October 11, 2012

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Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
(*via e-mail: gcregs@dtsc.ca.gov*)

Re: Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Proposed Safer Consumer Products Regulations* released on July 27, 2012 by the California Department of Toxic Substances Control (DTSC or the Department) for the implementation of AB 1879 (2008).

ACI is the trade association representing the $30 billion U.S. cleaning products market, with about $3 billion associated with business in the State of California. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy. As a trade association for a particular consumer product sector (cleaning products), we are acutely aware of the public's concern for the safety of the products they purchase both in their homes during use and in the environment following disposal. Human and environmental safety is at the core of the mission of our member companies and our association.

At the Federal level, ACI has been very active in engaging key legislators on the reform of the Toxic Substances Control Act (TSCA). Moreover, we have worked closely with the U.S. Environmental Protection Agency in their implementation of TSCA including a number of areas related to the proposed Safer Consumer Products regulations such as the prioritization of chemicals for risk assessment and the protection of trade secret information.

We have a number of detailed comments on the text of the proposed Safer Consumer Products regulations in an attachment to this letter, but would like to first share our perspective on some more general considerations in the proposed regulations.

Lack of Clarity Will Lead to Regulatory Uncertainty

The proposed regulations will be implemented through a series of vaguely described processes with many of the critical details being left for future guidance documents or regulatory findings. While such an approach is not unusual *to some extent* for regulatory development, the scope in this case is breathtaking, and will result in significant confusion in the marketplace. The proposed regulations do not comport with the Office of Administrative Law's standard of clarity – that is, "written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them."[1] Because the regulations contain so many vagaries, the regulated community cannot know how they may comply. While DTSC has indicated that they will elucidate their intentions in the future, it does not appear that such findings and guidance will be consistent with the Administrative Procedure Act. DTSC has an obligation to provide clear and complete regulations for public review and comment such that the requirements on the regulated community are readily apparent. This is not just the law, but it is good public policy.

Distinguishing Between Intentionally-Added Ingredients and Contaminants

The proposed regulations do not make a distinction between intentionally-added ingredients and potential contaminants. Chemicals which are contaminants serve no useful function in a product. They should not be the subject of an alternatives assessment, and DTSC should not require one in such a situation – it is a poor use of resources for a company to conduct such an analysis and for the Department to potentially review it. We note that the proposed regulations *do* make such a distinction with respect to components of assembled consumer products defining them as "required to complete or finish an item," "performs a distinctive and necessary function in the operation of a system," or "is intended to be included as a part of a finished item."[2] The same concepts should be extended to ingredients used in a formulated consumer product.

Additionally, we note that the regulations implementing the Children's Safe Products Act in Washington State define a *contaminant* as "trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products."[3] The same regulations define an *intentionally added chemical* as "a chemical in a product that serves an intended function in the product component."[3] We believe this distinction is critical to the workability of the Safer Consumer Product regulations as the focus of the alternatives assessment will be the function of a chemical in a product. An alternatives assessment for a contaminant in a product is not a meaningful exercise. DTSC may well believe that manufacturers need to address and reduce contaminants in products. However, the present regulations, as designed, would not achieve such an objective.

As such, we request that DTSC include a definition of "contaminant" in the regulation that differentiates between intentionally-added ingredients and contaminants in products. Such a distinction and provisions for handling each appropriately are critical to the program's success.

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[1] California Government Code, §11349(c)
[2] Section 69501.1(a)(21)
[3] WAC 173-334-040 – What definitions apply to terms used in this chapter? (https://fortress.wa.gov/ecy/publications/publications/wac173334.pdf)

Chemicals of Concern Identification Process

As currently written, the proposed regulations would establish Chemicals of Concern (COCs) based on 22 lists from various state, US Federal, and international government bodies. The Department has stated that this "List-of-Lists" comprises roughly 1,200 chemicals. We have conducted our own count of chemicals which are the subject of these lists and find they contain over 4,000 chemicals. The Department needs to articulate how it has determined that there are only 1,200 chemicals on these lists.

More importantly, as we have stated numerous times, the Department's approach continues to ignore the statutory mandate to identify and prioritize chemicals of concern. While it may be appropriate to use the various lists to identify candidate chemicals, there should be clear criteria and an established process for screening which chemicals are ultimately deemed a COC.

Consumer Product Prioritization Process

The Department included in this proposed regulation a number of prioritization factors and process steps to identify and list products as Priority Products. However, the factors and process are not transparent and it is entirely unclear how the Department would actually select a Priority Product. The Initial Statement of Reason (ISOR) states that the process identification includes a two-fold evaluation: 1) where a Chemical of Concern's behavior in terms of its toxicity and physical profile in the product, and 2) exposures to the Chemical of Concern in the product in quantities that may contribute to or cause enumerated adverse impacts. This is an appropriate framework to use. However, the execution of that evaluation would be entirely internal within DTSC. The details provided in the regulation and associated documents are insufficient permit prediction of an end result, and leave too much discretion to the Department. The proposed process lacks sufficient transparency such that decisions by the Department on Priority Products will not be greeted with confidence by stakeholders.

In determining the Initial Priority Product List (Section 69503.3(g)) for the first three years of the program (roughly), the Department would focus only on those chemicals that are found on one of the 14 lists under Section 69502.2(a)(1) and on one of the 8 lists under Section 69502.2(a)(2). We note that the former 14 lists are viewed by DTSC as hazard trait lists and the latter 8 lists are viewed as exposure/monitoring related lists. We believe that the approach for selection of Chemicals of Concern and Priority Products should consider both hazard traits and exposure. The approach proposed by the Department is pragmatic, though potentially subject to criticism. Nonetheless, we believe it is suitable for the initial list of Priority Products. However, going forward beyond the initial stages of the program, the Department should have an approach that considers elements of hazard and exposure more rigorously.

In selecting Priority Products, the Department should use a standardized product nomenclature system. We note that the ISOR makes reference to the GS1 Global Product Classification (GPC) system (http://www.gs1.org/gdsn/gpc) when describing Section 69503.3(f). We agree that the GS1 GPC is an appropriate source for describing products and that Priority Products should be identified at the Brick Level. Priority Product categories should be described at the Class Level for the purposes of the Department's Priority Product Work Plan.

Alternatives Analysis Threshold Determination
ACI is greatly troubled by the Department's abandonment of the simple concentration based approach it had proposed earlier in favor of a process-based approach that will be primarily based on the minimum detectable concentration for the Chemical of Concern in a product. Moreover, we find it disturbing that the Department proposes this approach even though it acknowledges that the AA Threshold may well be below a level that represents an insignificant or negligible risk, too small to be of concern. It is unclear why the Department would impose such heavy regulatory burdens on companies in cases where it knows there is little or no opportunity to improve public protection or improve environmental quality.

In the interest of regulatory efficiency, we recommend that the Department return to its previous proposal (October 31, 2011) of an administrative, concentration-based AA Thresholds of 0.01% for chemicals with particular hazard traits (e.g., carcinogens, neurotoxins, reproductive toxicants, etc.) and 0.1% for all other chemicals until it can develop a credible risk-based approach.

We believe that any process-based approach should be self-implementing and risk-based. An example is the Proposition 65 Safe Harbor provisions which are used by companies to determine whether they have to label a product as containing a Prop 65 chemical. We believe that no Prop 65 chemical should have an AA Threshold below its No Significant Risk Levels for carcinogens or the Maximum Allowable Dose Level for chemicals causing reproductive toxicity.

Regulatory Duplication
The California Health and Safety Code § 25257.1 prohibits the Department from superseding the regulatory authority of any other California department or agency and from duplicating or adopting conflicting regulations for product categories already regulated. There are a number of conflicts in the proposed regulations with other California agencies and various laws. For example, the California Division of Occupational Safety and Health is responsible for regulating worker exposures in occupational settings and the California Air Resources Board has extensive regulatory oversight of volatile organic compounds (VOCs) in consumer products. At the Federal level, over-the-counter drugs and food contact materials are regulated by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. The Department should clearly articulate the limits of the regulations so that it complies with Section 25257.1.

Peer-Review of Scientific Components
The notice for the proposed rule states that DTSC is having the scientific basis of these regulations peer reviewed pursuant to Health and Safety Code § 57004. We believe that the Department should select peer-reviewers who are familiar with the context of the regulations and have some experiences with the many challenges DTSC is facing in developing the regulations. We recommend that DTSC publicly release the charge questions for peer-reviewers and solicit comments on the charge questions in advance of the initiation of the peer-review.

CEQA Exemption
The notice for the proposed regulations stated that DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.) and DTSC prepared a Notice of Exemption from the California Environmental Quality Act. While it might be difficult to quantify all of the potential impacts of the proposed Safer

Consumer Products regulations at this time, that does not justify a complete exemption from such an analysis. DTSC should initiate CEQA analysis as part of this rulemaking.

We believe several impacts of the regulations can be anticipated and analyzed. For example, because the Alternatives Assessment Threshold would be primarily based on the minimum detectable concentration for the COC in a product we believe that will drive manufacturers to seek high purity source materials for their products. This will result in several impacts:

1) Recycled materials would be disfavored in the market because of residuals present in them, or merely because their purity cannot be guaranteed easily. As a result, the price for such materials will decline leading to reduced viability of recycling collection and distribution systems. This may directly impact California municipalities and may require greater disposal of diverted recyclable material.

2) Similarly, complex natural materials would be disfavored for the same reasons that recycled materials would be. Complex substances that could be derived directly from a natural source will lose favor in the market to complex substances synthesized from known feedstocks; the feedstock could be synthetic (petrochemical) or natural in its source. However, bio-based materials could be disadvantages by the construct of the final rule.

3) Manufacturers will seek higher purity source material that will require greater processing to remove residuals. This would require greater energy for purification and higher costs of feedstocks. Life-cycle inherent energy in products will increase.

There are likely other macroeconomic impacts that could be anticipated based on policies incorporated into the regulations that are currently not assessed. To the extent that it is possible to do so, such an analysis should be initiated.

ACI would like to express, once again, its appreciation in being able to comment on the proposed Safer Consumer Product regulations. We would be happy to further assist DTSC in the development of regulations implementing AB 1879 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Sincerely,

Paul C. DeLeo, Ph.D.
Senior Director, Environmental Safety

Enclosure

cc: The Honorable Matthew Rodriquez, Acting Secretary, CalEPA (MRodriquez@calepa.ca.gov)
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SPECIFIC COMMENTS – DRAFT

Article 1. General

Section 69501.1 – Definitions

- (3) Adverse air quality impacts – revise to read "means air emissions of any of the air contaminants listed below in quantities that present an unacceptable public health or environmental risk:"
- (4) Adverse ecological impacts – this definition lacks clarity regarding the threshold at which the stated adverse impacts occur. The definition should be revised so that those thresholds are clearly identified.
- (6) Adverse public health impacts – We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.[4,5] We maintain that the regulations, as proposed, include many elements that are not authorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. As such, the Safer Consumer Product regulations should not reference Chapter 54.
- (8) Adverse soil quality impacts – revise to read "means emissions to soil of contaminants in quantities that present an unacceptable public health or environmental risk."
- (9) Adverse waste and end-of-life impacts – the definition is unclear. No adverse impacts are identified. The definition should be revised to indicate what adverse waste and end-of-life impacts are covered by the definition.
- (10) "Adverse water quality impacts" – it should be clear that any of the "increases" cited in the definition should be of a magnitude that result in an unacceptably high increase in risk to public health or the environment. With respect to subsections (A) "Increase in biological oxygen demand" and (B) "Increase in chemical oxygen demand," they are effectively measures of biodegradability and the oxidizeable (carbon) content of a chemical; these are generally not characterized as adverse impacts. Likewise, in subsection (D), "total dissolved solids" is simply a description of physical state of a material within water. These three subsections should be eliminated or a threshold at which the increase is adverse should be defined.
- (17) Bioaccumulation – Recently, the Society of Environmental Toxicology and Chemistry (SETAC) conducted a Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of

[4] http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf
[5] http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf

bioaccumulation science.[6,7] Much of this science was discussed at the May 2010 OEHHA workshop in Berkeley, California on *Indicators of Ecotoxicity Hazards and Exposure Potential*. The SETAC workshop developed the following definition for a bioaccumulative substance: "A substance is considered bioaccumulative if it biomagnifies in food chains." Standard criteria for reporting the extent to which a chemical may bioaccumulate were noted including trophic magnification factor (TMF), biomagnification factor (BMF, both laboratory and field), bioaccumulation factor (BAF), bioconcentration factor (BCF), octanol-water partition coefficient (K_{OW}) and octanol-air partition coefficient (K_{OA}). The workgroup concluded that the most relevant bioaccumulation criterion is the trophic magnification factor (TMF; also referred to as a "food-web magnification factor"); in the absence of data on the TMF, the BMF (either derived in the laboratory or based on field data) is a reliable indicator. They also concluded that "[t]he BCF is no longer recognized to be a good descriptor of the biomagnification capacity of chemical substances" and "that the K_{OW} is a highly useful chemical specific descriptor of the bioaccumulation potential of chemicals in fish and many other water breathing aquatic organisms." The SCP regulations should use a similar definition of bioaccumulation and accommodate these five criteria (TMF, BMF, BAF, K_{OW}, and K_{OA}) as appropriate means of measuring bioaccumulation potential. In addition, the regulations should establish thresholds for what constitutes a bioaccumulative chemical using each of the criteria consistent with the scientific consensus of the Pellston workshop (TMF > 1, BMF >1, BAF > 5,000, Log K_{OW} > 4, Log K_{OA} > 5) and in a tiered order of preference (TMF > BMF > BAF > K_{OW} or K_{OA}).

- (19)(A)2. Chemical ingredient – revise to read "means a chemical <u>intentionally used</u> in a consumer product <u>to impart a particular function in the product</u>." This definition should be made consistent with other state or Federal statutes or regulations whereby ingredients are recognized as functional components of a product intentionally added to impart a function. For example, the FDA's cosmetics regulations provide the following definition for an ingredient: "The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product" [21 CFR 700.3(e)].

- (20) Chemical of concern – The definition should be based on the Departmental listing, not on lists developed by other authoritative and non-authoritative bodies. Revise to read "means a chemical <u>ingredient</u> ~~identified as a Chemical of Concern under section 69502.2(a), or a chemical~~ listed by the Department under section 69502.3(b)." In the spirit of the statute (AB 1879), Chemicals of Concern should be limited to those ingredients intentionally added to a consumer product by a manufacturer in order to impart a function in the product. Moreover, by focusing the scope of the regulations, the stated intent of the Department to encourage

[6] Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.
[7] http://www.setac.org/sites/default/files/ExecutiveSummary.pdf

manufacturers to consider the necessity of ingredients in their products will be better effectuated.

- (29) Environmental or toxicological endpoints – We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.[8,9] We have noted the serious flaws in the process used by OEHHA; its unwillingness to consider comments from their peer-reviewers and the public at large, including numerous subject matter experts; and the flawed science at the heart of the regulation. We urge DTSC to reject this definition and the entire OEHHA regulation, and to develop scientifically sound definitions of environmental and toxicological endpoints.

- (32) Hazard trait – Hazards are, in the context of chemicals, inherent properties that have the potential to lead to adverse effects in humans or wildlife under particular conditions and levels of exposure. In the context of the present regulation, they are toxicities. The definition should be amended accordingly and reference to chapter 54 eliminated.

- (43) Persistence – Reference to section 69405.3 should be eliminated and the definition should read as follows: "means the propensity for an organic chemical substance to exist in an environmental medium (e.g., water, soil, sediment, air) in an unchanged form. The thresholds for a substance to be designated as a persistent substance are as follows: a half-life of greater than 60 days in water (marine or freshwater), greater than 180 days in soil or sediment, or greater than 2 days in air."

- (52) Reliable information – the proposed definition lacks any description or characteristics of what constitutes reliable information or studies. Publication of a report or study, whether in a peer-reviewed journal or otherwise, is no guarantee that the underlying data and information are appropriate for regulatory decisions. While the information sources cited in the definition may be appropriate to consider in a weight-of-evidence decision-making scheme, an entirely separate process is necessary to ensure that the information used is in fact a well conducted study. We support definitions of "reliable information" and "a well conducted study" consistent with the approach used by the Organization of Economic Cooperation and Development (OECD) in their Manual for Investigation of HPV Chemicals. As such, we suggest: *"Reliable information" is from studies or data generated according to valid and accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ("QSAR") approaches may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD)*

[8] http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf
[9] http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf

in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, December 2009) shall be used for the determination of reliable studies.

The definition of "authoritative organization" should include the Organization for Economic Cooperation and Development, and its member countries.

- (53) Reliable information demonstrating the occurrence of exposures to a chemical – Subsection (C), which includes chemical properties and does not inform whether exposure has occurred and should be eliminated. For subsection (D), modeling results may be important for exposure assessments but exposures estimated from models should be confirmed with collected monitoring data; as such, subsection (D) should be eliminated.
- (54) Responsible entity – The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the Federal Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (CARB, CPSC, etc.). All consumer commodities that are legally distributed in U.S. commerce must comply with the Federal Trade Commission labeling requirements, so identification of the responsible entity is simple. As such, subsections (B) and (C) should be eliminated.
- (56) Safer alternative – revise to read "means <u>a functionally acceptable</u> alternative that, …"

Section 69501.2 – Duty to Comply and Consequences of Non-Compliance

- In Section 69501.2(a), the requirements for compliance should be limited to the manufacturer of the product. As such, references to the importer or retailer should be eliminated.

Section 69501.3 – Information Submission and Retention Requirements

- The certification statement would create a new crime, and DTSC does not have that authority. It is sufficient that an officer of the company responsible for the information submission sign the documents.

Section 69501.4 – Chemical and Product Information

- Under subsection (a)(4), the Department would give itself unlimited authority to require a manufacturer or importer to generate and obtain information with no accountability. There should be boundaries regarding the kind of information that the Department may seek, and due process for those for whom the Department is making the request.

Section 69501.5 – Availability of Information on the Department's Website

- The Department should use official state regulatory dissemination methods (e.g., California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the Safer Consumer Product regulations.

- The Department proposes to require itself to post non-critical information on its websites. These provisions should be eliminated from the regulations as requirements, but the Department might optionally post them electronically as resources are available for such lower priority tasks. As such, the following subsections under Section 69501.5(a) should be eliminated: (4), (5) and (8). The following subsections under Section 69501.5(b) should be eliminated: (4), (5), (6), and (8).

Article 2. Chemicals of Concern Identification Process

The mechanisms for identifying Chemicals of Concern, namely, an initial listing, a Departmental listing process, and a petition process are good components to this section.

Section 69502.2 – Chemicals of Concern Identification

- Section 69502.2(a): Initial Chemicals of Concern List – The process contemplated for initial listing of chemicals has some good core elements, namely the identification of severe hazard traits and the use of existing authoritative listings to rapidly identify chemicals which have those severe hazard traits. However, we recommend additional criteria and screening parameters which will make the listing process more credible and transparent.
    - We recommend that the initial listing focus on known carcinogens and reproductive and developmental toxicants. In addition, the list should focus on persistent, bioaccumulative and toxic (PBT) substances using criteria consistent with the US EPA's definition of PBT substances.
    - A number of the proposed lists are not good sources and should not be used:
        - The Category 1 endocrine disruptors list (1)(C) has been disavowed by EU authorities. Endocrine disruptors will be captured by those chemicals identified as developmental or reproductive toxicants.
        - The Washington State PBT list (1)(N) did not use criteria consistent with the US EPA PBT list (1)(K).
        - The OSPAR list (2)(H) is not an authoritative list.
    - Using the other lists identified in the proposed regulation as potential sources to identify Chemicals of Concern, the Department should further screen the chemicals included to only those permitted in commerce in the United States, those chemicals that are in commerce in California large volumes, and those chemicals that are known to be used in consumer products. By using such screens, the Department will be left with a manageable and meaningful list of Chemicals of Concern.
- Section 69502.2(b): Additions to the Chemicals of Concern List – the narrative standard for identifying additions to the Chemicals of Concern list is not sufficiently transparent. The Department needs to provide additional clarity to this process so that it is objective and

repeatable if conducted by different sources. There is no indication what sorts of thresholds for the factors would be used in selecting additional Chemicals of Concern.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

Section 69503.2 – Priority Product Prioritization Factors

- While the principles embodied in this section are appropriate, the application of them is unclear. The decisions by the Department are likely to appear to be arbitrary if they are not *in fact* arbitrary. The Department should clarify how the prioritization of priority products will occur so that decisions are transparent before they are made.

Section 69503.5 – Alternative Analysis Threshold Exemption

- The Alternative Analysis Threshold Exemption process should be eliminated in favor of a self-assessment process. OEHHA uses a self-assessment process under the Proposition 65 Safe Harbor provisions for companies to determine whether they have to label a product. This aspect of Prop 65 has been very successful and may be a model for the application of the *de minimis* provisions of the Safer Consumer Product regulations.

Article 5. Alternatives Assessments (AA)

Section 69505 – Guidance Materials

- Under subsection (a), it is critical that substantive guidance documents be prepared and disseminated prior to Priority Products subject to the Alternatives Assessment process being identified. This provision should be retained.

Section 69505.1 – Alternatives Assessments: General Provisions

- Subsection (h) would require the responsible entity to consider all relevant information made available on the Department's website. The Department's website is quiet extensive and the Department intends to add numerous new elements under this program. This would be an enormous quantity of information for any entity to review. Since the Department will be best suited to know what materials on its website are appropriate for a particular Alternatives Assessment, they should specify them. Subsection (h) should be eliminated and the Department should instruct the AA preparer as to what information it believes is important for the preparer to consider in its assessment. Such guidance also will have the advantage of fostering consistency among assessments from multiple manufacturers for the same Chemical of Concern in a particular consumer product.

Section 69505.4 – Alternatives Assessment: Second Stage

- For Section 69505.4(a)(2)(A), the multimedia life cycle impacts and chemical hazards assessment should be limited to the chemical(s) of concern in the priority product that are the subject of the alternatives assessment, and not all ingredients in the product. Replace "chemical ingredients" with "Chemicals of Concern."

- Section 69505.4(a)(2)(C) – Economic Impacts should be eliminated as this will be well beyond the expertise of most responsible entities and any consultants they may hire to help prepare the AA report. Further the information is not relevant to the selection of an alternative and represents an undue burden to the responsible entity. The information may be relevant to the Department with respect to a regulatory response however the Department should find a more appropriate means of generating this data.
- Section 69505.4(c) – Step 3, Alternative Selection Decision should be eliminated. It is inappropriate and impractical for responsible entities to be incorporating their business plans in an AA report.

Section 69505.5 – Alternatives Assessment Reports

- In Section 69505.5(a)(4), the Department would require the responsible entity to include sufficient information in the Final AA Report for the Department to determine the appropriate regulatory response. The responsible entity cannot know what information is sufficient for the Department to make a decision. This requirement is unnecessary and inconsistent with the statute and should be eliminated from the regulations.
- Section 69505.5(d)(3) would require the name and contact information of all persons to whom the manufacturer or importer directly sold the Priority Product in California to be submitted to the agency. There are a number of large direct selling companies who do business in California and who have tens of thousands of independent business operators to whom they sell their products for further sale to consumers. For the state to require the name and contact information of potentially tens of thousands of private citizens to be submitted to the agency is both impractical and unnecessary. This provision should be removed from the regulations.
- Section 69505.5(e) should be revised to read "A description and location of the facilities <u>in California</u> where the Priority Product is produced." The state cannot extend its authority beyond its borders.
- Section 69505.5(i)(2) appears to be an attempt to identify data gaps that might exist. The Department should clarify that this is the intent of this provision.
- Section 69505.5(j) would require the Final AA Report to identify and describe the alternative that is selected. This requirement is unnecessary for the effectuation of the regulations including the Regulatory Response from the Department. These kinds of business decisions are very sensitive and may be very fluid for a company. Moreover, the Department lacks the authority to "approve" whether a particular product is permitted to be on the market. The Department's authority is specific to requiring an alternatives analysis to be conducted and for the Department to make a Regulatory Response with respect to that analysis. The Department does not have the authority to pick winners and losers in the market place and to

dictate what products a company may or may not produce. This section and its associated subsections should be stricken from the regulation.

- Section 69505.5(j)(2)(C) would require a list of all chemical ingredients known to be in the selected alternative that differ from the ingredients in the Priority Product or that are present at a higher concentration in the selected alternative to be submitted to the agency, as well as all available chemical identification and hazard information for those chemicals. This information is completely irrelevant to the alternatives assessment or the regulatory response. It is completely unnecessary. This section should be eliminated from the regulations.

Article 6. Regulatory Responses

Section 69506 – Regulatory Response Selection Principles

- This section conflicts with the statutory provision in section 25253. There, the Legislature has established the standard 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 posed by a chemical of concern." Limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection. This section should be revised to more clearly reflect the intent of the statute.

Section 69506.2 – AA Report Supplementary Information Requirements

- This section would give the Department unlimited authority to obtain information from the responsible entity. The statute does not give the Department such unlimited authority. This section should be clarified to specify the boundaries of the Department's authority.

Section 69506.3 – No Regulatory Response Required

- This section provides that no regulatory response is required if the Department determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts. Perhaps the Department believes that referring to preventing or limiting public health and environmental impacts is an adequate standard, but the truth of the matter is that it is little more than a tautology. That is, no regulatory response is required if the Department determines that no regulatory response is required. The Department should articulate the standards by which a determination is made that no regulatory response is required.

Section 69506.5 – Product Information for Consumers

- The Consumer Product Safety Commission (CPSC) has regulations specific to the labeling of product information on packages. CPSC requires identification on the label of those chemicals that are responsible for a hazard warning appearing on a label. They see this as critical to the consumer having access to essential, focused information that they can provide

over the phone to medical personnel in the case of an accidental exposure. Likewise, Poison Control Centers share a similar concern regarding product labeling. The Department should reconsider whether it is wise (and consistent with Federal regulations) to require product labeling (Section 69506.3(b)(2)(A)) that distracts from important safety warnings. Furthermore, the regulations should permit the dissemination of this information through electronic (website) or telephonic means.

Section 69506.5 – Use Restrictions on Chemical(s) of Concern and Consumer Products

- This section imposes restrictions on the use of one or more chemicals of concern and a selected alternative or in a priority product for which no alternative is selected or on the use of the product itself. The section spells out what the use restrictions may be, but it contains no standards as to when these restrictions may be imposed. The section simply says, "The Department may impose restrictions." Again, the Department has conferred unfettered and arbitrary discretion on itself. The standards by which such restrictions would be made by the Department should be clearly articulated.

Section 69506.6 – Product Sales Prohibition

- Subsection (a) of this section provides that the section does not apply to a product that does not contain any chemical of concern above the applicable alternatives analysis threshold. Subsection (b) provides "except as provided in section 69506.3" a sale prohibition may be imposed if a selected alternative contains one or more chemicals of concern or if no alternative is selected for a priority product and "there is a safer alternative that does not contain a chemical of concern and that is both functionally acceptable and technically and economically feasible."

  Perhaps a sales prohibition is appropriate in the circumstances set out in subsection (b). However, note that subsection (d) provides that the Department may issue a notification prohibiting the sale of a product "notwithstanding that there are no current identified safer alternatives that are both functionally acceptable and technically and economically feasible." Subsection (d) contains no standards as to when the Department would issue a notification prohibiting the sale.

  It should be noted that subsection (d) supersedes subsection (b) by allowing the Department to prohibit the sale whenever it chooses. Again, the absence of any standard enables the Department to impose unfettered and potentially arbitrary discretion.

Section 69506.7 – Engineered Safety Measures or Administrative Controls

- This section allows the Department to impose requirements that control access to or limit exposure to chemicals of concerns, to reduce the likelihood of adverse public health and/or environmental impacts. Subsection (b) sets out three circumstances when engineering or administrative controls may be imposed by the Department. However, they are themselves

inadequate. Engineering or administrative controls should be implemented to reduce real human health or environmental risks. This section should be revised to more fully consider the level of analysis necessary to make such determinations.

Section 69506.9 – Advancement of Green Chemistry and Green Engineering

- This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals. No standards are set out as to when the Department would do that. Again, the Department has conferred on itself unfettered and potentially arbitrary discretion. Appropriate standards indicating when such a research program would be required should be articulated in the regulation.

Section 69506.10 – Regulatory Response Selection and Reevaluation

- Subdivision (a) of this section provides that the Department may impose one or more regulatory responses specified in the preceding sections to situations other than those specified in those sections. As noted before, many of those sections do not contain specified situations. But here, the Department has conferred complete discretion on itself to impose any regulatory response under any set of circumstances that it may choose.

Section 69506.11 – Exemption from Regulatory Response Requirements

- This section is ostensibly designed to implement the provision in section 25257.1 of the statute. Subdivision (b) of the statutory section provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides that, "The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

  Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response "substantially duplicates" one or more requirements of another California or federal regulatory program, "without conferring additional public health or environmental protection benefits."

  Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department, providing the article does not authorize the Department to supersede, duplicate, or adopt conflicting regulations. The Legislature has imposed responsibility on the Department to implement that provision. It does not contemplate imposing the burden on responsible entities.

The Department exceeds its authority in subsection (a)(6)(B). The statute does not authorize the Department to duplicate other regulatory programs if the Department is conferring greater public health or environmental protection.

Finally, the Department has ignored the fact that section 25257.1(b) of the statute prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, supersedes the other agency's regulatory program. The Department is specifically prohibited by section 25257.1 from doing that. As such, the Department should acknowledge in the regulations that it is prohibited from superseding the regulatory authority of any other department or agency.

Section 69506.12 – Regulatory Response Report and Notifications

- This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. Section 25253(b) of the statute provides that the regulations adopted pursuant to this section shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. The notification to the retailers is not designated as a regulatory response. Rather, it is applied to a responsible entity after a regulatory response is imposed on that entity. Nothing in the statute authorizes the Department to impose such a reporting requirement. It exceeds the scope of the authority to specify the range of regulatory responses and should therefore be removed.

Article 7. Dispute Resolution Process

Section 69507.1 – Informal Dispute Resolution Procedures

- It should be the option of the party bringing forward the dispute whether they choose to follow the formal or informal dispute resolution process, and all Departmental decisions should be permitted to follow the formal dispute resolution process. However, the processes should be sequential with the option of an informal review occurring before a formal review.
- Failure to select a particular dispute resolution option should not preclude other administrative or non-administrative review of a Departmental decision (e.g., judicial review) that may be available.

Article 8. Accreditation Bodies and Certified Assessors

- The entirety of Article 8 is unnecessary to the efficient implementation of the statute and should be eliminated. The Department will be working closely with responsible entities preparing Alternatives Assessments, and given the authority of the Department to restrict or prohibit the use of a chemical of concern in a consumer product, the responsible entities will be highly motivated to comply with the regulations.

Article 9. Audits

- This article while describing the scope of coverage lacks clarity in its purpose and consequences. Of particular note is subparagraph (b)(3) – Implementation of the selected alternative. This implies that the Department will be auditing the business decisions of a company and making sure that they make the "right" choice. There is no evidence to suggest that DTSC is qualified in the least to design, manufacture or market products, or that it should be selecting which products are appropriate to be on the market. The Department should amend the regulations to clearly indicate the standards against which the audited documents are being compared. Further, subparagraph (b)(3) should be eliminated as it is unnecessary for the effectuation of the statute and unauthorized.

Article 10. Trade Secret Protection

Section 69510 – Assertion of a Claim of Trade Secret Protection

- Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes.

  Subsection (a) requires somebody making a claim for trade secret protection to provide specific information. Here, they are set out as subsection (6), the estimated value of the information to the person and the person's competitors; (7) the estimated amount of effort and/or money expended by the person in developing the information; and (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering.

  In addition, subsection (10) requires a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed.

  Further, subsection (11) requires the signature of the general counsel or other executive, certifying under penalty of perjury that there is a basis for asserting a trade secret protection.

  Subsections (a)(6), (a)(7), (a)(8), (a)(10) and (a)(11) should be eliminated

- Subsection (f) states that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trade submission or any chemical identity information associated with a hazard trade submission. This exceeds the scope of the statutory authority precluding protection for hazard trade submission but not chemical identity and is in conflict with the California Uniform Trade Secret Act and the Uniform Trade Secrets Act. It should be eliminated.

- Subdivision (g) provides that trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the claim is for a

proposed alternative to a chemical of concern in a priority product subject to certain requirements. Those requirements include demonstrating to the Department's satisfaction the chemical is a new chemical or a new use of an existing chemical, provide the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing chemical of concern of the priority product, and comply with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret in conflict with the California Uniform Trade Secret Act and the Uniform Trade Secrets Act. It should be eliminated.