives assessment that considers lifecycle factors in comparing alternatives. These are quite different. DTCS may wish to determine whether the focus of the alternatives assessment requirements is the full product, a component, or the chemicals in the product. Given that the focus of the Chemical and Product Prioritization Processes is focused on chemicals and how they are used in products, it would be logical for the Alternatives Assessment process to have a similar focus though it should have broad consideration of how an alternative chemical or product design may affect lifecycle impacts.

Primary Recommendation. *DTSC may wish to revise its Alternatives Assessment (AA) process to simplify and clarify the steps in the AA process.* It would be useful for the process to encourage broad consideration of alternatives and as there is no safe alternative, potential trade-offs between them that could be minimized. The following modifications are suggested. Following these proposed modifications, a section by section detailed analysis of the proposed alternatives assessment process is provided.

1) It would be useful for Tier I AA's to be applicable only to PCs as the CUC list is likely to contain a significant number of chemicals. Alternatively, DTSC could designate that certain types of hazard endpoints (e.g, CMR or PBT or chemicals

that have a high hazard for a hazard trait) automatically shift a chemical into the Tier I AA process. As noted, the Tier I AA is an opportunity to provide an early signal to Responsible Entities to engage in seeking safer alternatives with a lower administrative burden. The rest of the CUC list provides a market signal of chemicals that are of concern and should be explored for possible alternatives, but at this point in time are not critical for substitution.

2) The Tier II workplan and report seem duplicative. If the concern is the breadth and content of the Tier II AA report, this concern can be addressed through adequate training and guidance for AA assessors to ensure Tier II AA's are complete. Further, having an additional workplan review for DTSC would expend unnecessary agency resources. If the goal of the Tier II workplan is to build AA consortia, then DTSC, like the Substance Information Exchange Forums (SIEF) under REACH could establish an Internet-based approach for Responsible Entities to share AA responsibilities.
3) The two step Tier II AA seems reasonable. However, DTSC may consider modifying these steps.
    a. The Tier II A AA could consider only hazard and include a decision-tree so that chemicals of high concern are eliminated from further consideration. Other "elimination factors" could be built in at this step, such as exposure to high concern communities, etc (as noted in 69305.5(a)(2)(C) – though exposure alone at equal or greater levels as the Priority Chemical may not indicate a problem, particularly if the alternative is significantly less toxic).. This will narrow the number of alternatives that warrant a more detailed evaluation. The Green Screen or equivalent methodology could be used for the initial hazard screening, and it would be useful for Tier IIA hazard screening to be the similar as Tier I hazard screening. DTSC may need to make some determination of whether alternatives are required to move from a higher to a lower concern benchmark in the Green Screen to be considered "safer". This may also assist in determining regulatory responses. It may not make sense to have the Exposure Potential Assessment at this point nearly every chemical will likely exhibit one of the hazard traits indicated in the OEEHA draft guidance and in the Chemical Prioritization Process
    b. The Tier II B AA could consider life cycle impacts and how the alternative might increase or decrease exposure (compared to the PP). In this sense, exposure is considered to ensure that even if an alternative is less toxic that its use does not result in uncontrolled additional exposures that could result in higher risk, for example to workers in production or use, to consumers, or at end of life. The Economic and Technical Feasibility aspects of the Tier II B AA Multimedia Lifecycle Evaluation could be separated from the health and environmental evaluation into a new section called "Technical and Economic Viability Analysis"
    c. The Tier II A and B AAs could be combined into a Tier II AA report that includes an "Alternatives Assessment Profile" that compares alternatives in a disaggregated manner so that potential trade-offs are identified and actions to reduce them noted. It would also compare technical and

economic viability of alternatives. This comparison should be not be done only on the basis of quantitative comparison as LCA type quantifications tend to crumple large amounts of data (or often small amounts) into a single number that loses the context of the risks, is incomparable across products, and loses the trade-offs that might occur (for example between toxicity and carbon footprint). The MA Toxic Use Reduction Institute's P2OASyS includes a disaggregated and aggregated approach to considering a wide range of hazard and lifecycle factors for chemicals and products.[8] The Healthy Building Network's Pharos Wheel (modified from the original Dow LiDS wheel represents one graphical approach to compare alternatives.[9] It would be helpful for the AA report to include a plan to address potential risk trade-offs and continuous improvement plan so that modifications to the choice of alternative may be made as new information arises.

Specific comments on Tier II AA "Evaluation and Comparison Process and Factors" in 69.305.5. Specific comments have been provided above regarding prioritization factors for identification of CUCs and PCs. These considerations, in particular simplifying the list of hazard traits to be considered, separating hazard and exposure traits and having a categorization process for hazard traits carry into the alternatives assessment process.

69305.5(a)(3) – There should be consistency and comparability for alternatives in AAs. However, there may be better lifecycle information for one alternative over another (e.g., some evidence of high hazard) that should be considered. The entire lifecycle should be considered in comparison not only specific lifecycle segments. Again, the idea is to identify where there may be concerns in the lifecycle, not to quantify every impact.

The Hazard Traits for Chemical Hazard Assessment (section 69305.5(b)) are similar to those in the Chemical Prioritization process. These categories of properties should be exactly the same as in the Chemical Prioritization process (for example 69305.5(b)(1) should not be Chemical Information but rather "Chemical and Physical Properties") and would benefit from being simplified to the extent feasible as noted in comments for the Chemical Prioritization Process. These traits should be the same as the ones for the Tier I AA.

The Exposure Potential Assessment (69305.5(c)) could be simplified. Exposure is a less important consideration in alternatives assessment than it is in identifying priority chemicals. Most existing alternatives assessment processes consider exposure as a secondary factor after comparing alternatives on the basis of hazard. As one goal of the regulations is to promote green chemistry and green chemistry is by nature hazard reduction based, the consideration of exposure is primarily to minimize potential trade-offs from alternatives. As such exposure considerations here should include: potential

[8] See http://www.turi.org/toxics_use_home/hot_topics/cleaner_production/p2oasys_tool_to_compare_materials
[9] See http://www.pharosproject.net/

for exposure to a vulnerable population; dispersive volume; potential for releases throughout the chemical's lifecycle; concentration of chemical or use per unit of product, etc.

The Multimedia Lifecycle Evaluation factors (69305.5(d)) could also be simplified. Product Function and Performance and Economic Impacts could be separated from the lifecycle environmental and health impacts evaluation. While technical evaluation is very product, process, and industry specific, there are very specific tools for economic evaluation of alternatives (the Massachusetts Toxics Use Reduction Program has developed such tools and a new evaluation tool from the Northeast Waste Management Officers Association – EMFACT – contains economic analysis capabilities.[10]). Thus Section 69.305.5(d)(1) and (4) could be combined into one or two new sections after the lifecycle environmental and health impacts considerations. Further, Section (e) suggests that the requirements may be fulfilled by completing an ISO 14040 or equivalent LCA. DTSC may want to consider removing this section as an ISO 14040 may not consider all of the categories included in this section, in particular toxicity of upstream chemical manufacturing processes (unless these are considered in the Chemical Prioritization process).

Specific considerations with regards to lifecycle impacts in Section 69.305.5(d)(2) and (3) include: materials and resource consumption impacts should include extraction; worker health and safety impacts in upstream production should be considered (eg urethane production as an alternative to phthalates/PVC); agricultural impacts should be added in the case of alternatives that might be biobased. It is unclear whether upstream worker health considerations would be included in an "embedded" hazard evaluation in the Chemical Prioritization process.

Section 69305.5(d)(4) Economic impacts is very broad and likely very difficult for most Responsible Entities to complete. While most of the factors included could be evaluated qualitatively, very few could be quantified. DTSC may want to come up with a set of reasonable metrics for evaluating quantifiable costs – primarily so that firms can view the benefits of toxics reduction. The Massachusetts Toxics Use Reduction Program requirements for full-cost accounting, so that costs of toxics are internalized to the process or product; and net present value comparison of costs provide some mechanisms for cost comparisons.

Specific Comments on 69305.1 Alternatives Assessment Notifications and Tier I AA Reports.

As previously noted, it would be helpful for Tier I AAs to only apply to PCs and not CUCs. The requirement to submit a Tier I AA when a product is reformulated or redesigned might create a disincentive to reformulation. There should be a means to support reformulation through provision of information on safer alternatives. Publication of Tier I reports could provide an incentive so that companies do not need to repeat alternatives assessments already completed. DTSC may wish to consider development

[10] See http://www.newmoa.org/prevention/emfact/index.cfm

of a safer alternatives options database, like the EPA's Clean Gredients Database that creates a marketplace for safer alternatives.[11]

Specific comments on 69.305.2 Tier II Alternatives Assessment General Provisions

As noted above, DTSC may wish to consider eliminating the AA Workplan requirement in favor of submission of only an AA report.

The process for preparation and certification of AA reports would benefit from being simplified. The process, outlined in this section and section 69.308.3 is based on the Massachusetts Toxics Use Reduction Program, TUR Planner Certification Process. Using such a process for the proposed regulations makes sense as it will help ensure quality of AAs, help support training of a new generation of thinkers in firms who can support the application of safer chemicals and products, as well as reduce burdens on government to double check the effort on each one. However, the process could be simplified in the following manner:

1. The University of California could be a single accrediting body for Assessors and curriculum could be established by the state and partner entities. For example, an advisory council, as in the case of the MA TUR Program could be established to work on curriculum development. Having a point source for accrediting allows control over quality of curriculum and training and limits the amount of oversight of the state in ensuring quality control
2. DTSC may wish to eliminate the distinction between the various types of assessors.. Assessors would be individuals who have undertaken necessary training to ensure the quality of the alternatives assessments. Some of these may be from within particular companies, some may be consultants or other organizations for hire. What matters is the quality of the assessment. In Massachusetts about half of the certified TUR planners are in-house, half are from consultants. Whether a company conducts its own TUR planning or hires a consultant depends on numerous firm level factors. There is no particular need for a distinction between "normal" and "lead" assessors. Someone who is a certified AA planner should be responsible for signing the AA as well as the CEO or other officer of the company.
3. If there is concern about quality of in-house conducted AAs, then having a relatively simple and inexpensive review and certification by an external auditor (not as complex as an ISO 14,000 audit) may make sense. The final AA in the case of in-house or third party AAs should be signed by a corporate officer for completeness. DTSC could then do completeness checks for each Tier II dossier and a more thorough review of a subset of them (much like the 5% review of registration dossiers under REACH).

Specific comments on Section 69305.4 Tier II Alternatives Assessment Workplan

[11] See http://www.cleangredients.org/

DTSC may wish to consider integrating this section with 69305.5 so that there is only a Tier II AA report.

In Section 69305.4(a)(1), it is unclear why information on all persons involved in the Tier II AA need to be listed. Or why any organizations involved in providing guidance in the Tier II AA. If the AA is signed off by a certified Assessor and/or CEO that should be sufficient to ensure quality. Guidelines for who must be involved in the AA process could be developed that would alleviate this certification.

Section 69305.4(a)(3), in most cases there will be no way to know the suppliers beyond Tier I or Tier II suppliers. While trying to gain information on the entire supply chain is laudable, this may be extremely difficult. Further, gaining information on all responsible parties may also be challenging.

In Section 69305.4(a)(5) where impacts along lifecycle segments for alternatives are similar, the lifecycle review should look primarily at segments where there are differences between alternatives. However, it is useful to consider the entire lifecycle and where potential impacts might occur (for example, increased worker toxicity to a building block chemical).

IV. Chemical and Product Information

Section 69301.6 Chemical and Product Information sets out the types of Chemical and Product Information DTSC may request on chemicals. There is no "minimum chemical dataset" but rather a "data call-in" process to obtain necessary data in the prioritization and alternatives assessment process. This makes sense and as the OEHHA process of developing its toxics clearinghouse, data are more likely to become available. The hierarchy of obtaining data in 69301.6(b) makes sense in that the Department will first use available data in the public domain and lastly request generation of new data.

V. Definitions

There are numerous definitions included in Section 69301.2 that may change based on the recommended changes to the Proposed Regulations. Some additional comments include:

Hazard Trait – As noted, there is confusion between "hazard trait" and "prioritization factors." There should only be one definition – "hazard trait" and that the prioritization process prioritizes chemicals on the basis of "hazard traits" and "exposure and use". It makes no sense to include the limitation to hazard trait in this definition but to rather include it in defining the first list of PCs under the proposed regulations.

Reliable information – It would be useful to expand this definition to include authoritative lists of chemicals. In this way, DTSC can rely on the work of other agencies (such as IARC) and prioritization processes (such as in WA, ME, and other

countries such as Denmark) in compiling its lists of CUCs and PCs. Surrogates for testing data, such as structure activity data should be included as well in this definition.

Responsible Entity – While the rationale for the Responsible Entity being the point of distribution or sale is reasonable, in practice these organizations often have the least access to data on toxicity or alternatives and capacity to undertake an alternatives assessment. DTCS may wish to develop processes to provide technical support for Responsible Entities as well as to pressure supply chains to provide data and input into alternatives assessment efforts. DTSC may want to look at models, such as mercury legislation, that place a greater burden on those who have the greatest control over production decisions.

Safer – the definition of safer is not clear - net reduction of projected public health and environmental adverse effects - and DTSC may want to develop a more detailed definition that provides guidance to manufacturers of how the Department will review AA's to determine what the appropriate regulatory response is or whether alternatives are indeed safer. This could be elimination of a chemical of concern (ie not on the CUC list), moving down a benchmark on the Green Screen etc. The goal should be continuous improvement in safer products.

VI. Additional Comments on Technical Support

The Proposed Regulations form a central part of the California Green Chemistry Initiative, the goal of which is to advance green chemistry, safer products, and innovation in the state. Innovation theory talks about two key factors in innovation: willingness and capacity. The Proposed Regulations advance willingness by prioritizing the chemical universe, providing strong market signals of chemicals to avoid, and establishing a process to review and implement safer alternatives. However, the Proposed Regulations do not establish a process or framework to advance "capacity". Capacity refers to the ability of firms to innovate. Small and medium sized firms often do not have the ability to generate data or complete complex assessments. DTSC may want to as part of the Proposed Regulations establish a research and technical assistance framework for safer alternatives. DTSC could use existing pollution prevention capacity as well as state manufacturing extension support to education, train, and provide technical support to firms to conduct alternatives assessments and implement safer chemicals in products. Research and testing of safer alternatives; demonstration projects; and supply chain and sector dialogs to advance safer products may provide an important impetus to achieve AB1879's goals. The MA Toxics Use Reduction Program may provide a model of integrated alternatives assessment planning and support.

The scientific rigor of the Proposed Regulations does not only refer to the processes for prioritization and alternatives assessment but also to the use of science to advance safer chemistry.