November 1, 2010

California Department of Toxic Substances Control
Office of Legislation and Regulatory Policy
Jeff Woled, MS 22A
P.O. Box 806
Sacramento, CA 95812
(*via e-mail: gcregs@dtsc.ca.gov*)

Re: Proposed Safer Consumer Product Alternatives Regulations

Dear Mr. Woled:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the proposed regulations for *Safer Consumer Product Alternatives* released on September 14, 2010 by the California Department of Toxic Substances Control (DTSC or the Department) for the implementation of AB 1879.

ACI is the trade association representing the $30 billion U.S. cleaning products market. 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. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate. We hope by sharing our insights from these experiences we can enhance the Department's implementation of AB 1879 and SB 509.

The Department has been given the Herculean task of implementing AB 1879 and SB 509 in a very political and contentious environment. We commend the Department on its very open approach and the work ethic which with it has approached the job at hand. However, we are deeply disappointed with the turn the proposed regulations have taken since the pre-regulatory draft regulations were released on June 23, 2010, especially in light of comments on the draft regulations provided by ourselves and other industry stakeholders including the Green Chemistry

Alliance (see attachments). Unfortunately, the Department has elected to take a very bureaucratic and adversarial approach with the proposed regulations, one which challenges the economic vitality of the State's industry at a time when jobs and economic well-being are a high priority. We believe the proposed Safer Consumer Product Alternatives regulations require significant revision and the Department should work in a cooperative fashion with all stakeholders to focus on development of effective and efficient regulations before issuing a final rule. We believe we have consistently advocated for substantive and workable regulations to implement AB 1879 and SB 509, working with a broad coalition of industry stakeholders, including the Green Chemistry Alliance. For your consideration, we have included a complete set of draft regulations prepared by the Green Chemistry Alliance and submitted to DTSC in June 2009 and ACI's comments to the Department's October 2009 "Straw II" proposals (see attachments).

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

Scope of Regulations

With these proposed regulations, the Department has grossly exceeded both the letter and the spirit of the authorizing statute. What is a pretty simple law has been turned into an attempt by the Department to control the entire economy of California. We note that in Section 69301.6, the Department proposes to give itself the authority to take any information it believes to effectuate the regulations from any person (responsible entity) it deems to have offered for sale any product in the state, whether as a big box retailer or an ordinary citizen on Craigslist. Moreover, the Department may compel the generation of data or testing with virtually no restriction.

In Section 69305.1, the Department would require any manufacturer using a chemical of concern (of which there are likely to be thousands) in any consumer product (of which there are likely to be tens of thousands) to comply with burdensome reporting requirements before placing a redesigned product on the market. First, this is completely counter to the stated purpose of the Safer Consumer Product Alternatives regulations, namely to bring safer products to the market sooner. Second, the purpose of these requirements seems to be solely to educate the Department regarding product design; the Department's conceptual flow chart shows this as a dead-end. The Initial Statement of Reasons states that "The AA Notification is necessary so that DTSC can keep an eye out for any regrettable substitutions…." So, the Department has put itself in the position of being the gatekeeper of new products coming on the market in California. This is unnecessary, unauthorized and unworkable.

Solutions: We believe the Department can adequately implement the regulations with publicly available data by using existing information and conservative assumptions to assess re-designed products and use that assessment to determine the need to obtain some or all of the information listed in this section. If an interested party has access to information that they believe would help inform the analysis, they can volunteer it. Section 69301.6 should be modified to reflect those changes. We note that similar exercises have been completed by national and state governments with fewer resources than California.

We believe the Department has erred significantly by re-defining Chemical of Concerns as including Chemicals Under Consideration and Priority Chemicals. This pre-judges those Chemicals Under Consideration as being problematic when the whole idea of the statute is to identify those use specific chemicals of concern in consumer products. The Department should return to a process whereby a Chemical of Concern is selected from those Chemicals Under Consideration, then Chemicals of Concern are prioritized based on their use in consumer products for alternatives assessment.

Section 69305.1 should be amended so, at most, it is a voluntary submission process, and DTSC should provide incentives for participation so that safer products are brought to the market quickly. If the Department needs to develop its capacity in the arena of product development, it should find a more effective (and authorized) approach. Also, the scope of these provisions should be limited to Priority Chemicals in Priority Products.

Chemical Prioritization Process

We believe the Chemical Prioritization Process specified in Article 2 of the regulations is seriously flawed. More to the point, the "process" lacks clarity because there is no process specified. Section 69302.2 is a laundry list of dozens of "prioritization factors" that are supposed to be used by the Department to populate the list of Chemicals Under Consideration. Again, there is no process here, just an identification of anything knowable about a chemical. We note that this section appears to mirror very closely the *Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints* released on August 11, 2010 by the California Office of Environmental Health Hazard Assessment (OEHHA) for the implementation of SB 509. We provided comments to OEHHA on September 13, 2010 and we attach them to this letter so that you may consider them in the context of these regulations (see attachment).

Solution: The identification of Chemicals Under Consideration could be accomplished efficiently and in a manner that minimizes the possibility for "false negatives". We expect it would be based on human health and environmental hazard traits, and chemical characteristics that might lead to greater exposure (e.g., persistence, biomagnification up the food chain, long range transport). We agree that carcinogens, reproductive toxicants and PBT (persistent, bioaccumulative and toxic) chemicals should be the first considered. The key feature missing from the proposed regulations are the thresholds, or process for establishing thresholds for the prioritization factors (criteria) that will be used for listing chemicals. DTSC needs to go back to the drawing board and correct these deficiencies.

Onerous Reporting Requirements and Needless Bureaucracy

There are numerous examples where excessive reporting requirements are specified by the regulations that are unclear, unnecessary and unauthorized:

- Options for Responsible Entities to be exempt from various requirements (§69301.4(e))
- The names of the parties that will be involved in funding, directing, overseeing, preparing or reviewing the Tier II AA (§69305.4(a)(1)(C))
- Contact information for all responsible entities for the product and any other person in the supply chain (§69305.4(a)(3)(C) and (D), and other places)
- Identification of any other Chemicals of Concern that are, or reasonably should be known to be in the Priority Product (§69305.6(b)(5)(C) and other places)

- A list of all chemical ingredients contained in the selected alternative and hazard trait information for any of those chemicals for which hazard trait information has not already been provided to the Department (§69305.8(f)(3))
- Chemical/Product Removal Intent/Confirmation Notifications
- *De minimis* exemption request (§69305.3)

The list above is by no means exhaustive. There are many other cases where data, information or confirmation are required by the Department but are extraneous, duplicative or excessive.

Solutions: The Department needs to seriously reexamine how it would implement the statute. It should eliminate extraneous data and information submission requirements. It should provide a clear pathway for safer products to be introduced in California; there is no need for the state to be notified of such changes. It should eliminate obstacles, or at a minimum streamline the way, for companies that wish to reformulate their products with lesser or no Chemicals of Concern.

With regard to *de minimis* exemptions, the Department should use a 0.1% threshold, or when necessary establish an intake-based *de minimis* threshold for priority chemicals and make those values known. It should then be up to the manufacturer to determine whether exposure to their product would result in consumers exceeding the threshold. This is similar to the Safe Harbor process for Prop. 65 chemicals. It would be far more efficient and effective.

Disincentives and other impediments to the Development of Safer Consumer Products
The proposed regulations provide many disincentives or impediments to safer consumer product being brought to market in California. As mentioned above, the Tier I AA notification process in Section 69305.1 discourages companies from reformulating products containing a Chemical of Concern until it is identified by the state as a Priority Product containing Priority Chemicals.

Similarly, Chemical/Product Removal Intent/Confirmation Notifications are a disincentive to removing a product containing a Chemical of Concern from the market. The bureaucratic burden provides more incentive to wait for the state to force a product off the market rather than replacing it with a safer product. These unnecessary processes should be eliminated

The accreditation and qualification requirements for the performance of alternatives assessments described in Article 8 could delay or restrict the development of alternatives assessments as there will be a steep learning curve and slow development of the required expertise. Furthermore, the requirements for a lack of affiliation or economic interest with any responsible entity, manufacturer, consortium of manufacturers, retailer or trade associations effectively outlaws public-private partnerships from collaborating to help develop the needed capacity to perform alternatives assessments.

Solutions: The Department should not have any pre-market requirements for a replacement product that reduces or eliminates chemicals of concern in a consumer product as this will slow their introduction to the market. It will be important for the Department to become educated as to the possible consequences of listing Priority Chemicals to prevent regrettable substitutions, but we believe formulators and manufacturers are better suited to make those assessments and the benefits of new products are likely to outweigh the potential for a regrettable substitution.

The Department needs to streamline the accreditation and qualification processes, if not eliminate them entirely. The work product (alternative assessment) will be the ultimate measure of the capabilities of an organization, and many companies already have sophisticated product development programs that will only be hindered by the Department's proposal.

Nanotechnology

The Department needs to harmonize its definitions and understanding of nanomaterials and nanotechnology with other regulatory efforts and standard setting organizations across the globe. Furthermore, it is unwarranted, unscientific, excessive and arbitrary to single out nanotechnology as a particularly dangerous technology that should be avoided or restricted. The identification and prioritization process should be allowed to run its course. Similarly, the prohibition for *de minimis* exemption of materials engineered at the nanoscale [§69303.2(d)(3)] is arbitrary, unsubstantiated, and excessive; this prohibition should be eliminated.

Confidential Information

The Department's vision of a new generation of consumer products that will be safer and reduce consumer exposure to, and environmental release of chemicals of concern will be built upon highly creative innovations and significant investments in research and development, and testing. For the Safer Consumer Product Alternatives regulations to be successful the state will have to foster an environment in which those innovations and investments are protected.

Trade secrets, as intellectual property, are among a business's most valuable assets; as valuable as hard assets such as manufacturing equipment and facilities. Moreover, trade secrets provide enormous societal and environmental benefits. Without trade secret protection, the incentive to innovate, to develop better products and even safer products, would be greatly diminished. If, for example, competitors could gain access to new formulations and new products as soon as they are developed, businesses could not justify expending millions and even billions of dollars in researching and developing better products. These expenditures can be justified by the expectation that new formulas and new products, will result in increased sales, providing a return on the research and development investment.

For the expectations of the Green Chemistry Initiative to be met, innovation has to be incentivized, and research and development has to be rewarded in the marketplace. That can occur only if manufacturers' trade secrets are protected. The survivability of manufacturers doing business in California and the success of green chemistry depends on protecting trade secrets to the full extent of the law.

Article 10 Should be Struck in Its Entirety

Article 10 is fundamentally unnecessary; it is generally duplicative of the statutes that it is intended to implement, interpret, or make specific. Where the regulations do not duplicate the underlying statutes, they are either inconsistent with the statutes or they expand the scope of the statute. Article 10 fails to meet the statutory standards set out in Government Code sections 11342.1, 11342.2, and 11349.1.

Article 10 Is Not Necessary

The principle statute that Article 10 is intended to implement, interpret, or make specific is Health and Safety Code section 25257, the portion of AB 1879 dealing specifically with trade secrets. That section sets out a detailed process for claiming protection for a trade secret, for supporting the claim, and for DTSC determining whether the trade secret is to be protected. That section provides:

- A person submitting information may, at the time of submission, identify information as a trade secret. Subdivision (a).
- That person shall support the claim upon the written request of the Department. Subdivision (a).
- The information claimed to be a trade secret is not to be released to the public unless a request for its release is made, the department provides at least 30 days' notice of the request to the person submitting the information, the department determines that the information is not a trade secret and the submitter has not filed a lawsuit challenging the decision within 30 days after the department notifies the submitter of its decision. Subdivisions (a) and (d).
- Information pertaining to hazard traits for chemicals cannot be protected. Subdivision (f).

Civil Code section 3426.1(d) defines a trade secret as information that derives economic value, actual or potential, from not being generally known and that is the subject of reasonable efforts to maintain its secrecy.

When Article 10 is shorn of its invalid excesses, it does no more than provide that support for a trade secret claim should satisfy the components of the statutory definition of a trade secret, and to do so pursuant to the process set out in AB 1879. As such, Article 10 is unnecessary. Further, the Initial Statement of Reasons prepared by DTSC provides no basis for concluding that Article 10 is necessary. The ISOR principally describes the regulatory provisions, stating that the provisions are necessary to make it easier for DTSC to process claims for trade secret protection and to handle requests for disclosure with greater efficiency.

As noted at the outset of the comments pertaining to Article 10, it is either unnecessary or it is invalid because it is inconsistent and expands the scope of the underlying statute. Health and Safety Code section 25257 provides for the protection of trade secret information, it sets out an adequate process from submission of trade secret to a determination whether the claim is substantiated to judicial review. Certainly, DTSC should not impose processes and burdens that are inconsistent with the specific language of section 25257. Nor should it expand the plain meaning of the provisions of section 25257, the statutory definition of a trade secret, and the provisions of the Public Records Act.

Accordingly, Article 10 should be stricken in its entirety. Even if a piecemeal review is made, no significant portion of the article avoids running afoul of the statutory standards by which regulations are to be judged, and as such it should be rejected in its entirety.

Summary

The American Cleaning Institute and its member companies have been proponents of California's Green Chemistry Initiative since its outset nearly four years ago. We have attended dozens of meetings, both public and private, with DTSC and OEHHA, often traveling across the

country to attend. We have invested countless hours seeking to provide reasonable and actionable advice to the agencies for design and implementation of workable programs including our participation with the Green Chemistry Alliance to prepare a complete regulatory draft for the implementation of AB 1879 in June 2009. We have marshaled our best technical resources from across the country, investing them into the regulatory system in California. We have made these investments because the goals and objectives of the Green Chemistry Initiative are basic functions our companies practice every day in their businesses, and we believe, as industry leaders, they are best practices that should be modeled economy-wide.

Sadly, the proposed *Safer Consumer Product Alternatives* regulations will accomplish none of the goals of the Initiative and will actually hinder their attainment. The Department has proposed regulations that are bureaucratic in the extreme, resource intensive for California government and the regulated community, punitive and adversarial. It is unfortunate that DTSC has taken such a dim view of the regulated community, and the current state of products available to consumers in California. This attitude is misplaced and inconsistent with the current quality of life of most Californians. We believe AB 1879 and SB 509 will be best implemented if industry is leveraged as a partner in the process, and the leaders are used to drive continual improvement of products and to diminish the human health and environmental footprint.

We believe the *Safer Consumer Product Alternatives* regulations require substantial revision and abbreviation. We point, once again, to comment documents and regulatory language provided in our attachments. We believe any revised regulations should be subject to another public release, a substantive comment period (60 day minimum) and public hearing.

ACI would like to express, once again, its appreciation in being able to comment on the proposed Safer Consumer Product Alternatives regulations. We would be happy to further assist DTSC in your development of regulations implementing AB 1879 and SB 509 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

Enclosures:

ATTACHMENT 1: Editorial Comments from the American Cleaning Institute for the Proposed California Safer Consumer Product Alternatives Regulations

ATTACHMENT 2: July 15, 2010 Comments from the American Cleaning Institute on the June 23, 2010 DTSC Draft Regulations for Safer Consumer Products

ATTACHMENT 3:July 2, 2010 Comments from the Green Chemistry Alliance on the June 23, 2010 DTSC Draft Regulations for Safer Consumer Products

ATTACHMENT 4: November 9, 2009 Comments from the Soap and Detergent Association (now the American Cleaning Institute) on the DTSC Straw Proposal for Safer Alternatives Regulations released on October 1, 2009

ATTACHMENT 5: June 24, 2009 Comprehensive Proposal for the Implementation of AB 1879 from the Green Chemistry Alliance

ATTACHMENT 6: September 13, 2010 comments from the American Cleaning Institute on Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints from the California Office of Environmental Health Hazard Assessment (OEHHA) released on August 11, 2010

cc: The Honorable Linda Adams, Secretary, CalEPA (LAdams@calepa.ca.gov)
Cindy Tuck, Undersecretary, CalEPA (ctuck@calepa.ca.gov)
Patty Zwarts, Deputy Secretary, CalEPA (pattyz@calepa.ca.gov)
John Moffatt, Legislative Affairs, Office of the Governor (john.moffatt@gov.ca.gov)
Maziar Movassaghi, Acting Director, DTSC (mmovassa@dtsc.ca.gov)
Scott Reid, Cabinet Secretary, Office of the Governor (scott.reid@gov.ca.gov)
Jeff Wong, Chief Scientist, DTSC (jwong@dtsc.ca.gov)
Odette Madriago, Chief Deputy, DTSC (omadriag@dtsc.ca.gov)
Hank Dempsey, Special Advisor, DTSC (HDempsey@dtsc.ca.gov)

ATTACHMENT 1
Editorial Comments from the American Cleaning Institute
for the Proposed California Safer Consumer Product Alternatives Regulations

Article 1. General
§ 69301.2. Definitions

Many of the definitions provided are unnecessary and unique to the particular program while conflicting with definitions recognized by other state programs, the Federal government or international programs. The Department should only create a new definition where an existing one doesn't exist, and existing, widely accepted definitions should be used wherever possible.

(11) Chemical ingredient – revise to read "…means a chemical intentionally added to a consumer product or component." **Rationale:** Ingredients are intentionally added to product with the purpose of imparting specific functions. The definition should reflect the purposeful nature of their formulation. There will be other chemicals present that are not added intentionally, and they should be characterized as such.

(14) Chemical of Concern – Delete "either the Chemicals Under Consideration List or". **Rationale:** Chemicals under Consideration should not be considered Chemicals of Concern.

(15) Chemical Removal Confirmation Notification – remove "Chemical under Consideration" where it occurs in the definition. **Rationale:** The Department should not be requiring action on chemicals while it is still deliberating over the status of the chemical. Action should not be taken or required until a finding has been made by the Department.

(16) Chemical Removal Intent Notification – remove "Chemical under Consideration" where it occurs in the definition. **Rationale:** The Department should not be requiring action on chemicals while it is still deliberating over the status of the chemical. Action should not be taken or required until a finding has been made by the Department.

(18) Chemical Under Consideration – replace "listed" with "being evaluated". **Rationale:** The Department in evaluating Chemicals Under Consideration should not be developing a list that is permanent.

(24) De minimis level – revise (A)(2) to read "The intake equivalent to the lowest federal or California State public health…" and add "(C) For the lowest federal or California State public health or environmental regulatory threshold, the Department will identify the threshold that applies and the equivalent intake level." **Rationale:** The regulatory thresholds cited in Subsection (B) are all risk-based levels. The Maximum Contaminant Levels (MCLs) for drinking water are based on ingestion of several liters of water each day over a lifetime. The product specific *de minimus* level should consider relevant routes of exposure and the level of exposure based on intended use of a product in determining the threshold concentration for a particular product.

(41) Intentionally-added chemical or chemical ingredient – this definition should be eliminated and the substance incorporated into the definition of Chemical Ingredient as described above. **Rationale:** Ingredients are intentionally added to product with the purpose of imparting

specific functions. There will be other chemicals present that are not added intentionally, and they should be characterized as such.

(59) Product Removal Confirmation Notification – remove "Chemical under Consideration" where it occurs in the definition. **Rationale:** The Department should not be requiring action on chemicals while it is still deliberating over the status of the chemical. Action should not be taken or required until a finding has been made by the Department.

(60) Product Removal Intent Notification – remove "Chemical under Consideration" where it occurs in the definition. **Rationale:** The Department should not be requiring action on chemicals while it is still deliberating over the status of the chemical. Action should not be taken or required until a finding has been made by the Department.

(61) Product Stewardship – insert "users" into first sentence to read "…means the shared responsibility of product producers, manufacturers, responsible entities and users, for end-of-life management." **Rationale:** Users have a responsibility in the product stewardship continuum to see that they use and dispose of products properly.

(67) Responsible entity – strike paragraphs (B) through (E). **Rationale**: The only relevant responsible party for that should be identified is the manufacturer of the product 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 US commerce must comply with the Federal Trade Commission labeling requirements.

§ 69301.4. Duty to Comply and Consequences of Non-Compliance

(a)(1) – add "in their possession" to the first sentence so it reads "…a responsible entity for a product that is the subject of the request shall make the information in their possession available to the Department by the date requested." **Rationale:** A requirement for a responsible entity to collect information that is not in their possession is unduly burdensome.

(e)(1)(A) – eliminate the second half of the paragraph "notifies the Department of this action no later than thirty (30) days after the original or extended due date for the applicable requirement, and provides any additional related information subsequently requested by the Department within the time specified." **Rationale:** The burdens placed on the responsible entity by the Department to satisfy these provisions are extremely onerous. In many cases, the responsible entity will be a small business, perhaps an individual, and compliance with these provisions could be devastating. The language found in (e)(2) is much more reasonable: "…if the responsible entity provides documentation to the Department demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California by any person."

(e)(1)(B) – eliminate; **Rationale:** see Rationale for (e)(1)(A).

(e)(2) – add "at the Department's request" so the sentence reads "…if, at the Department's request, the responsible entity provides documentation to the Department demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California by any person." **Rationale:** By making it easier for manufacturers to remove Priority Products from the market with fewer burdens, they will be removed sooner.

(f)(1)(A) – replace "all responsible entities" with "the non-compliant entity". **Rationale:** It will be extremely burdensome and wasteful for the Department to provide so many notifications. Broader notification might be appropriate if there is an imminent safety threat, but generally such notification will only provide confusion in the supply chain. It is sufficient that the non-compliant entity is notified, and the notification is placed on the Department's website. In addition, while there is a provision in paragraph (f)(4) to remove a product from the Failure to Comply List, there is no provision for the Department to notify "all responsible entities" that the conditions of non-compliance have been rectified.

§ 69301.5. Information Submission and Retention Requirements

(a) – strike "data and information shall be submitted in English". **Rationale:** Many chemical and product manufacturers are global companies. Data may be generated in non-English speaking countries or published in non-English journals. A complete translation of a study or research article could be very expensive. A simple English language summary should be sufficient.

(b) – eliminate from the certification statement the sentence "I also certify that in carrying out the duties above, life cycle thinking and green chemistry principles were considered." **Rationale:** Life cycle analysis and green chemistry principles are still very new for many businesses. Until capacity is sufficiently built up throughout the supply chain, many companies will not be able to certify to this statement. This puts the company officer in a "Catch-22" situation whereby they can't submit a false certification, but they also are not sufficiently familiar with green chemistry and life cycle analysis to certify truthfully.

(c) – insert "for which the Department has notified the person of those requirements" so the sentence reads "Any information or documentation required to be obtained or prepared for which the Department has notified the person of those requirements, but that is not required to be submitted to the Department or has not yet been requested to be submitted to the Department,…" **Rationale:** Persons should be on notice that they are required to retain records in order to comply with the regulations or they might be unwittingly destroyed or disposed of.

§ 69301.6. Chemical and Product Information

(b)(3) – eliminate "and require" and insert "in their possession" so the paragraph reads "Request a responsible entity to make available to the Department to review and/or obtain existing data and other information in their possession that is needed by the Department…" **Rationale:** The requirement for a responsible entity to obtain data not in their possession is unreasonable and unduly burdensome.

(b)(4) – eliminate "and require" so the paragraph reads "Request a responsible entity to generate and make available to the Department…" **Rationale:** Testing or other data generation will likely be very costly and such requirements should not be put upon a responsible entity in the absence of a significant public health threat.

(c)(1)(D) – eliminate subparagraphs 2., 3., and 4. **Rationale:** Such detailed market data is beyond the scope of the regulations and beyond the needs of the Department to carry out its mandate.

(d)(3) – remove the second two sentences of this provision: "If the manufacturer does not make the requested information available to the Department by the date specified by the

Department, the Department shall include the request, and a notice that the manufacturer has not made the requested information available to the Department, along with information identifying the manufacturer and the chemical and/or product that are the subject of the request, on a Failure to Respond List posted on its website. The Department shall remove this information from its website upon determining that the manufacturer or another person has fulfilled the request for data or other information." **Rationale:** In many cases, the manufacturer will be located outside of California, and the action of the Department is simple "blacklisting." Such behavior only encourages companies to further relocate outside of the state.

Add a paragraph (g) which reads "In complying with paragraph (b) of this section, the Department will treat as confidential according to the statute and other relevant state and federal laws, data and information which is appropriately designated as such. The Department shall not publicly release data and information for which there is value to the owner of such data and information without appropriate compensation of the owner; summaries of such data may be released with the consent of the owner" or words to that effect. **Rationale:** The Department needs to provide protections for data and information which is confidential and/or intellectual property if it wishes companies to make it available for the purposes of this program.

Article 2. Chemical Prioritization Process

§ 69302.2. Chemical Lists

Add a paragraph (a)(3) which reads "Prior to issuing the list of Chemicals Under Consideration or the list of Priority Chemicals, the Department shall publish the threshold(s) for the factors specified in section 69302.3 and 69302.4, respectively, which will be used to list chemicals" or words to that effect. **Rationale:** The lists of prioritizing factors do not divulge the process by which the Department will select Chemicals Under Consideration or Priority Chemicals. This is a critical feature of the regulations and it should stand the test of scientific peer review.

§ 69302.3. Chemicals Under Consideration

(b)(2) – delete "Bioaccumulation in humans"; bioaccumulation is not an adverse public health impact.

(b)(20) – delete "Persistence"; it is not an adverse public health impact.

(b)(24) – delete "Toxicokinetics"; it is not an adverse public health impact.

(g)(1) – insert "…in concentrations or volumes that present a public health threat" so that the paragraph reads "California Environmental Contaminant Biomonitoring Program data, or other biomonitoring data meeting the definition of reliable information, that show the chemical to be present in human bodily tissues or fluids in concentrations or volumes that present public health threat." **Rationale:** Mere presence of a chemical in biological tissue is not relevant, but the concentrations should be such that they indicate a possible public health threat.

(g)(2) – insert "…in concentrations or volumes that present a public health threat" so that the paragraph reads "Data that meets the definition of reliable information and that show the

chemical to be present in household dust, indoor air, drinking water, or elsewhere in the indoor household environment in concentrations or volumes that present a public health threat." **Rationale:** The capabilities of analytical chemistry are such that any chemical can be detected anywhere. It is important to clarify that chemicals present in sufficient concentrations are what may be important.

(g)(2) – insert "…in concentrations or volumes that present an environmental threat" so that the paragraph reads "Monitoring data that meet the definition of reliable information, or that have been produced or reviewed and accepted by a California State or local agency for compliance and regulatory purposes, and that show the chemical to be present in the environment, including aquatic, avian or terrestrial organisms in concentrations or volumes that present an environmental threat." **Rationale:** The capabilities of analytical chemistry are such that any chemical can be detected anywhere. It is important to clarify that chemicals present in sufficient concentrations are what may be important.

(g)(7) – delete "or short term in vitro bioassays". **Rationale:** Short term in vitro bioassays are not really relevant to chemical exposure.

§ 69302.5. Products Containing a Priority Chemical

(b)(2) – incorporate (b)(3) into (b)(2) so it reads "Information made available by a responsible entity or the manufacturer of the product including product labeling information or a product information sheet." **Rationale:** Section (b)(3) is redundant, and by specifying "product labeling" there is a much broader set of information that is available for consideration.

Article 3. Product Prioritization Process

§ 69303.2. Product Lists

(d)(2)(B) – insert "and the particular product concentration represents a significant portion of the aggregate exposure" at the end of the paragraph. **Rationale:** While the aggregate exposure to a chemical may still be a concern, the Department should not concern itself with trivial exposures and should focus on the greatest contributing components to the aggregate exposure.

(d)(3) – delete this provision. **Rationale:** It represents an arbitrary conclusion that there is no safe concentration level for a nanoscale material in a product.

(e) – insert "above the de minimis threshold" in the paragraph so it reads "if the product does not contain above the de minimis threshold any known or detectable amount of the Priority Chemical which is the basis for that product type being placed on the product lists." **Rationale:** The regulations should reflect the fact that the de minimis threshold still applies, even for a priority product.

Article 4. Petition for Inclusion of a Chemical or Product in the Prioritization Process

§ 69304. Applicability and Petition Contents

Add paragraph (d) which states "For petitions determined to be complete, the Department will provide notice to the public of the completeness and nature of the petition, and will allow additional reliable information to be submitted to inform the Department during the technical

review period of the petition" or words to that effect. **Rationale:** A petition may be complete for the purposes of the regulation, but may not contain all of the data or information pertinent to the Chemical and Product Prioritization Processes.

Article 5. Alternatives Assessments

§ 69305.1. Alternatives Assessment Notifications and Tier I AA Reports

Remove "Chemical under Consideration" from paragraphs (a), (a)(4), (a)(5)(C). **Rationale:** This provision is completely unworkable as the list of Chemicals Under Consideration is likely to include thousands of chemicals which means tens of thousands of products would be subject to the reporting requirements. This places an unnecessary burden on manufacturers of products, the majority of which are not Priority Products and are completely safe for human health and the environment. Moreover, this provision provides disincentive for manufacturers to reformulate, redesign or remove products containing a Chemical Under Consideration from the market. It will be simpler to leave the product on the market until it is listed as a Priority Product.

§ 69305.2. Tier II Alternatives Assessment: General Provisions

(c)(3)(A)5. – delete this provision. **Rationale:** Given the nature of today's retirement systems (i.e., primarily 401(k) stocks and mutual funds) and investment holdings, and the breadth of the economy that will be covered by the scope of "any entity that manufactures, or places into the stream of commerce in California, any Chemical of Concern, Product under Consideration, or Priority Product", it will be difficult if not possible for individuals to comply and to know whether they are in compliance.

§ 69305.3. De Minimis Exemption

(a) – revise this paragraph to read "A responsible entity shall be exempt from the requirements of this article for any particular product, if that product does not contain a Priority Chemical above the de minimis threshold established by the Department."

Delete subparagraphs (a)(2), (a)(5) and (a)(7).

Rationale: This provision as proposed contains needless bureaucracy that provides no value to product producers or the citizens of the state.

(b) – Replace "a de minimis exemption may not be considered for the product" with "there is no de minimis threshold for the Priority Chemical." **Rationale:** Makes the provision consistent with revised paragraph (a).

Delete paragraphs (c) and (d). **Rationale:** The paragraph is not relevant if the approval process is eliminated.

(e) – Revise to read as paragraph (c): "If the Department revises the de minimis threshold for a Priority Chemical, products shall be exempt from the requirements of this article pertaining to Tier II AAs based on the revised threshold" or words to that effect.

Delete paragraphs (f) and (g). **Rationale:** The paragraph is not relevant if the approval process is eliminated.

§ 69305.4. Tier II Alternatives Assessment Work Plan

Delete paragraphs (a)(1)(C) and (D). **Rationale:** This information is irrelevant and speculative, and not valuable to the preparation of the work plan.

§ 69305.6. Tier II Alternatives Assessment Report

(b)(1)(C) – delete this paragraph . **Rationale:** This information is not relevant to the report or the results of the report.

(b)(5)(C) – delete this "and any other Chemical of Concern(s) that are, or reasonably should be known to be in the Priority Product." **Rationale:** This is vague and difficult to achieve and enforce.

(b)(6)(C) and (D) – delete these paragraphs here and elsewhere in the regulation. **Rationale:** This information is extraneous to the report and unduly burdensome for the preparer of the report.

(b)(9)(B) – delete this paragraph. **Rationale:** The contractual agreement between preparer and lead assessor is extraneous to the substance of the report, unduly burdensome and invasive to the privacy of the two parties.

§ 69305.8. Tier II-B Alternatives Assessment Reports

(f)(3) – delete this paragraph. **Rationale:** This provision is excessive and punitive. The responsibility should be solely with regard to a replacement chemical(s).

Article 6. Regulatory Responses

§ 69306.1. AA Report Supplemental Information Requirements

(a) – this paragraph should be eliminated or heavily edited. **Rationale:** There are no bounds to what the Department may ask for and no limit to the time period covered.

§ 69306.2. No Regulatory Response Required

(c) – delete the second half of the paragraph and revise to read: "The Priority Product, which was the subject of the Tier II AA is no longer placed into the stream of commerce in California by the manufacturer."

§ 69306.4. End-of-Life Management

(a)(2)(D) – delete "The manufacturer or responsible entity of the product shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product." **Rationale:** The Department does not have the authority to require such financial guarantee mechanisms.

§ 69306.5. Product Sales Prohibition

(b) – delete "and the responsible entity or the manufacturer shall ensure that an inventory recall program for the product or component is implemented and completed within two (2) years after the notification is issued by the Department." **Rationale:** This provision is excessive; discontinuation of the sale of the product should be sufficient. Further, to recall and dispose of products with existing useful life may be a waste of resources and have its own negative consequences. This is particularly unreasonable when it's recognized that products in the

marketplace comply with existing risk management regulations and are deemed safe, absent any unforeseen unreasonable risks posed by a product that are discovered in the course of new assessments.

§ 69306.6. Other Regulatory Responses

(a) – delete this paragraph. **Rationale:** it is without bounds and lacks clarity.

§ 69306.9. Regulatory Response Report and Notifications

(a) and (b) – delete these paragraphs. **Rationale:** This requirement is outside of the scope of the regulations and unnecessary.

(d)(1)(B) – delete this paragraph. **Rationale:** This provision and others requiring identification of all persons in the supply chain is unnecessary and excessive. The supply chain extends all the way to every cashier and stock boy at every retail establishment where a product has been offered for sale.

Article 8. Accreditation and Qualification Requirements for Performance of Alternatives Assessments

§ 69308. Requirements for Qualified Third-Party Assessment Entities.

(a)(4) – These provisions are very severe and will disqualify virtually all potential certifiers. In particular we note that this provision would prohibit public-private partnerships in the development of third-party assessments.

Article 10. Confidentiality of Information

Article 10 Should be Struck in Its Entirety

Article 10 is fundamentally unnecessary; it is generally duplicative of the statutes that it is intended to implement, interpret, or make specific.

§ 69310. Confidentiality of Information

This section solely provides that DTSC shall comply with the existing laws pertaining to nondisclosure of confidential information, and that it will use existing laws to determine what is confidential information. DTSC is obligated to follow existing law; it has no authority to ignore that law. While it is reassuring to know that DTSC will follow existing law, it is not necessary to state it.

§ 69310.1. Assertion of a Claim of Confidential Information

In this section, DTSC begins by following the dictates of existing law, requiring a person who wishes to claim information as confidential information to identify the portion of the information that is subject to the trade secret claim. That, of course, is set out explicitly in Health and Safety Code section 25257. Accordingly, that portion of this section is unnecessary.

Section 69310.1 goes beyond requiring the submitter to identify the portion of the information that is a trade secret and requires it to specify the statutory authority constituting the basis for

the trade secret claim, to provide a claims index as required in section 69310.2, and to provide supporting information required by section 69310.4. The latter section sets out 12 specific requirements for supporting a claim that certain information is a trade secret.

This requirement in section 69310.1 to provide substantial justification for a claim at the time of submission is inconsistent with the express provision of Health and Safety Code section 25257. That section, as noted above, does not require a person making a trade secret claim to provide support for the claim until DTSC has made a written request.

In addition, section 69310.1 provides that a person who makes a trade secret claim shall, at the time of submission, provide the department with a redacted copy of the document being submitted in which the trade secret information is excluded. Nothing in Health and Safety Code section 25257, the Public Records Act, the Civil Code defining a trade secret, or any other provision of law, requires a person submitting information to provide a redacted copy that can be made available in full to the public. This portion of section 69310.1 expands the scope of the underlying statutes and, as such, is invalid.

§ 69310.2. Marking and Indexing of Documents

(a) – this section again requires a person who submits information, claiming that some portion of the information is trade secret, shall assert that claim at the time of submission. As noted above, this is already required by Health and Safety Code section 25257; it simply duplicates it, and as such, it is unnecessary.

(b) – this section requires that a person who asserts a claim of confidential information shall provide at the time of submission a separate claims index summarizing the kind of confidential information for which the claim is made, the factual or legal basis for the claim, and the place in the submitted document where the confidential information was originally located. This subdivision of section 69310.2 also provides that the claims index shall be made available in full to the public.

As noted above, with respect to the requirement in the preceding section that a redacted copy of the submitted information be provided at the time of submission, no provision in any existing law authorizes DTSC to require a person submitting information to include a claims index. As such, this portion of section 69310.2 is inconsistent and expands the scope of the underlying law.

The California Public records Act provides that "Any reasonably segregable portion of a record shall be available for inspection by any person requesting the record after deletion of the portions that are exempted by law." Government Code section 6253(a). Hence, it is recognized that if trade secret information can be segregated from a document, that the balance of the document will be provided to the public upon request made consistently with the provisions of the Public Records Act. If the segregation is handled properly, the portion made available to the public should not diminish the protection afforded to the trade secret information. While someone obtaining information released in this form might speculate about the type of information released or even its context, the goal of segregation should be to provide no clues that would diminish the protection.

Despite the explicit provisions of Government Code section 6253, requiring segregation to assure full protection of the trade secret information, section 69310.2 undermines the purpose and specific language of the Public Records Act. It does so by requiring the person

submitting the information to describe the type of information that has been excluded and to indicate the specific location in the document where the information was originally located.

A description of the information, together with the specific context of that information, provides insights, particularly to competitors, that threaten the protection of the trade secret information. As a consequence, this provision of section 69310.2 not only violates the purpose of the Public Records Act, but it is bad public policy. It threatens to cause substantial harm to companies who are motivated to develop new formulations and new products. It threatens substantial harm to society and the environment by diminishing the incentive for companies to innovate. It threatens substantial harm to the purposes and goals of the Green Chemistry Initiative, and as a consequence, it is inconsistent with the purposes of AB 1879.

§ 69310.4. Support of a Claim of Trade Secret Protection

This section requires a person who asserts a trade secret claim to support that claim within ten days of a request for support and to meet 12 requirements to support the claim. A portion of this section is ambiguous, lacking clarity; a portion is unrealistic and contrary to specific provisions in Health and Safety Code section 25257, and significant portions are unnecessary and inconsistent with the statutory definition of a trade secret.

(a) – this section provides that a person asserting a trade secret claim "and receives a request from the department to support trade secret claims shall, at the time of submission, or within ten (10) days of receipt of a request for support, provide substantiating information." The lack of clarity arises from the inclusion of the phrase "at the time of submission." The introductory part of the section refers to the receipt of a request from the department to support the trade secret claim. Hence, the two choices of providing information at the time of submission or within ten days of receipt of a request creates uncertainty as to what is intended. It would appear that it is impossible to submit the substantiating information at the time of submission of the trade secret information if the person asserting the trade secret claim has already received a request from the department. This needs to be rewritten to make clear what the department has in mind.

DTSC has set out substantial information that it requires to support a trade secret claim. While much of that information is challenged in the following comments, the requirement that substantiating information be provided within ten days is infeasible. Under virtually any scenario, it would take more time than ten days for a company having received a request for support, to route it to the appropriate staff, to gather information from several departments within the business to address the substantiation requirements, and to obtain legal review to enable either the general counsel or an executive to certify as required in paragraph 12 of subdivision (a).

Moreover, it is unnecessary to impose such a limited amount of time on a person making a trade secret claim. Two circumstances exist where substantiating information needs to be provided. The first is where the department makes a request for the information prior to having received a request for release of the information. In that circumstance, the department is under no time pressure to obtain supporting information, and it can afford the person asserting a trade secret claim more time to comply with the request.

The second circumstance in which the department may request support for a trade secret claim is after a request has been made pursuant to the Public Records Act for the release of information. Health and Safety Code section 25257 provides that the department shall make a decision within 60 days after receiving a request for the release of information, having provided 30 days to the person submitting the information to provide substantiation for the claim. Hence, under the most stringent set of circumstances, in which the statute imposes a time limit, the person submitting the claim shall have at least 30 days to respond.

The requirement that supporting information be provided within ten days should be substantially revised. It is infeasible; it is unnecessary; it is inconsistent with the specific provision of the underlying law.

The first two paragraphs under subdivision (a) requiring the identity of a person making a claim in a description of the information for which a trade secret protection is claimed are basic to any response for supporting information. As such, it is unnecessary to provide that.

(a)(3) – requires the period of time for which trade secret protection is claimed and the justification for that period. Nothing in section 25257, the Public Records Act, or the definition of trade secret hint at a trade secret having a limited life. Trade secrets, unlike patents and copyrights, are to be protected indefinitely. They are to be protected for as long as they meet the statutory definition of a trade secret. They are to be protected for as long as they provide economic value and reasonable steps are made to maintain their secrecy. This paragraph exceeds the scope of the underlying law and, as a consequence, is invalid.

This paragraph is also unnecessary. Nothing in the regulation addresses how DTSC is to handle a trade secret claim as a result of any response made to the requirement of para. 3. It is simply a requirement for information that has no purpose and is, therefore, unnecessary.

(a)(4), (5) and (6) – these relate to the extent to which information is known by employees involved with the business and to those outside the business, whether such individuals are bound by nondisclosure agreements, and the measures taken to restrict access to the information and to safeguard it. While these requirements relate to the portion of the trade secret definition "subject of the efforts that are reasonable under the circumstances to maintain its secrecy," they add nothing toward implementing, interpreting, or making specific the statutory definition of a trade secret. The requirements set out in these three paragraphs may or may not be relevant to the reasonable steps taken to maintain the secrecy of all trade secrets. They add nothing beyond what is required within the definition of a trade secret and they serve only to create confusion in circumstances where they are not relevant.

(a)(9) – DTSC asserts, is also related to the reasonableness of the efforts to maintain secrecy. It requires information about the relative ease or difficulty with which the information could be properly acquired or duplicated by others. In fact, it has nothing to do with the reasonableness of the efforts to maintain secrecy. Nor is it inherent within the statutory definition of a trade secret. Accordingly, it is irrelevant to the determination whether information is a trade secret or not and, as such, it is unnecessary.

Also, as noted above, this provision has no relationship to the definition of a trade secret. In fact, the implementation of this provision could be inconsistent with the definition of a trade secret. For example, the definition of a trade secret states that the information derives independent economic value from not being **generally** known to the public. Information can

still be a trade secret even if it has been acquired or duplicated by limited other entities. The test is whether it still derives economic value and not whether it is known by anyone else.

Because paragraph 9 is ambiguous, unnecessary, and inconsistent with the definition of a trade secret, it should be stricken.

Moreover, the implication of paragraph 9 raises confusion and, as such, lacks clarity. The implication of this requirement is that DTSC, in making a decision whether to substantiate a trade secret claim, may exercise discretion and deny a claim if in its judgment someone, such as a competitor, might be able to acquire or duplicate the information. That introduces substantial uncertainty into the decision process.

(a)(7), (8), and (11) – call for the estimated value of the trade secret information, the estimated amount of effort or money expended in developing the information, and a description and nature of the extent of harm that would be caused if the information were released. These requirements are included, according to the Initial Statement of Reasons, to determine whether information has independent economic value. Once again, these requirements are ambiguous, creating a lack of clarity, and are unnecessary and inconsistent with the statutory definition of a trade secret.

By requiring the estimated value of the information and the amount of effort or money expended in developing the information, the regulation raises the inference that DTSC will apply a sliding scale in deciding whether information is a trade secret or not. If the information has great value and was derived after expending substantial sums of money in conducting research, then the information is more likely to be a trade secret. On the other hand, if the value of the information is relatively small, then it may not be determined to be a trade secret. Similarly, if the information was developed in an "Eureka!" moment, for example, with little expenditure, then again the department may determine that it is not a trade secret. Nothing is set out in the regulations describing how the department would make decisions about trade secret claims having different economic value and having different costs to obtain it. Accordingly, these requirements lack clarity.

In addition, the fact that the department provides no process for making decisions about trade secret claims means that the information required by paragraphs 7 and 8 are unnecessary. The statutory definition of a trade secret is, does the information derive economic value. If yes, it has satisfied that prong for being a trade secret. It is not necessary to know how much value. In fact, that, in and of itself, is probably trade secret information and the problem is simply compounded by asking for trade secret information to justify trade secret information. Certainly nothing in the statutory definition of a trade secret references the cost in developing the information. Hence, it adds nothing to determining whether information is a trade secret or not. As such, it is also unnecessary.

Much of what has been said with respect to paragraphs 7 and 8 is also applicable to paragraph 11. That paragraph, as noted above, requires a description of the nature and extent of harm that would be caused if the trade secret information was made public.

Again, the department creates ambiguity and uncertainty by including this as a required component of substantiating information. Resulting harm from unlawful misappropriation is not an element of the statutory definition of a trade secret. Yet, requiring this information implies that the department would consider that in making its decision to support a trade

secret claim or not. Although the department has not explained how it would use this information, the implication is that it is a relevant factor. If harm is great, is the information more likely to be a trade secret than if the harm is relatively slight? The ambiguity and uncertainty renders this provision invalid for lacking clarity.

Further, paragraph 11, as noted, is irrelevant to the statutory definition of a trade secret. Lacking any relevancy for deciding whether information is a trade secret or not, this requirement is unnecessary.

Finally, since nothing in the definition of a trade secret refers to the harm caused by a misappropriation of information, this requirement is inconsistent with that statutory definition. As such, it is invalid.

§ 69310.5. Departmental Review of Trade Secret Claims

This section describes the process that DTSC intends to follow in determining whether a trade secret claim is substantiated or not in two different circumstances. The first circumstance is prior to any request for the release of the information having been made and the department initiates on its own such a determination. The second circumstance is following a request for release of the information and the process that DTSC will follow in making a determination in response to that request.

(a) – this section essentially provides that DTSC, after asking a person to support a trade secret claim, will determine whether that claim is substantiated or not. If not, it will provide notice to the person submitting the information and will not release the information to the public for 30 days or for any time extended by order of a court. Subdivision (a) is inconsistent with Health and Safety Code section 25257. The statute provides that information shall be released to the public only in accordance with subdivision (d) of that section. Subdivision (d) sets out the process that the department is to follow after receiving a request for the release of information. In other words, no information claimed as a trade secret is to be made public until first there is a request for the release of that information. Hence, DTSC cannot, as it proposes to do in subdivision (a), release information claimed as a trade secret solely because it decides that the claim has not be adequately substantiated.

In addition, subdivision (a) of section 69310.5 provides that DTSC will not release information claimed as a trade secret for 30 days after notifying the person submitting the information or to such time as extended by an order of the court. In other words, DTSC is providing in this regulatory provision that it will release information after 30 days unless the person submitting the information has not only filed a lawsuit, but obtained an order from the court enjoining DTSC from releasing it. In contrast, subdivision (d) of section 25257 provides that the department may not release the information if, within the 30 days, the person submitting the information files a lawsuit for declaratory judgment or preliminary injunction. Section 25257 does not require the entry of an order preventing the department from releasing the information.

Subdivision (a) of section 69310.5 is inconsistent with the section that it is intended to implement, interpret, or make specific, Health and Safety Code section 25257, in two significant aspects. As a consequence, it is invalid and should be stricken.

(b) – this subdivision deals with the circumstance when the department receives a Public Records Act request for the release of trade secret information. The provisions set out in subdivision

(b) simply reiterate the process set out in Health and Safety Code section 25257 and the Public Records Act. It adds nothing toward implementing, interpreting, or making specific either of those existing statutory provisions. As such, subdivision (b) of this section is unnecessary and should be stricken.

§ 69310.6. Hazard Trait Submissions

This section seeks to implement, interpret, or make specific subdivision (f) of Health and Safety Code section 25257. That subdivision provides that trade secret protection shall not be afforded the submission of information pertaining to the hazard traits of chemicals. To the extent section 69310.6 duplicates subdivision (f), it is unnecessary. To the extent that it expands on the definition of hazard trait submissions, it is inconsistent with subdivision (f) and is, therefore, invalid.

As noted above, subdivision (f) of section 25257 provides that hazardous trait information for chemicals is not subject to trade secret protection. Subdivision (a) of section 69310.6 provides that "hazard trait submissions" is synonymous with "hazardous trait submissions." That subdivision is not made necessary by the fact that the statute uses the phrase hazardous trait submissions and DTSC chooses in the regulation to use hazard trait submissions. No one would be confused by dropping the adjectival form of hazard.

(b) – DTSC provides that "hazard trait submission" means information submitted to the department pertaining to a hazard trait of any chemical or chemical ingredient. While not a precise verbatim iteration of subdivision (f) of section 25257, its meaning is identical. No purpose is served by reiterating the statutory language. It does not further the implementation or interpretation of the statute. As such, it is unnecessary and should be stricken from the regulations.

(b) – after stating that a hazard trait submission is information on hazard traits submitted to the department, an obvious tautology, the regulation provides that the term hazard trait submission also includes the identification of the manufacturer of a product containing a chemical of concern or a chosen alternative. That term also includes information that a particular chemical of concern or an alternative is present in a product.

The regulatory language itself demonstrates that DTSC is expanding the plain meaning of the hazard trait submission. Under no circumstance can hazard trait submission be construed to mean the name of a manufacturer of a product containing a chemical of concern or the name of a product in which a chemical of concern is present. Whether that information is to be made available elsewhere, and regardless of whether it is entitled to trade secret protection, it is inappropriate to expand the scope of the term "hazard trait submission" in this regulation.

DTSC's expansion of the term hazard trait submission to include information that is plainly not hazard trait information opens the door to an unlimited definition of "hazard trait submission." Unless that term is limited to its plain meaning, DTSC has the discretion to add components to that definition to essentially blot out any trade secret protection. The place to draw the line is at the plain meaning of the term hazard trait submission. No expansion should be permitted.

DTSC's attempt in this regulation to expand the definition of the term hazard trait submission renders the regulation inconsistent with subdivision (f) of section 25257. As such, that portion of subdivision (b) of section 69310.6 is invalid and should be stricken.

Article 11. Small Businesses

§ 69311. Applicability.

(a) – the definition of small business should be larger than that specified. We propose fifty (50) or fewer employees, and average annual gross receipts of five million dollars ($5,000,000).

ATTACHMENT 2

July 15, 2010 Comments from the American Cleaning Institute

on the June 23, 2010 DTSC Draft Regulations for Safer Consumer Products

July 15, 2010

Maziar Movassaghi
c/o Heather Jones, MS 22A
California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
P.O Box 806
Sacramento, CA 95812
(via e-mail: GCRegs@dtsc.ca.gov*)*

Re: ACI comments on DTSC Draft Regulations for Safer Consumer Products

Dear Mr. Movassaghi:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Draft Regulation for Safer Consumer Products* released on June 23, 2010 by the California Department of Toxic Substances Control (DTSC or the Department) for the implementation of AB 1879.

ACI is a trade association representing the $30 billion U.S. cleaning products industry. 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. 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. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate. We hope by sharing our insights from these experiences we can enhance the Department's implementation of AB 1879 and SB 509.

We have a number of detailed comments below, but would like to share perspective on some more general considerations in your draft regulations. In particular we note the Department's desire to incorporate complete and high quality data and information into its decision-making. We appreciate this desire and acknowledge the Department's conscientious effort to incorporate sound science in its actions. However, there is a balance between the data and information necessary to make a sound decision, and that data and information that would be nice to have for a finely refined result. In many instances, there is publicly available data with which to make worst-case scenario assessments of chemicals and products. We believe it would be a more efficient use of agency resources and would make for a more rapid implementation of the statute if the Department utilized readily available data and information to make an initial worst-case

analysis of chemicals and products. As the Department makes their decision public, companies with an interest in further refinement of the analysis can provide that data at their disposal to inform the analysis. Similarly, if other stakeholders believe the Department's analysis does not adequately represent reality, there should be opportunity for relevant data and information to be submitted to the Department.

In addition, we are concerned about vague language in the regulations related to various findings and regulatory decisions that the Department is required to make (e.g., "degree of threat posed" (69302.4(a)(1)), definition of "environmental impact" as "any change to the environment, whether adverse or beneficial," and "public health impact" as "effects on the health of the general population or sensitive subpopulations" (69301.2)). We are very concerned that, unless already well defined in California or Federal health or environmental statutes or regulations (or associated case law), the attempts to satisfy these vague standards will lead to controversial and arbitrary outcomes that are likely to be challenged.

Also, we note that there are a number of instances where the manufacturer is required to notify the retailer following a decision or action by the Department (e.g., 69301.5(a)(2)(A), 69305.1(i)(4), 69303.5, 69306.8(a)). In those cases, this notice is duplicative of public notification by the Department and public notification by the manufacturer. Further, the requirement to be notified places a burden on the retailer in having to process such notices without benefit to the manufacturer, retailer or the public. These notifications to the retailer should be eliminated and notices made by the Department should be the definitive source of public notice.

In addition, please find a number of detailed comments below:

Article 1. General

1. 69301(a)(1): Change "made available for use" to "sold or offered for sale" here and elsewhere throughout the text (e.g., 69302(a)); the language in the draft is ambiguous and the change would make the regulation more consistent with other California laws.

2. 69301.2, Definition of "Chemical" subpara. (2): The term "chemical" is generally equivalent to the term "substance." Also, the identification of 'chemical mixture' as a chemical should make clear that what is meant here are distinct chemical substances that are multi-component due to their sourcing from natural raw materials or as a result of standard processing of commodity chemicals, not intentionally engineered and produced mixtures. A suggested revision of the subparagraph follows:

> "(2) A chemical substance, including a multi-component chemical substance mixture, chemical compound, chemical ingredient, or element. Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical"

3. 69301.2, Definition of "Green Chemistry Principles": To the extent that Green Chemistry Principles are cited, they should come from existing sources such as *Green Chemistry: Theory and Practice* (Anastas and Warner, 1998; p. 30). The principles cited in the "Green Chemistry Principles" definition are hybrids developed by DTSC that may not be

beneficial to the environment in some cases (e.g., subpara. (5) – water is a common solvent; to arbitrarily call for its phase-out does not make sense; also, subpara. (7)). Additionally, green engineering principles are valuable for consideration (see Anastas, P.T., and Zimmerman, J.B., Design through the Twelve Principles of Green Engineering, *Env. Sci. and Tech*., 37, 5, 94A-101A, 2003.)

4. 69301.2, Definition of "Hazard trait" (2)(a): The subparagraph should reference Health and Safety Code 25249.8(b) solely as identification of chemicals based on a scientific process. The subparagraph should not reference H&SC 25249.8(a) as these "Labor Code" listings are not scientifically based.

5. 69301.2, Definition of "Intermediate manufacturing process": 'formulating' should be included in subpara. (2)

6. 69301.2, Definition of "Manufacturer": More than one entity may be the manufacturer under the proposed definition. The definition should be clear such that there is only one responsible party as manufacturer.

7. 69301.2, Definition of "Nanoscale": The definition of "Nanoscale" should be 1-100 nm. This would be consistent with what is essentially a harmonized global understanding of what constitutes nanoscale materials and nanotechnology. For example, in the 2007 EPA Nanotechnology White Paper, nanotechnology is defined as research and technology development at the atomic, molecular, or macromolecular levels using a length scale of approximately one to one hundred nanometers in any dimension. The more recent EPA Nanoscale Materials Stewardship Program defines nanoscale materials or nanomaterials as chemical substances organized in structures in the scale of approximately 1 to 100 nanometers, and may have different organizations and properties than the same chemical substances in a larger size. The National Nanotechnology Initiative defines nanotechnology as the ability to understand and control matter at the nanoscale or about 1 to 100 nanometers.

8. 69301.4: Paragraph (a) provides that all three of the entities that constitute the proposed definition of a manufacturer -- the producer, the importer, the private label -- are "jointly and severally responsible" for complying with the provisions of these regulations. The section in subdivisions (b) and (c) go on to make it clear that only one of those entities has to actually comply. Nevertheless, the provision that makes them jointly and severally responsible means that all three of them are obligated to comply with the provisions of the regulations. This raises the specter that bounty hunters could bring Business and Professions Code section 17200 actions against two of the entities if only one of the entities is actually complying. It would be sufficient to simply say the manufacturer has to comply in subdivision (a), and then make it clear in (b) and (c) how that would be implemented in practice. There is no reason, other than to create potential liability, to introduce the concept of joint and several responsibility.

9. 69301.7(a): This provision should be changed to read "The Department may request from the manufacturer of a chemical or a consumer product the following information in its possession:" It does not appear that DTSC has the authority under AB 1879 to compel this information though it is in a company's best interest to comply.

10. 69301.7(a)(5): This is a request for trade secret formulation information which is unnecessary for the implementing regulations of the statute. This provision should be stricken.

The only thing the Department needs to know is whether a COC is intentionally added and whether it is added at a level above de minimus.

11. 69301.7(a)(6): The request for consumer product market data is unnecessary. This provision should be stricken. It may be necessary to know which products contain COCs, but not detailed marketing data which would be proprietary.

12. 69301.7(a)(8): Analytical methods can be highly proprietary. It should be clear that these can be protected as trade secret upon request.

13. 69301.7(b): This subparagraph allows the Department to post a data call-in on its website. The Department should include substantial outreach and notice of its data call-ins so that small businesses which might not normally monitor its actions are fully aware of the request and can remain in compliance.

14. 69301.7(d): This provision should be removed. If a company chooses to reformulate a product so as to remove a CUC or COC, and does not offer the former product for sale, there is no need for the State of California to become involved in that company's business.

Article 2. Chemical Prioritization Process

15. 69302.1(a): "Hazard trait" should be qualified to specify the reference to OEHHA designated hazard traits subject to the SB 509 process, or in the absence of such specification, those listed in 69302.4(c)

16. 69302.3: This section on Chemicals Under Consideration is valuable, however the means by which it is implemented is seriously flawed. There are virtually no 'prioritization factors' specified. DTSC needs to reconsider how each of the factors specified would be used as a criterion for inclusion of a chemical on the CUC list. Additionally, it should be specified how the Department concludes that a chemical is no longer under consideration and is removed from the list. Other comments:

(c)(1) "Projected annual sales based on volume" should be modified to specify a consistent time period for which annual sales volume would be reported rather than a "projected" sales volume in the future.

(d)(2) Bioaccumulation in humans is not a toxicological endpoint; should be removed

(d)(6) Endocrine disruption is not a toxicological endpoint; should be removed

(d)(12) Persistence is not a toxicological endpoint; should be removed

Article 3. Product Prioritization Process

17. 69303(a): The regulations should provide some indication of the level of 'granularity' for the term "product." For example, is a shoe a product? Or is a woman's shoe a product? Or is a pair of Nike Air Max+ 2009 Women's Running Shoes a product?

18. 69303.1(a): This paragraph and other sections of the draft regulations make reference to "consumer products that are, or that contain, a COC (Chemical of Concern)." The designation of a consumer product as a chemical of concern is inconsistent with the statute (AB 1879). The statute is specific to chemicals of concern in consumer products. All references of chemicals of concern <u>as</u> consumer products should be stricken from the regulations.

19. 69303.2(a)(2)2: Nanoscale materials should not be (arbitrarily) excluded from de minimus exemptions. Strike this section.

20. 69303.3(c)(6): Materials used in intermediate manufacturing processes should be exempted as being potential Products Under Consideration.

21. 69303.3(d): This paragraph should be removed. Biomonitoring and environmental monitoring of a chemical are not relevant to the consideration of products.

22. 69303.5: This section requires a manufacturer of a listed priority product to notify its retailers who sell that priority product that the product is a priority product. This places a burden on retailers as well as manufactures with no apparent benefit to either. This section should be removed.

Article 5. Alternatives Assessment

23. 69305.1(c)-(i): These subparagraphs of the section on Exemption Determination and Department Concurrence should be eliminated. The Department should establish exemption criteria that are easily verifiable, and for which there are significant consequences if exemption is erroneously claimed.

24. 69305.3(c)(8): Chemical information for alternatives may not be available at the time of submission of the workplan. Moreover, the workplan should not be the place for such data, but should specify that such data will be compiled and perhaps specify how it will be compiled.

Article 6. Regulatory Reponses

25. 69306.2(a): A non-detectable standard is not feasible in this day and age, especially for many metals which are ubiquitous. There will have to be de minimus standards established for each Chemical of Concern; the 0.1% de minimus default is appropriate.

26. 69306.2(b): This provision requires the Department to make a safety determination which is not feasible. The language "does not present a significant threat to public health or the environment due to" should be removed. Instead, to the extent necessary, it should say that the alternative product contains no more than de minimus levels of any chemical of concern.

27. 69306.3(e)(1): The Department has to make an awful lot of determinations in this paragraph. It is probably not feasible.

28. 69306.3(e)(1)(B): Change "address" to "mitigate"

29. 69306.3(e)(1)(C): Any reference to resource conservation should be specific to California.

30. 69306.4(a): This subparagraph requires the manufacturer of a product which is "required to be managed as a hazardous waste" to establish a take-back program. It would appear that this regulation is inconsistent with the provision in AB 1879 that prohibits duplicative regulation. Under the law today, if a product is to be managed as a hazardous waste, a mechanism for handling that waste is already set out in the law. To require a specific method of handling those products, i.e., a take-back program, duplicates the existing provisions in the law today. This subparagraph should be removed.

31. 69306.5(b): This provision requiring a product recall is unacceptable except in the case where a product is shown to be unsafe. Safety should be the basis for a recall. This provision

should be amended to include language to the effect "When the Department has determined that a Priority Product is unsafe…."

32. 69306.6(a): This subparagraph should specify that the "regulatory responses that the Department determines are necessary" are with respect to a chemical of concern in a consumer product which is a selected alternative consumer product.

Article 10. Confidentiality of Information

33. 69310.1(d)(2): The Department should confirm that an Executive Summary is acceptable as an "edited copy" of the submitted information.

34. 69310.4: Sections 69310.4 and 69310.7 contain criteria for justification and determination of trade secrets that are inconsistent with the trade secret definition in the California Civil Code.

35. 69310.4(a)(3): It may be difficult, if not impossible, for a company to know how long to make a claim of confidentiality. It should be permitted that claims be made for indefinite periods of time. There is only an issue in the case where a request for public disclosure of information claimed trade secret is made, and the justification of a trade secret claim could be evaluated any time such a request is made.

36. 69310.5: This section provides that DTSC may make the determination of the validity of a claim for trade secret even though no one has requested that information. This does not seem like a particularly good use of the Department's limited resources, however, if DTSC does make determinations on the validity of trade secret claims, it should inform the claimant of any negative determinations prior to release of the information and provide an opportunity for submission of an appeal of DTSC's decision.

37. 69310.7(c): Add after "or" on page 60, line 14, the following phrase, "in the absence of an express exemption".

Article 11. Small Businesses

38. 69311: Retailers that are small businesses should be exempted from the regulations as there are a number of burdens placed on retailers as well as manufacturers.

ACI would like to express once again its appreciation in being able to comment on the draft regulations. We would be happy to further assist DTSC in your development of regulations for the implementation of AB 1879 and SB 509 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

ATTACHMENT 3

July 2, 2010 Comments from the Green Chemistry Alliance

on the June 23, 2010 DTSC Draft Regulations for Safer Consumer Products

July 22, 2010

Maziar Movassaghi
Acting Director
Department of Toxic Substances Control
California Environmental Protection Agency
1101 I Street, 25th Floor
Sacramento, CA 95814

Re: Draft Safer Consumer Product Alternatives (June 23, 2010)

Dear Director Movassaghi:

On behalf of the Green Chemistry Alliance (GCA), we respectfully submit the following comments relative to the *Safer Consumer Product Alternatives* draft regulation of June 23, 2010. While GCA and its members appreciate the complexity of drafting the *Safer Consumer Product Alternatives* regulation, we are concerned that the latest draft has increased the number of significant issues yet to be resolved rather than decreased them.

GCA continues to strongly advocate for science-based regulations which will fully and successfully implement AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). We reject recent criticism that the regulations under consideration do too little and take too long. The regulatory process proposed by California's Department of Toxic Substances Control (DTSC) for the management of chemicals in consumer products is the most aggressive in the world. To suggest that these draft regulations propose to do too little and take too long is to ignore the aforementioned complexity of the task at hand. Members of DTSC's Green Ribbon Science Panel cautioned DTSC against trying to do too much too soon, and with good reason. GCA believes there are insufficient human, technical and monetary resources available within the public and private sectors to simultaneously conduct all the studies, evaluations, regulatory actions and prohibitions in the time frame some stakeholders have proposed.

Moreover, GCA is concerned about expanding the scope of the regulations from everyday consumer products on store shelves to intermediate and bulk chemicals in the workplace; increasing public participation and oversight at every step; requiring costly and unnecessary third party certification; and disclosing legitimate confidential business information and trade secrets. Such expansion will only serve to impede progress rather than stimulate it.

The regulated community can only act as quickly as the regulators can put workable systems in place to perform their regulatory functions, *e.g.,* the more complicated the regulation the slower the progress. Calls for greater regulation beyond that which is already proposed will not stimulate product innovation and development of safer alternatives, economic growth, and green job creation in California. More regulation may in fact have quite the opposite effect.

Given the current economic challenges to the state and business community, the Department must be realistic and pragmatic in assigning costly responsibilities that provide little or no benefit. At a time when California needs desperately to kick-start its economy by creating jobs, these draft rules as proposed impose layer upon layer of additional cost on companies, impede innovation and technology transfer, and drive product development out of the state when California can least afford it. This is not the scenario the Governor enunciated during the signing ceremony for AB 1879 and SB 508. Further, and more fundamental, GCA believes a number of provisions in the draft regulation are outside the authority provided to the Department under the provisions of the subject legislation and other federal grants of regulatory authority.

Specific to the scope of the draft regulations, GCA is concerned that they fail to adequately consider exposure and therefore fall short of a hazard and exposure based decision process. Such an approach of not adequately considering and integrating hazard and exposure is contrary to GCA's position, and moves the Governor's Green Chemistry Initiative away from a risk-based process and closer to the application of scientifically unjustified precautionary measures.

GCA also remains highly concerned that more work, particularly on detailed matters, is needed to craft an effective and workable regulation. The regulated community needs clarity in design and consistency in implementation. Without question, these remaining issues are critical for virtually all industry sectors that manufacture or sell consumer products in the state. Without further changes to the draft regulation, GCA is highly concerned that some manufacturers will flee the state and those who remain will be forced to pass the increased regulatory costs on to customers. Among the major issues addressed in our comments are the following:

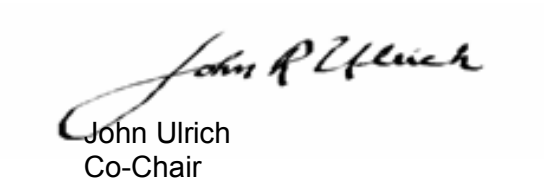
- Absence of clear and workable science-based standards to support priority decisions - language such as, "pose threats" and "adverse impacts to public health and the environment" are not specific enough to be workable;
- *De minimis* as an all or nothing proposition and the expansion of scope beyond intentionally added Ingredients;
- Considerations of regulatory duplication must be more clearly addressed;
- The exposure standard must be "reasonable and foreseeable exposure" in the applicability section;
- The requirement of 3rd Party verification for every Alternatives Assessment is wasteful, costly and unnecessary;
- Legitimate trade secrets are not adequately protected;
- Compression of the timeline for releasing *Chemicals under Consideration* and *Chemicals of Concern*, and *Products under Consideration* and *Priority Products* undermines the stepwise prioritization process;
- Objections to the provision which upon being published as a *Chemical of Concern* the subject chemical and products containing said chemical are subject to regulation and Alternatives Assessment requirements;
- Regulation of "intermediates" in addition to consumer products;
- Definition and obligations of the responsible entity; and

- Numerous issues regarding development of an Alternatives Assessment Work plan, and the actual conduct of the Alternative Assessment.

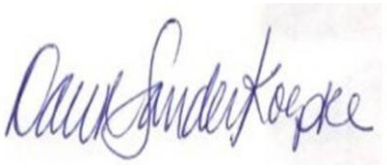
GCA and its members appreciate the work DTSC and other interested stakeholders have invested in this process. And while GCA remains highly concerned about the direction of the draft regulation, we remain committed to working with DTSC and other stakeholders to finalize reasonable and effective regulations that reflect the intent and specific requirements of AB 1879 and SB 509.

GCA respectfully submits the attached comments regarding the draft *Safer Consumer Product Alternatives* (June 23, 2010). For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments please contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. Thank you!

Sincerely,



John Ulrich
Co-Chair
Chemical Industry Council of California



Dawn Sanders Koepke
Co-Chair
McHugh & Associates

CC: The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
John Moffatt, Legislative Affairs, Office of the Governor
Scott Reid, Cabinet Secretary, Office of the Governor
Jeff Wong, Chief Scientist, DTSC
Odette Madriago, Chief Deputy, DTSC
Hank Dempsey, Special Advisor, DTSC

The Green Chemistry Alliance (GCA) has its roots in a group of business trade associations and companies that lobbied effectively during the closing weeks, days and hours of the 2008 California legislative session in support of bi-partisan measures to create a new science based framework for chemicals management. The driving force behind the legislation was a broad based desire for state regulators, rather than the legislators, to exercise their expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting chemicals of concern in consumer products. In the wake of this groundbreaking legislation, the GCA was formalized for the purpose of constructively informing the implementation effort such that the promulgated regulations remain true to the objective and scientific ideals of the authorizing legislation.

In a proactive fashion and in response to the Department of Toxic Substances Control (DTSC) requests for comments, GCA members have invested countless hours over the last year and a half developing regulatory text and comments for implementing the regulation. This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, product stewardship, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy. GCA has strongly advocated for crafting regulations to enable the DTSC to fully and successfully implement AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008), which would in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development.

Green Chemistry Alliance
Signatories

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Cleaning Institute
American Forest & Paper Association
Amway
Association of Home Appliance Manufacturers
Association of International Automobile Manufacturers
BASF
The Boeing Company
California Aerospace Technology Association
California Chamber Commerce
California Grocers Association
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
California New Car Dealers Association
California Paint Council
California Restaurant Association
Can Manufacturers Institute
Chemical Industry Council of California
Chevron
Citizens for Fire Safety Institute
Consumer Healthcare Products Association
Consumer Specialty Products Association
Dart Container Corporation
Defoamer Industry Trade Association
Del Monte
Dow Chemical Company
DuPont
Ecolab
Ellis Paint
ExxonMobil
Fashion Accessories Shippers Assoc
Florida Chemical Company, Inc.
Fragrance Materials Association
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Hyundai-Kia America
Independent Lubricant Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Companies Public Sector
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National Paint & Coatings Association
National Shooting Sports Foundation (NSSF)
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
SABIC Innovative Plastics
Silicones Environmental Health and Safety Council
Solar Turbines
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
TechAmerica
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

# # #

Applicability & Definitions – Article 1

Section 69301. Applicability & Severability

The draft regulations apply to "all consumer products made available for use in California." While defined in the draft regulations, "Made available for use" remains an ambiguous term. It is much more workable and definitive to apply the regulations to consumer products sold or offered for sale in California. This would include promotional, bonus, or free items that are included with the product that is sold or offered for sale in California. That is comprehensive enough and it eliminates potentially confusing ambiguity.

Section 36301.1 Guiding Precepts

The draft regulations seem to supersede the legislative intent of the statute and possibly conflict with it. For example, precept (b) presumes that adverse public health and environmental impacts will be reduced significantly "by encouraging the redesign of consumer products and manufacturing processes and approaches," which prejudges the regulatory response appropriate for consumer products and also how DTSC might be encouraged to implement the regulation. This conflicts with the overall purpose of AB 1879 which calls for a Department process and manufacturer analysis to determine the appropriate response actions, if any, to address the risks associated with high priority chemicals in consumer products.

Additionally, what is the purpose of the guiding precepts? There is no consideration of economic value or product performance. There are numerous undefined terms (i.e. "adverse impact," "overall costs of those impacts on the State's society") that are undefined, vague, and/or have no standards associated with them by which to judge "compliance" (if that applies to these). The Guiding Precepts seem to apply to both the Department and manufacturers implying that they are enforceable. Another precept states that less ingredients are preferred; what is the basis of this? This precept suggests that manufacturers intentionally add unnecessary chemicals or amounts of chemicals in to products. Stifling innovation and second guessing manufacturer decisions should not be the guiding precept for DTSC; however, as written that is exactly the consequence of these guiding precepts. The purpose of the guiding precepts section is unclear and, as written, creates substantial confusion. GCA urges DTSC to delete this section in its entirety.

Section 69301.2 Definitions

- **"Bioaccumulation"** – DTSC should define this term within the regulations. GCA recommends the following language, which is consistent with EPA's definition:

  "The accumulation of chemicals in the tissue of organisms through any route, including respiration, ingestion, or direct contact with contaminated water, sediment, and pore water in the sediment."

- **"Chemical"** – In the proposed regulations the term "chemical" is broadly defined to include, among other things, chemical substances, chemical mixtures, chemical compounds, chemical ingredients and chemical elements. The identification of "chemical mixture" as a chemical should make clear that what is meant here are mixtures of distinct chemical substances that might occur naturally or as a result of standard processing of commodity chemicals, not intentionally engineered and produced formulations. More specifically, DTSC should revise the definition to exclude, or at least better define, "chemical mixtures" to avoid undermining the

proposed regulation's basic architecture of first focusing on chemicals and then moving onto products that contain particular chemicals.

Commonly recognized products, such as paint or lubricants, are carefully engineered "chemical mixtures" designed to have certain performance characteristics. On the other hand, "chemicals" are usually individual substances defined by a CAS number. There are many mixtures that are defined by TSCA as chemical substances because these mixtures are a result of a chemical reaction. These mixtures are assigned a single CAS number for listing on the TSCA Inventory.

To assure that products are regulated as the products that they are (rather than chemicals), the DTSC regulatory definition for chemical should align with the federal approach and adopt the TSCA definition or could include chemical mixtures, but only when such chemical mixtures have a CAS number.

GCA urges DTSC to include the following language consistent with TSCA:

(A) Except as provided in subparagraph (B), the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including—

(i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and
(ii) any element or uncombined radical.

(B) Such term does not include—

(i) any mixture,
(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. §§ 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,
(iii) tobacco or any tobacco product,
(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. §§ 2011 et seq.] and regulations issued under such Act),
(v) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1954 [1986] [26 U.S.C. § 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 [26 U.S.C. § 4182 or 4221] or any other provision of such Code), and
(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in sections 4(e) and 4(f) of the Poultry Products Inspection Act [21 U.S.C. Section 453(e) and 4(f)]), meat and meat food products (as defined in section 1(j) of the Federal Meat Inspection Act [21 U.S.C. Section 601(j)]), and eggs and egg products (as defined in section 4 of the Egg Products Inspection Act [21 U.S.C. § 1033]).

The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in

whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

- **"Chemical under Consideration (CuC), Chemical of Concern (CoC), Product under Consideration and Priority Product"** – GCA recommends the inclusion of definitions for each of these important concepts in the regulations. The definitions will help to provide context and intent for the regulation.

- ***"De minimis"*** – While we appreciate this particular baseline, for which we've advocated strongly, we have concerns with the way it's structured in the regulations.

  GCA advocated for a **baseline** threshold at 0.1% by weight, with the ability for DTSC to set a *higher or lower* threshold based on science. We understand DTSC's concern with establishing criteria and setting differences in-house. However, resources exist that DTSC could use as guidance, including endpoint-specific cutoff values articulated in the GHS guidance materials (which explicitly discuss adjusting thresholds) or those used by other countries in their GHS-based classification and labeling programs. Such a system would allow DTSC to alter thresholds based on chemical characteristic(s) of interest without having to completely "reinvent the wheel," which is the concern. As part of DTSC's prioritization process, product manufacturers would have the ability to submit comments on DTSC's proposal to set a higher or lower threshold before the list of priority products is finalized.

  Additionally, the definition needs to be clarified to specify the threshold "***by weight***," as the default unit, consistent with other systems with which manufacturers must comply. From a technical perspective companies need to understand what the threshold is being measured represents, for consistency and clarity purposes.

  The de minimis threshold should be applied to the total product; however, a manufacturer may submit an AA work plan indicating the presence of a chemical above that threshold is related to only one component. Applying this threshold per component, particularly for complex small articles, will be difficult to calculate and differentiate given destructive testing protocols and the interrelated nature of complex articles and formulations.

- **"Environmental Impact"** – GCA argues that this definition be revised to mean "***any significant*** adverse impact to the environment…" to align with AB1879 statutory language. (Note: This change is also relevant in other places throughout the document, such as "***significant*** adverse impacts on the environment.")

- **"Green Chemistry Principles"** – The principles provided in the definition are not consistent with original Anastas and Warner version or even those listed on the Green Chemistry Initiative website.

  GCA recommends that to the extent that Green Chemistry Principles are cited, they should come from existing sources such as Green Chemistry: Theory and Practice (Anastas and Warner, 1998; p. 30). The principles cited in the "Green Chemistry Principles" definition are hybrids developed by DTSC that are not automatically consistent with life cycle thinking (e.g., subpara. (7)). We would argue that any of the chemical characteristic, process, or life cycle considerations mentioned in the principles must be considered as a whole, and not in isolation, to ensure a sound alternatives assessment process. Additionally, green engineering principles are also valuable for consideration (see Anastas, P.T., and Zimmerman, J.B., "Design through the Twelve Principles of Green Engineering", Env. Sci. and Tech., 37, 5, 94A-101A, 2003.)

- **"Hazard Traits"** – Hazard trait is defined to include carcinogens and reproductive toxicants contained on the Proposition 65 list. GCA argues the definition should exclude those chemical entities added pursuant to the Labor Code mechanism.
  Additionally, endocrine disruption and mutagenicity are mechanisms of potential toxicity, not toxic end-points themselves, and thus not hazard traits. True hazard traits should be measurable by recognized, validated tests.

- **"Intermediate Manufacturing Processes"** – 'Formulating' and „Repackaging' should be included in the definition.

- **"Life Cycle" and "Life Cycle Thinking"** – These terms are defined but no definition is offered for "life cycle assessment." In addition to these vague requirements of life cycle thinking and assessment, the alternatives assessment process outlined in the draft extends further to require detailed requirements unrelated to the common practice of life cycle assessment. These complexities and the extensive requirements for an alternatives assessment leads to the conclusion that the regulation intends to force the producer, distributor, or importer to look for ways for a product to fit within an exception based on 69305.1 or reducing the COC in the product or a product component to lower than 0.1%.

- **"Manufacturer"** – GCA urges the Department to use the Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current "manufacturer" definition in the regulation, providing for uniformity of laws (CARB, CPSC, etc.).

  All consumer commodities that are distributed in US commerce must comply with the Federal Trade Commission's labeling requirements. These requirements, as outlined in FPLA, include a statement of identity, net quantity statement and name and place of business of the manufacturer, packer or distributor. All of these items must appear in English on the product label, so if a product is imported from China for example, the entity that is receiving the shipment and packaging the commodity into US-compliant labeling is identified on the label with the qualifier "manufactured for……." or "distributed by……". FPLA exempts retailers unless they specifically repackage the commodity or if it is manufactured *for* the retailer (i.e. private label). This framework also applies to importers, as long as the product meets the definition of a "consumer commodity" under FPLA – the label must display the name of the manufacturer, distributor or packer. This requirement takes care of imports because the entity packaging the commodity into US-compliant labeling will be identified as "manufactured for…" or "distributed by…."

  The problem with the "manufacturer" definition in the draft DTSC regulation is that it is needlessly complicated to really get at the same requirements as FTC/CPSC. GCA feels that the FTC/CPSC labeling requirements will adequately "cast the net" in cases of enforcement to include the entity responsible for distribution of the commodity in US commerce. If needed, the responsible entity can go back to domestic or foreign suppliers to address DTSC needs.

- **"Nanomaterials, Nanoscale, Nanostructure"** – GCA is concerned that these definitions are inconsistent with the emerging standards being formed between many national and global organizations and authorities. These entities define "nanoscale," in particular, as particles with dimensions in the 1 - 100 nm range. The Joint Research Centre of the EU recently released its "Considerations on a Definition of Nanomaterial For Regulatory Purposes" with an excellent overview of existing definitions, making a strong case for convergence in this regard. GCA also supports the work of the California Nano Industry Network Regulatory Committee, which we understand has provided specific recommendations for amendment of these terms.

- **Open Source** – DTSC should provide clarity relative to the concept of "open source" alternatives assessments. More specifically, DTSC should provide indication of the parameters and quality criteria for what assures the integrity of the document.
- **"Orphan Product"** – The definition of "orphan product" is too subjective. It appears that DTSC will have the final say in determining which products, in their opinion, have an end-of-life longer than the manufacturer or producer who introduced it into commerce. GCA feels strongly that manufacturers should be the ones to determine the reasonable length of a product's life. What if the manufacturer does not agree with DTSC's calculation for the life of a product? What recourse will the manufacturer have?

- **"Reliable Information"** – GCA recommends the inclusion of a definition for "reliable information" that would be considered the test for acceptability to ensure that studies used are reliable, relevant and adequate. GCA recommends the following language based on the Organization for Economic Cooperation and Development (OECD) Manual reference for "rating" studies:

  "Reliable information" is from studies or data generated according to valid 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 validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies.
  http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

- **"Technologically and economically feasible alternative"** – GCA is highly concerned that this definition specifically related to economic feasibility seems to depend wholly on the costs to the consumer and the public health/environment but does not seem to be swayed by costs to retool/redesign. It lacks any consideration of product efficacy, performance, safety and value-added; instead it is primarily cost-oriented. As such, GCA urges the Department to modify its definition for "technologically and economically feasible alternative" and replace "alternative" with "functionally-equivalent alternative."

69301.4 Duty to Comply

The draft regulation in section 69301.4(a) provides that all three of the entities that constitute the definition of a manufacturer -- the producer, the importer, the private label -- are "jointly and severally responsible" for complying with the provisions of these regulations. The section in subdivisions (b) and (c) go on to make it clear that only one of those entities has to actually comply. Nevertheless, the provision that makes them jointly and severally responsible means that all three of them are obligated to comply with the provisions of the regulations. This raises the specter that bounty hunters could bring Business and Professions Code section 17200 actions against two of the entities if only one of the entities is actually complying. It would be sufficient to simply say the manufacturer has to comply in subdivision (a), and then make it clear in (b) and (c) how that would be implemented in practice. There is no reason, other than to create potential liability, to introduce the concept of joint and several responsibility. This can be greatly simplified by the adoption of GCA's recommendation to use the FPLA responsible party as the focus for compliance as is done by federal agencies as well as by CARB.

Section 69301.5 Products Listed on Failure to Comply List

The draft regulation requires the manufacturer found to be in non-compliance to notify the retailers that its product cannot be sold in California and to recall the product, providing a take-back mechanism for retailers. While the manufacturer can file a dispute, this still seems like a draconian step for compliance violations that could be administrative in nature (i.e. being a day late on a report). GCA argues that DTSC may not have the authority to impose such actions on a non-complying manufacturer, particularly with respect to early requirements of the regulatory process.

Additionally, the mandate related to a product being listed on the "failure to comply" list which provides that no person shall make product available for use within 60 days is extreme. It implies that every product on every shelf of every store or shop must be controlled in that time frame. This would seem particularly burdensome for "mom and pop" establishments and for retailers and distributors with significant investments in inventory.

The only basis for a product to be subject to a recall should be if a determination is made by the Department that the product is unsafe and poses an imminent risk.

Section 69301.7 Submission of Manufacturer Chemical and Product Information

- **REACh Data & SIEFs** – GCA is concerned regarding complete availability of data from the European Registration, Evaluation, Authorisation and Restriction of Chemicals REACh and the ability for an individual manufacturer to provide it directly to DTSC per the draft regulations. Manufacturers participating in a Substance Information Exchange Forum (SIEF) sign an agreement with the lead/consortium allowing that manufacturer to refer to the data in the joint technical dossier related to a specific chemical. Data ownership and the license to use it depend on private arrangements between the participating companies and other data providers (i.e. universities). Manufacturers cannot legally give away what is not their own; thus, a generic requirement to provide the state with data that has been submitted under REACh is not possible. Most data sharing agreements explicitly exclude use of data generated for REACh compliance for non-REACh purposes. Moreover, a "simple" SIEF member – one who only obtains the right to refer to studies and results – very often will not even see the full study reports, only what has been captured in the International Uniform Chemical Information Database (IUCLID) Robust Study Summary submitted to ECHA. In the end, the vast majority of REACh data will be publicly available on the European Chemical Agency's website, following submission and acceptance by the Agency. The data from some 180 registered chemicals is already posted in the form of Robust Study Summaries from the IUCLID file.
- (See http://apps.echa.europa.eu/registered/registered-sub.aspx)

  GCA urges DTSC to clarify the provisions regarding REACh and others data submittals to indicate specifically that they be limited to the information the particular product/chemical manufacturer in question actually owns or to which it has license to access for the purposes of complying with this regulation. Additionally, GCA urges that data submitters be permitted to provide links to the information in REACh registrations as well as other data sources such as the OECD eChem Portal and EPA's High Production Volume Information System (HPVIS).

- **"Identification of all intentionally added ingredients…including quantities"** – This provision generates unnecessary claims for trade secret protection. We understand the likely rationale – a product containing a high concentration of a chemical of concern would probably be given a higher priority than a product containing a low concentration of a chemical of concern. If that's the case, then the only quantities needed are for chemicals of concern. No

rationale can exist for requiring the revelation of product formulas where chemicals not otherwise designated as Chemicals of Concern are involved.

- **Data call-in notification** – This provision allows the department to post a data call-in on its website. There is no obligation imposed on the department to contact manufacturers individually. A manufacturer then who is unaware of the data call-in could be found to be in non-compliance and ordered to cease making its product available in California and to recall it from retailers' shelves. GCA is not aware of any legal requirement for a company to monitor the DTSC website so it is conceivable that such a call in could be missed and so constitute a manufacturer out of compliance. In addition to a website posting, DTSC should publish the data request in the California Regulatory Notice Register and communicate directly with manufacturers when at all possible.

- **Test Data Reports** – California should follow the lead of REACh and not permit the public posting or release under any circumstances of complete test data reports in which a company has ownership rights. To allow or contemplate such posting, would allow competitors to unfairly use the data for their own advantage and without compensation to the owner of the data. Consistent with REACh, GCA suggests the posting of summaries that respect confidential business information and trade secrets instead.

- **Redesign/reformulation requirements** – If a manufacturer reformulates or redesigns a consumer product to remove a chemical that has been listed as a Chemical under Consideration or a Chemical of Concern, it would have to provide substantial information about the reformulated or redesigned product. This results in the unnecessary revelation of trade secret information. Further, no authority exists for requiring information about reformulated and redesigned products until such time as they are reformulated or redesigned pursuant to an alternatives assessment, following DTSC's determination that a product is a Priority Product containing a Chemical of Concern.

Chemical & Product Prioritization Processes – Article 2 & 3

Section 69302 & 69303 General

The prioritization processes (chemicals and products) provide for a very detailed list of information that the Department may/must consider (this is unclear). It is not clear that the draft regulation establishes prioritization processes as called for in the authorizing legislation. Moreover, this section includes a broad statement which states that the Department is not limited to using information obtained from this process in making its determinations. This overly broad idea allows the Department to consider anything without recourse as there is no standard associated with this catchall provision.

The regulations are marked by the absence of a clear, science-based standard to support priority decisions. The regulations target situations that "pose threats to public health and the environment" or that cause "adverse impacts to public health and the environment". GCA supported AB1879 and SB509 as a means to place decisions about product safety in the hands of DTSC scientists. We do not believe that the current language provides workable scientific standards for making those decisions in a credible manner.

Section 69302.1 & 69303.1 Applicability

- **Regulatory Duplication** – Remains an Issue – The language in the regulations does not reflect what is provided for in statute. If a product category is regulated by a federal agency for the same public health or environmental risk as the concern that is being addressed under DTSC's proposal, the product category should be automatically exempted from regulation. The section

refers to "governmental entities" (plural) as opposed to "governmental entity" (singular). The *authority to regulate* something (even if they choose to not do so) should be sufficient to justify an exemption. If not granted, and DTSC were to regulate, this would lead to overlapping authorities should the other governmental entity decide to do so at some time in the future. This would cause confusion in the marketplace. This concept should also apply in situations where a regulatory authority has undertaken efforts to address a risk, even if it has not completed regulatory actions.

- **Exposure Pathway** – The absence of the qualifying phrase "reasonable and foreseeable use" to describe exposure leads GCA to conclude that the existence of an improbable scenario or combination of circumstances that might only theoretically result in exposure would prohibit the product from being exempted. No one can ever prove a negative, and the lack of qualification puts both DTSC and consumer product manufacturers in an untenable position. For "no exposure" exemptions the process must be simple and streamlined; and only if a question or alleged violation is presented, should DTSC be required to make an affirmative declaration. GCA urges DTSC to revise the language as follows:

  "There are no <u>reasonable and foreseeable</u> exposure pathways by which …."

<u>Section 69302.2 & 69303.2 Chemical & Product Lists</u>

- **Timeline –** GCA is concerned with DTSC's statement at the July 7th workshop that the two tiers of chemical and product lists would be compiled and released simultaneously. This is contrary to our understanding of the process, what was stated in the draft regulation, and what is included in DTSC's FAQ for the draft regulation. There are two concerns.

  First, the primary purpose of the "under Consideration" list is to allow manufacturers and the public to provide information on whether the chemical or product should progress to the next step and for the Department to consider that information in their decision-making.

  Second, an additional purpose in a step-wise process is to provide a "signal" to the marketplace, allowing manufacturers to make judgments about their product or use of the chemicals under consideration. Manufacturers will need a sufficient amount of time to perform impact assessments on the presence of Chemicals under Consideration (as determined by DTSC) in their products, <u>before</u> the Chemicals of Concern list is released and triggers the Product Prioritization process. Releasing the two lists in approximately the same time frame does not allow this.

  A good precedent for this portion of the process comes from REACh, where member states or the European Chemicals Agency (ECHA) first prepare Annex XV dossiers for identification of substances of very high concern (SVHC), forming a "Candidate List." Interested parties then have 45 days to provide comments as well as further information that will facilitate evaluation, ECHA then leads consultations among member states after which draft recommendations for Annex XIV, the list of substances subject to authorization. A 3-month public comment period follows the publication of recommendations. The European Commission then takes decisions on these recommendations in consideration of the public comments to establish chemicals that are Prioritized for Authorisation. ECHA must make recommendations at least every second year, but to date, they have done so each year for the past three. (http://echa.europa.eu/chem_data/authorisation_process_en.asp)

  Each step gives manufacturers a chance to react and <u>prioritize</u> the replacement of substances with suitable alternatives. In the absence of a staged process, manufacturers are deprived of

an important tool to make business decisions. This is particularly true for considering alternatives to substances used in complex products with a long development time.

- **Chemicals as Products** – The application of chemicals of concern as products ("a product or part of a product") is in direct conflict with AB 1879 that refers to "chemicals or chemical ingredients **in** consumer products" not as products themselves. DTSC should strike this provision entirely.

- **Public Comments & DTSC Response** – While GCA understands that not all of the comments received may be worthy of a detailed response, we are concerned that the language is such that gives DTSC the opportunity to forgo responses regardless of the quality of comment. Furthermore, if an entity provides comment and fails to receive a formal response, they will be unable to challenge a DTSC decision since a full record is needed.

Section 69302.3, 69302.4, 69303.3 & 69303.4 Chemical & Product Prioritization

- **Data Quality** – GCA submits that peer-review alone is an insufficient metric of study quality. Instead, we strongly recommend that DTSC consider and incorporate into the regulation the notion of quality. The OECD methodology for determining the quality of data in chemical dossiers described in their *Manual for Investigation of HPV Chemicals* is a globally accepted way to rate the reliability, relevance and adequacy of existing data; as such, it should be applied to all studies used in compliance and decisions under the Safer Alternatives Regulation. It has been applied to all studies in the US and OECD HPV programs and to those submitted under REACh. It's been found to be an excellent approach to separate good studies from those that are not of sufficient quality and reliability for science-based regulatory decisions.

  In this regard, GCA recommends changing the language in Section 69302.4 (a) (2) from "Availability of peer-reviewed data to substantiate..." to:

  ***"Availability of reliable information to substantiate**..."*

- **Hazard Traits** – Hazard trait is defined to include carcinogens and reproductive toxicants contained on the Proposition 65 list. GCA argues it should exclude those added pursuant to the Labor Code mechanism.

  Furthermore, GCA feels strongly that the regulations should specify that the information on the "endpoints" be derived from reliable information such as GLP guideline studies and not un-validated assessment techniques, and that sufficient reliable information should be available on the alternatives under consideration as exists on the material to be replaced. This is the only way to ensure a robust "apples to apples" comparison and to avoid regrettable substitution of chemicals.

- **Intentionally Added** – DTSC should frame the scope of the regulation to include intentionally added chemicals in consumer products as well as any substance formed via chemical reaction of intentionally added chemicals in the finished product. However, non-intentionally added elements should be specifically excluded from consideration as they will vary from product sample to product sample based on factors like chemical variability of municipal water supplies used in factories. Manufacturers go to great lengths to assure that their products are safe for their intended uses and must already comply with a myriad of state and federal laws and regulations. Concerns regarding trace levels of contaminants arising in air, water, etc. should be the focus of appropriate environmental regulations focused on those media. For example, if there is concern about a drinking water contaminant, it should be addressed through the

California or federal drinking water program and not foisted upon consumer product manufacturers through these regulations. GCA had proposed language parallel to that used in California's Safer Consumer Products Regulation to consider chemicals in products only for those intentionally added above the de minimis threshold. Under this proposed language, incidental presence would not be subject to the alternatives assessment requirements.

GCA urges DTSC to include the following language:

> ***(a) (1) "Intentional introduction" means the act of deliberately utilizing a priority chemical in the formulation or assembly of a consumer product where its continued presence is desired in the final consumer product to provide a specific characteristic, appearance, or quality.***
>
> ***(2) "Incidental presence" includes:***
>
> ***(A) The use of a priority chemical as a processing agent or intermediate to impart certain chemical or physical changes during manufacturing, where the retention of a residue of that chemical in the final consumer product is not desired or deliberate.***
>
> ***(B) The use of recycled materials as feedstock for the manufacture of new consumer products, where some incidental retention of a residue from recycled materials may be present in the consumer product.***
>
> ***(C) The incidental retention of a residue of a contaminate unintentionally included in the final consumer product.***

- **Intermediates** – Although intermediates were exempt as outlined in the detailed outline released in April 2010, they were subsequently included in the draft regulations. Intermediate chemicals must be excluded as they are not the focus of the statue. Furthermore, DTSC will have no authority over the use of intermediates outside of California; therefore this regulation would be a disincentive to California-based businesses, jobs, and operations.

- **Prioritization Factors** – The prioritization factors are a comprehensive list with no indication of which factors carry more weight than others or how DTSC might use them for prioritization. The articulation of these factors gives DTSC unfettered discretion in making any prioritization decision in an arbitrary manner with respect to any chemical or product. The "standard" for prioritization decisions is loosely defined, using terms such as "pose threats" and "adverse impacts" to public health and the environment, not even recognizing the statutory direction to address "significant adverse impacts". Environmental impact is defined as "any change to the environment, whether adverse or beneficial." Public health impact is defined as "effects on the health of the general population or sensitive subpopulations." Use of such terms fails to achieve a science based and predictable business environment and will lead all parties observing this process to make claims of controversial and arbitrary outcomes.
  Furthermore, under the current framework overly extensive criteria can be used to list a chemical as a CUC or COC. The listing criteria are overly broad and should be reconsidered for inclusion at the outset of the program, *i.e.,* "found in biomonitoring data" should not be the basis to regulate because such a finding does not indicate the potential for harm according to the CDC; epigenetic evidence should not be the basis of listing because it is unclear whether or what kind of epigenetic effects produce adverse effects on health. Also, CUC prioritization factors should be measurable by validated tests and not the subject of speculation or unsettled science. When the science is not conclusive a prioritization factor like endocrine disruption should not be included.

DTSC should consider also that human biology gravitates towards homeostasis through compensatory mechanisms. In its July 2008 Statement of Need and Reasonableness relating to health risk limits for groundwater, the Minnesota Department of Health describes the inherent corrective nature of the underlying human biology as: "Because some effects observed may be normal compensatory responses, professional judgment is required to decide whether any particular effect is adverse, or biologically significant. If an endpoint is quantal (i.e. all or nothing), such as birth defects or tumors, designation of an effect as "adverse" may be a straight forward decision. However, for subtle effects and/or continuous measurements such as body weight or enzyme activity, this may ultimately be a qualitative decision. Professional judgment may be required to determine the point at which normal compensatory metabolic or physiological processes are compromised.

The draft regulations must set forth criteria or a formula that will be used to prioritize chemicals and products. Providing such an algorithm will provide clarity and certainty in the Department's prioritization. Without such a process, questions will arise as to the subjectivity and biased nature of priority determinations.

- **Workplace** – GCA is highly concerned about the prioritization factors related to the workplace. The related provisions are particularly troubling given that products used in an "intermediate manufacturing process" are not to be exempted, but simply given a lower priority. A possible solution to this problem is that products in the workplace that are subject to the hazardous communication standards, that is, an MSDS, should be exempt from these regulations. It provides clarity and prevents intrusion into Cal-OSHA's PEL responsibilities by DTSC in the future.

- **"Threats" versus "Adverse Impacts"** – The decision criterion of "threats" to human health or the environment is not clearly defined. The decision / prioritization criterion for chemicals and products should be risk-based, integrating hazard with exposure when determining potential concern about public health and the environment and further refined to a more scientifically clear standard.

  The factors for prioritization include "adverse impacts on the environment" related to air quality impacts, soil contamination, and water quality impacts. Many manufacturers already must adhere to strict air and water quality control requirements by both the State and Regional Air and Water Quality Control Boards. This draft may supersede or conflict with the regulatory authority of these bodies.

  Furthermore, the draft regulations state that a factor of consideration will be "scope and consistency across jurisdictions, of other governmental regulatory programs, and the *extent to which these other programs address the public health and environmental threats…"* (sub-section h, page 17-18 lines 38-39). GCA remains highly concerned that this is broad and open to varying interpretations and arbitrary judgments about the "extent" of existing programs and the lack of scientific clarity in "threats."

- **Product Listing & Liability** – Specific to the listing of products as "under consideration" and "priority products," GCA stakeholders are highly concerned about the lack of liability protections for manufacturers providing data to DTSC and the ability for that data to be used against them. Furthermore, we are concerned that the mere listing of these products could be used against a manufacturer under Business and Professions Code section 17200 actions.

Section 69303.5 Manufacturer Priority Product Notification

Nothing in AB 1879 provides authority for DTSC to impose the burden on a manufacturer of a listed priority product to notify its retailers who sell that priority product that the product is a priority product. GCA is highly concerned that manufacturer-retailer communication at every stage of the alternatives assessment process will become onerous and will be a burden to the supply-chain. DTSC should direct retailers to regularly check the DTSC website to determine which products are identified as "priority products" and for which required alternatives assessment reports are on file. DTSC should also publish this list in the California Regulatory Notice Register.

Furthermore, the draft regulations provide for a long list of information requirements that must be included in a notice 30 days after listing. This includes bar codes and the method of identifying products prior to listing. GCA is not confident this can be done. Even if it were possible, DTSC should be aware that the number of unique bar codes for any single product can be in the thousands because each container type and size typically must have its own code. Further, if products are packaged with multiple products in each package, the same products will have a different bar code for each package (i.e. 4 pack, 6 pack, 12 pack, 24, pack, etc.). Also, that same product may come in different colors or prints, each of those would then have a separate bar code and if different variations of those colors/prints are included in the packages those will have different bar codes. This same product may have other attributes that do not change the chemical makeup of the product, but may be a consumer preference leading to additional bar codes for that same product.

GCA argues that no action in this regard is necessary or appropriate until after the completion of the alternative assessment process and the determination of a Regulatory Response.

Chemical/Product Petition Process – Article 4

While GCA supports the inclusion of a petition process, we are concerned that the provisions fail to clearly provide for requests to remove chemicals/products from priority lists. GCA is adamant that the process must work both ways and be fully open to public comment. Petitions that are approved should only enter the prioritization process at Chemicals Under Consideration or Products Under Consideration, so that other stakeholders have the opportunity to provide additional information for DTSC's decision-making.

Alternatives Assessments – Article 5

The alternatives assessment remains very demanding in terms of the scope of review for every alternative. Additionally, it relies heavily on "Life Cycle Thinking" without consideration that impacts may be outside of California. For example, raw material extraction and manufacturing often occurs outside of the boundaries and jurisdiction of California. What statutory authority does California have to regulate a chemical because of a concern outside of California? If life cycle analysis reveals potential impacts that occur outside of California, such impacts must be given less weight under the California Safer Alternatives Regulation than those that occur within the state's boundaries.

Section 69305 General

- **Open Source** – DTSC should provide clarity relative to the concept of "open source" alternatives assessments. More specifically, DTSC should provide indication of the parameters of what assures the integrity of the document.

- **3rd Party Verification & Audits** – The requirement to have the alternatives assessment work plan and report(s) verified by a third party will be costly and hinder timeframes for completion of the alternatives assessment given our understanding of the supply of 3rd parties to accomplish this work. Furthermore, 3rd Party verification should only be required in limited situations and should not apply if a manufacturer reformulates/redesigns product to remove COC from product and does not replace it with another COC.

  DTSC audits should address any conflict of interest concerns with an alternatives assessment. Moreover, if DTSC is going to certify a party to perform verification of alternatives assessments, DTSC must also develop criteria for such certification including provisions for certifications to be revoked. Granting credentials in the absence of a process to assure quality work is not acceptable.

  In addition, DTSC should establish quality criteria for the performance of alternatives assessment verification by certified third parties, including grievance and dispute resolution procedures for parties who believe their alternatives assessments have been improperly denied verification.

  GCA believes the strict requirements pertaining to contact with the 3rd party entity reviewing an alternatives assessment are extreme. Given the subjective nature of the assessments and the extensive information covered, contact may be warranted to provide insight to the process and choices made by a manufacturer. This provision points to another need for a formal grievance process.

- **In-House Certification** – Under the draft regulations, all declarations and reports must be signed by "an officer of the company." Such action must be executed under penalty of law for reports that are subjective in nature and that the "officer of the company" may not have the competency to address.

Section 69305.1 Exemption Determination & Department Concurrence

A positive DTSC declaration must not be required before an exemption is provided. The Department should establish exemption criteria that are easily verifiable, and for which there are significant consequences if exemption is falsely claimed. Filing for the exemption should provide relief from a requirement unless DTSC finds that regulation is NOT duplicative or new information becomes available that would cause the manufacturer or DTSC to re-examine an existing exemption. DTSC must enable a simple system for filing for exemptions. All products in a category should be exempted if there is duplication of regulation by federal regulation. Additionally, the de minimis threshold should be self determining and not require an exemption determination and Department concurrence under this Section.

Section 69305.3 Alternatives Assessment Work Plan Required Contents

Under the draft regulations, the alternatives assessment work plan provision seems to require that manufacturers already know the alternatives to be assessed and are in a position to quickly summarize all existing information on those alternatives. The work plan should be about scoping out an overall plan for the alternative assessment, not doing it. Going beyond will delay submission of a work plan for DTSC review. Chemical information for alternatives may not be available at the time of submission of the work plan. Moreover, the work plan should not be the place for such data, but should specify that such data will be compiled and perhaps specify how it will be compiled. Perhaps this was DTSC's

intention, but it is not clear. The work plan appears to be more of a mid-course progress report on the overall alternatives assessment process than a plan of work for carrying out the assessment.

Section 69305.4 & 69305.9 Alternatives Assessment Work Plan Detailed Executive Summary Required Contents

The draft regulations appear to have two similar sections related to the executive summary. While there are minor differences, DTSC may have overlooked the fact that this concept was included twice.

In terms of the content requirements for the alternatives assessment work plan, they are excessive in scope and fail to fully account for information that would be considered confidential business information or trade secret claims.

One specific area of concern relates to the requirement to disclose "all chemical ingredients in the selected alternative" in an alternatives assessment report. Doing so would unnecessarily raise the need for additional confidential business information/trade secret claims. Disclosure within the report should be limited to only those ingredients that are considered chemicals of concern.

Regulatory Responses – Article 6

The draft regulation provides that the department may impose regulatory responses on a selected alternative consumer product, or an alternative consumer product component, or a priority product for which the manufacturer does not select an alternative. Those responses include all of the responses set out in sections 69306.3 through 69306.5, as well as requiring engineered safety measures, placing restrictions on the use, and requiring a research and development project. However, there is no provision in this section that the selected alternative product or component has to contain a CoC to be subject to any of those regulatory responses. Perhaps that is an omission by DTSC; however, DTSC has no authority to impose any regulatory response if it is not a priority product containing a CoC or if that CoC is below the de minimis level. DTSC seems to recognize this in section 69306.2, providing that no regulatory response is needed. Sections 69306.2 and 69306.6 are, accordingly, inconsistent.

Section 69306.2 No Regulatory Response Required

This section applies only if an alternative with a chemical of concern concentration of less than de minimis is chosen, there is no significant threat to exposure, and the priority product is phased out in 3 years. This approach raises two issues for the GCA: (1) an alternative could have more than 0.1% and not pose a safety risk to health or the environment; and (2) if an alternative is chosen, it may take more than 3 years in California just to get a permit to start building the equipment necessary to produce the alternative.

The bottom line is DTSC fails to recognize that "no action" on the original priority product containing the chemical of concern may be the best solution. The alternatives assessment may clearly demonstrate the safety of the original product and the lack of a technologically and economically feasible alternative. DTSC should alter the language to provide for no action in these circumstances.

Section 69306.3 Product Information to Consumers

GCA argues that this section is reminiscent of Prop 65 in that it requires product labeling or an informational insert in the packaging that informs the consumer that the product contains a COC for

which an alternative was not substituted or for a chosen alternative that contains a COC. This provision flies in the face of responsible risk communication and is a hazard-only, presence-only means of causing potentially unnecessary consumer concern. If the manufacturer clearly demonstrates to DTSC the safety of the product and that substitution of the COC is not required, labeling should not be required. It is irresponsible to require otherwise.

Section 69306.4 Manufacturer End-of-Life Management Requirements

Extended Producer Responsibility (EPR) and take-back should not be automatically mandated for every end-of-life concern. Other methodologies for addressing end-of-life concerns must be approved by the California Legislature; take-back and recycling programs may not always be the best solution.

With regard to end of life management as a regulatory response, the draft regulation goes beyond the scope of statute and is overly burdensome. It requires take back programs, public education programs, and defining "roles and responsibilities of manufacturers, retailers, consumers and government." How does the manufacturer define (and presumably monitor and enforce) the roles and responsibilities of entities not under the manufacturers' control (i.e. government, consumers, etc.)? Also, for products with a long life span, how does the manufacturer manage the end of life? It is also not clear that DTSC has authority to mandate how manufacturers will finance their programs as the draft appears to assume.

Furthermore, this response action requires the manufacturer of a product "required to be managed as a hazardous waste" to establish a take-back program. It would appear that this regulation is inconsistent with the provision in AB 1879 that prohibits duplicative regulation. Under the law today, if a product is to be managed as a hazardous waste, a mechanism for handling that waste is already set out in the law. To require a specific method of handling those products (i.e. a take-back program) duplicates the existing provisions in the law today.

Finally, take back programs, in particular, are very impractical for some consumer products that are actually consumed during use. Would the unused fraction of such products have to be managed as hazardous waste? Would the non-consumables that people don't want to recycle have to be managed as hazardous waste?

Section 69306.5 Product Sales Prohibition

GCA is concerned with the requirement of a "recall program" if the regulatory response is a product sales prohibition. This seems to be an extreme and punitive response, especially where there is no safety issue.

Section 69306.8 Regulatory Response Report & Notifications

GCA is highly concerned that manufacturer-retailer communication at every stage of the alternatives assessment process will become onerous and will be a burden to the supply chain. DTSC should direct retailers to regularly check the DTSC website to determine which products are a "priority" have filed alternatives assessment reports as required.. DTSC should also publish this list in the California Regulatory Notice Register. Only following the Alternatives Assessment and determination of Regulatory Response action should there be any requirements in this regard.

Dispute Resolution Processes – Article 7

The draft regulations do not appear to include a stay of requirements while this process unfolds. Additionally, most provisions under the Chapter do not have the right of formal challenge.

Since prioritization of chemicals/products is the basis of the program, this section at a minimum should have a right to appeal. A formal review (Petition for Review) process allows the Department to review a challenge to the Department's various determinations. This biased review does not provide for an independent evaluation of the Department decisions in dispute. This step must be completed prior to seeking judicial review; it is unclear what happens to the regulatory responses called for in those sections pending the Department review and possible judicial appeal.

Lastly, Section 69307.5(a) should read as follows: "(1) Facts, assumptions, or other information or approaches not supported by clear and convincing evidence, or (2) conclusions in violation of applicable law, or (3) An exercise of discretion or an important policy consideration which the Department should, in its discretion, review."

Accreditation & Qualification Alternatives Assessment Requirements – Article 8

Section 69308.1 Requirements for Qualified In-House Assessment Entities

Although GCA had proposed a section be included in the work plan to illustrate a manufacturer's competence to conduct an alternatives assessment, DTSC's proposal in the draft is much more complicated and fails to consider the points raised with regard to tying competence to individuals with expertise rather than overall corporate expertise (draft requires individual's information, expertise, education, and more). This process will vary product to product and must be more general with respect to the required credentials. Companies should have a "cafeteria-style" approach to using alternatives assessment processes, particularly those that are valid in other jurisdictions.

Also under this section, if a manufacturer is in violation they will lose their ability to be an In-House Assessment Entity for at least 10 years and any alternatives assessment report cannot be done by a trade association or consortium of which the manufacturer is a member. This provision is incredibly harsh for what could be paperwork errors (*i.e.,* turning in a re-qualification request a day late), assessment mistakes, etc; and certainly harsh for losing the ability to look to a trade association/consortium for assistance. Prohibiting the use of a consortium/trade association creates significant inefficiencies and removes significant expertise (likely greater than many third party entities that will emerge to take advantage of this business opportunity) from the process.

Finally, a qualified third party assessor must prove independence and lack of affiliation with any manufacturer, consortium of manufacturers, or trade association. If this provision remains, it must extend to affiliation with any non-governmental organization or activist group with a demonstrable track record of chemical or product policy advocacy and lobbying. Otherwise it is clearly prejudicial and discriminatory. A preferable alternative would be a transparent system in which all potential interests/conflicts/advocacy of qualified third party assessors are disclosed such that potential conflicts can be identified and minimized during the manufacturer's assessor selection process.

Section 69308.2 Lead Assessor Criteria

GCA is concerned that the criteria for a lead assessor is too narrowly focused on Life Cycle and not other relevant criteria. This could result in a monopoly problem with training requirements at the "Accrediting Body," which could lead to pricing problems and antitrust issues.

Auditing & Compliance – Article 9

With regard to Section 69309.1, related to violations, GCA is highly concerned that this Article is far too open-ended.

Confidentiality of Information – Article 10

GCA supports the Confidential Business Information (CBI) process set forth in AB 1879 (Feuer, 2008).

Section 69310 Confidentiality of Information

Although the statement in Section 63910(a) seems appropriate as written, it is beyond the authority of DTSC to attempt to regulate the interplay between statutes. Only a court or the legislature may do so. This statement should be struck as *ultra vires*.

Section 69310.2 Marking and Indexing of Documents

GCA is adamant that indexed and redacted reports are not made publicly available. The particular concern is that confidentiality may be compromised by context in redacted reports and therefore could violate the very confidential business information/trade secret protections provided for in the statute.

Section 69310.3 Safeguarding of Confidential Information

DTSC should delete Section 69310.3(c) in its entirety. This provision substitutes agency interpretation in place of class determination by regulation and merely gives DTSC the opportunity to make decisions without notice or the opportunity for comment that are keep to procedural due process under the California and U.S. Constitutions.

Section 69310.4 Support of a Claim of Trade Secret Protection

GCA is concerned that the provisions of this section, which require up-front justification for trade secret claims, go beyond the authority provided in the statute and the trade secret definition in the California Civil Code. The statute requires justification only when a request for the information under the Public Records Act is submitted.

More specifically, Sections 69310.4(a)(8) and (9) are beyond the DTSC's authority, and merely designed to create a barrier to confidential protection. Nowhere in Health & Safety Code Section 25257 or Section 57020 nor in Government Code Section 6254.7 is estimated dollar costs conceived of as a measure of trade secret. Indeed, Section 6254.7 states that a trade secret is something "having commercial value and which gives its user an opportunity to obtain a business advantage;" however, the measure of that value is not within the scope of DTSC's determination. It is unrealistic to ask any manufacturer to put a specific dollar value on the harm that will come from the loss of trade secret because no manufacturer can estimate future profits that may result with certainty.

Section 69310.5 Departmental Review of Individual Trade Secret Claims

GCA is highly concerned with this section, which provides that DTSC may make the determination of the validity of a claim for trade secret even though no one has requested that information. The regulation should provide liability for the state in wrongly releasing trade secret information – intentionally or inadvertent. Under TSCA, criminal penalties for wrongful and willful disclosure of CBI have been established. DTSC should revise this section to provide liability for the state.

Section 69310.6 Treatment of Certain Categories of Information

GCA argues that this section should be eliminated from the regulations. Subdivision (c) of section 69310.6 simply restates subdivision (f) of Health and Safety Code Sction 25257 although the articulation is different and broader.

Additionally, the rest of this section authorizes DTSC to release trade secret information upon a showing "of substantial need based on an urgent matter of public health, safety, or the environmental protection." Such disclosure would apply to manufacturing processes and portion data, as well as customer list. This is completely unacceptable. No authority exists for this kind of exception. In no case does DTSC have authority to make marketing information publicly available. As such, this section should be eliminated from the regulation.

Section 69310.7 Substantive Criteria for Use in Trade Secret Determinations

The provisions of this section exceed DTSC's authority to judge a trade secret under Government Code Section 6254.7 by establishing criteria not found the in California Public Records Act. Further, it is inconsistent and beyond the scope of the trade secret definition in the California Civil Code.

Small Business – Article 11

GCA argues that the definition of "small business" needs to be revised. In the draft regulation, small business is defined at 25 or fewer employees. CA DGS already defines small business as 100 or fewer employees. The 25 employee threshold is used by DGS to define "microbusiness". The draft regulation should be revised to use the 100 employee number already used by the state. If DTSC is intent on using the 25 employee number, however, it should, at the very least, change the term to "microbusiness" and clarify whether it will provide "small businesses" with the same or different time frame.

# # #

ATTACHMENT 4

November 9, 2009 Comments from the Soap and Detergent Association (now the American Cleaning Institute) on the DTSC Straw Proposal for Safer Alternatives Regulations released on October 1, 2009

The Soap and Detergent Association

November 9, 2009

Maziar Movassaghi
Acting Director
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95814
(via e-mail: green.chemistry@dtsc.ca.gov)

Re: SDA comments on DTSC Straw Proposal for Regulation on AB 1879

Dear Mr. Movassaghi:

The Soap and Detergent Association (SDA) appreciates this opportunity to provide comments on the *Straw Proposal for Safer Alternatives Regulations* released on October 1, 2009 by the California Department of Toxic Substances Control for the implementation of AB 1879. These comments also relate to presentations and comments made by DTSC staff and other stakeholders at the October 14, 2009 meeting of the Green Ribbon Science Panel (GRSP) and the October 21, 2009 stakeholders' workshop in Sacramento.

SDA is a trade association representing the $30 billion U.S. cleaning products market. SDA 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. 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. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate.

SDA has been participating directly in the California Green Chemistry Initiative and through the industry coalition know as the Green Chemistry Alliance over the past two and a half years. SDA appreciates the tremendous effort by your staff to develop a complete set of regulations and to present them at these two recent meetings. However, we are greatly disappointed that SDA's interactions with DTSC, the input of our individual members to DTSC and the suggestions of the Green Chemistry Alliance have been largely ignored. Likewise, SDA was surprised by your opening remarks at the GRSP meeting where you stated that DTSC had not received much in the way of proposed regulatory language from stakeholders. The Green Chemistry Alliance presented a complete set of regulations to the Department in June that would fulfill the requirements, as well as meet the intent and spirit of AB 1879; I am enclosing a copy of that submission for your further consideration. In addition, we offer the following comments on the straw proposal.

Identification and Prioritization of Chemicals of Concern in Consumer Products (Article X)

Identification of Chemicals of Concern in Consumer Products

The DTSC straw proposal does not "establish a process to identify… chemicals of concern" (COCs) in consumer products contrary to Section 25252(a) of the subject statute (AB 1879). The designated product category applicability in Section 6xxxx.1 is arbitrary, and in some cases vague and in conflict with the specific exemptions cited in the statute. Product Categories (1) through (7) are expansive and not tightly focused. For instance, Category (1), "products designed for use by infants or children" is overly broad and does not identify or prioritize product classes that would be of highest concern. Such vagueness here and elsewhere in the proposal unnecessarily burdens companies who do not have the expertise to make such determinations. The scope of products captured by Category (2), "products designed for use in K-12 schools," is potentially endless, extends well beyond US EPA's definition of age 14 for "children", and fails to focus on what DTSC believes to be the most important sources of exposure in schools. Category (3) would include a number of over-the-counter drugs which are regulated by the US FDA for safety and efficacy. Category (8) targets food contact products, which would be duplicative and in direct conflict with existing FDA regulation. Category (9) targets products designed, or reasonably anticipated, to release any chemicals during intended use and disposal. Considering current analytical capabilities to detect trace chemicals in migration studies, the term "reasonably anticipated" has the potential to greatly expand covered products to virtually everything. Category (10) covers "Any products that contain" chemicals of concern, essentially sweeping in 100% of commerce in California. Category (11) covers every chemical triggered as a COC, essentially setting up direct chemical bans for over 10,000 chemicals in California. These bans would also affect reactive bulk chemicals that are transformed in California into innocuous products within manufacturing facilities. This would not only ban raw chemical use in covered products and categories, but also ban use in the manufacture of exempted product categories in California—pharmaceuticals, medical devices, food, dental restoratives, etc. All affected manufacturers would have to move their operations to another state or offshore.

The designated list of COCs in Section 6xxxx.2(a) of the proposal, the "List of Lists" in Section 6xxxx.2(b) and the Hazard Traits in Section 6xxxx.7(b) are arbitrary. The Department should identify criteria for establishing hazard traits that would serve as the initial tool for identifying candidate chemicals of concern. The severest human health hazard traits such as cancer, or other developmental or reproductive harm (CMR), and persistence, bioaccumulation and toxicity (PBT) as inclusive characteristics for environmental concern would be consensus selections.

The process for identification of candidate chemicals of concern should be a dynamic, on-going process with the most severe hazards being considered first and additional hazards considered based on resources available to DTSC and related agencies over time.

Prioritization of Chemicals of Concern in Consumer Products

The proposal does not "establish a process to… prioritize… chemicals of concern" (COCs) in consumer products contrary to Section 25252(a) of AB 1879 (not withstanding Section 6xxxx.8 which does not really constitute prioritization). The proposal does not consider "the volume of the chemical in commerce in the state" or "the potential for exposure to the chemical in a

consumer product" when identifying and prioritizing chemicals of concern, contrary to Sections 25252(a)(1) and (2) of the Statute, respectively.

Proposed Activities beyond the Scope of the Statute
AB 1879 does not authorize DTSC to require the generation of data to assess hazard traits of all chemicals in commerce and consumer products as part of the identification and prioritization process (Section 25252) contrary to the provisions proposed in 6xxxx.6 *Data Requirements*. In Section 25253, the Department is authorized to require additional data following completion of the alternatives analysis as a regulatory response.

AB 1879 does not provide the authority for DTSC to require manufacturers to populate the Toxics Information Clearinghouse (Section 6xxxx.7(a)(4)). Moreover, the proposal misses the intent of the statute authorizing the Clearinghouse (SB 509) which is to develop a web-based portal that can be used to collect hazard data on chemicals that exists in the public domain (i.e., a Google-like tool).

AB 1879 does not provide the authority for DTSC to require supply chain information dissemination of information (Section 6xxxx.9); and those proposed requirements are in conflict with the trade secret provisions of the statute (Section 25257).

Alternatives Analysis (Article XX)

DTSC has proposed that the manufacturer (each manufacturer) of a subject product would conduct an alternatives assessment on the product. However, the statute (AB 1879) does not give DTSC the authority to require manufacturers to conduct the alternatives assessment. In fact, it would be counterproductive for many manufacturers to be conducting separate analysis. In addition, manufacturers of current products may not be well suited to conduct an alternatives assessment on their own. They may not use an alternative technology and the information on performance and safety would likely be in the hands of suppliers who they may not work with and who might also be a competitor. Since the alternatives assessments will be use-specific for a particular chemical, it would be more efficient and effective if a single assessment was conducted with broad stakeholder participation including participants from manufacturers of conventional products as well as alternatives.

The proposed process envisions a clear "safer" alternative being identified as a result of the analysis. This may occur in some instances, but it is more likely that there will be substantial variability and uncertainty in the various parameters evaluated such that the results are inconclusive. In those instances where a safer alternative is identified, there may be numerous legitimate business reasons why a company does not select the "safer" alternative due to circumstances beyond its control; e.g., there is not sufficient supply in the market place to reliably replace the subject chemical, consumers may not accept the performance of the alternative product, a reformulated/re-engineered product cannot be produced profitably, etc. It would be more efficient for the state to examine those cases where "safer" alternatives are not selected and assist in bringing them to market if the social and environmental benefits justify it. Consequently, the alternatives assessment process should not be arbitrarily repeated every two years if the "safer" alternative is not selected. In addition, the statute does not authorize the

requirement of a justification of the continued use of the consumer product containing the Chemical of Concern.

The Department has proposed a one year timeline for completing the Alternatives Assessment. The Department should have evidence that such an analysis can be successfully completed within a year before moving forward on this proposal. The proposal fails to acknowledge the time it takes for chemical suppliers and product manufacturers to educate one another about the needs, benefits, and applications with regard to a new technology. Furthermore, product development and consumer testing, supply chain development and roll-out of a new product can be very time consuming for a number of industries, some of whom work on cycles of multiple years. So consideration and implementation of what may be considered a feasible alternative could take several years on its own. Such realities of market substitutions must be considered.

Response Actions (Article XXX)

Contrary to the proposal, the statute does not authorize manufacturers to take response actions following the completion of an alternatives analysis. In fact, the statute is clear and unambiguous that the regulatory responses shall be taken by the department (Section 25233(b)). As such, manufacturers should not be required to prepare a Response Action Implementation Plan.

Under Section (a)(4)(B), the proposal states that "if the Department determines… the continued availability in California of the consumer product… would pose a significant risk to human health or the environment, the Department may impose response actions…." The statute does not authorize the Department to conduct safety assessments of the products or the alternatives, nor does DTSC describe how they would conduct such assessments.

Under Section (c)(3), the Department has proposed that a consumer product <u>containing</u> one or more of the proposed <u>thousands</u> of Chemicals of Concern would be prohibited from being made available for use in California within 20 years, regardless of the safety of that product, the use of the product, the content of the chemical and the exposure to the chemical. This is completely unacceptable and counterproductive since there will be little incentive to participate in the Alternatives Assessment process if your product is subject to elimination at the outset.

The statute authorizes regulatory responses and specifies nine responses including a "no action" option and "any other option the department determines accomplishes the requirement of this article;" the article in question is Section 25253 of the Health and Safety Code. That distinction is important because the context is the alternatives assessment process found in the same article, and the ultimate goal of the process also is specified. That is, "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." Therefore, all response actions should be taken in the context of reducing exposure or reducing hazard, and those actions should result in material benefit (i.e. material reduction in exposure or material reduction in hazard). Based on the requirements of the statute, if a chemical is identified and prioritized as a chemical of concern based on a hazard trait that has an exposure threshold, and the use of that chemical in a consumer product leads to exposures less than that threshold level (e.g. acceptable daily intake (ADI)), then no action should be necessary.

Required Agency Resources

It is imperative that the Department clearly delineate those responsibilities and burdens that will be borne by it. Likewise, it must understand its current capabilities in those areas and the capabilities that need to be established in order to successfully implement the regulation. The Department could not hope to meet the requirements of the straw proposal which would only lead to a widespread lack of compliance.

Possible Solutions

Identification and Prioritization of Chemicals of Concern

SDA and its industry partners in the Green Chemistry Alliance proposed a simple process for identifying candidate chemicals of concern at the outset (see enclosure). DTSC should identify those chemicals of the highest hazard, particularly those known to cause cancer, or reproductive or developmental harm (CMR) and those chemicals which are persistent, bioaccumulative and toxic (PBTs). Using data from authoritative bodies around the world, you will find over 2,000 chemicals identified. Next DTSC should consider the volume of those chemicals in commerce in the state by comparing the 2,000 CMR-PBT chemicals against the U.S. EPA's 2006 Inventory Update Rule (IUR) which reports use volume data on high and medium production volume chemicals in the U.S.; there is no reason to believe use patterns in California are largely different from use patterns across the U.S. You will find approximately 650 CMR-PBT chemicals on the 2006 IUR. In order to consider the "potential effects on sensitive subpopulations" as specified in AB 1879, DTSC should look closely at those chemicals identified specifically in the 2006 IUR as being used in children's products, and also any chemicals on the CDC's biomonitoring program as CDC has made such considerations in selecting chemicals for analysis. In addition, DTSC should utilize adverse event report information collected by the US EPA under TSCA and FIFRA, and by the US FDA under FFDCA to assist them in prioritizing Chemicals of Concern.

SDA acknowledges that particular human health or environmental issues that might warrant early attention but might not be captured by a broad screen. DSTC should establish a process by which citizens can petition for consideration of particular chemicals and their uses. However, more to the point, DTSC should have a process whereby they can seek out the expertise within their agency or sister agencies to address pointed particular questions.

Once DTSC has narrowed the universe of candidate chemicals of concern in consumer products, it should work with stakeholder groups including the chemical suppliers and the consumer product manufacturers to better understand the uses of the candidate chemicals in consumer products and to select the high priority Chemicals of Concern that would be the subject of an Alternatives Assessment.

Alternatives Assessment

The Alternatives Assessment portion of the regulations should be sufficiently broad and flexible, and the details of the process should be outlined in guidance issued by the Department in 2011 or beyond as it gains more expertise with the activity. The Department should pilot test the framework to determine the feasibility of the approach and the resources needed to successfully complete an assessment. It would be useful if such a pilot test was conducted on materials and uses that have already been studied such as those evaluated by the Massachusetts Toxics Use Reduction Institute's *Five Chemicals Alternatives Assessment Study* or under EPA's Design for

the Environment Program. The notion of pilot testing was broadly echoed during the Green Ribbon Science Panel meeting.

In order for the Department to consider the full range of regulatory responses within the goal of the statute to best "limit exposure or to reduce the level of hazard posed by a chemical of concern" it must have a complete hazard assessment and exposure assessment for each prioritized chemical of concern in a consumer product. This information should be developed as part of the Alternatives Assessment. Complete assessments will bring to light the opportunities to reduce hazard or exposure. It is important to note that the statute specifies that "the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes" and that the REACH regulation in Europe will result in chemical safety assessments for the highest volume, and other highly environmentally hazardous chemicals next year. This will greatly facilitate the development of hazard and exposure assessments for chemicals that would be considered under the AB 1879 process.

Regulatory Responses and Compliance
There are a number of hypothetical compliance issues that could arise, but the primary response that might need to be enforced would occur when the Department places a restriction on the permitted concentration of a chemical of concern in a consumer product, or prohibits it entirely. It is likely that such a provision would be the exception rather than the rule. Also, it is likely that there would be strong industry incentive to assist in enforcing those kinds of regulatory responses especially when those not respecting the restriction could have a competitive business advantage over those in compliance.

For many products, especially formulated products, it will be relatively easy to enforce any restriction in presence or concentration since more and more formulated product manufacturers are informing consumers of their ingredients. Those who choose to identify ingredients are subject to the Fair Labeling and Packaging Act so their labeling must be truthful.

Summary

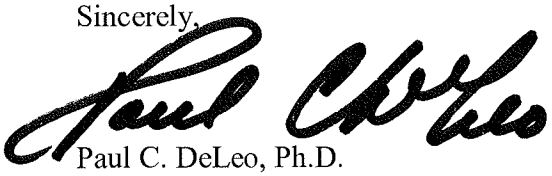
The regulations developed by DTSC for the implementation of AB 1879 should carry out the three basic charges of the statute: developing a process for identification and prioritization of chemical of concern in consumer products, developing a process for evaluating chemicals of concern in consumer products and their alternatives (in order to determine how best to limit exposure or reduce the level of hazard posed), and specification of the range of regulatory responses the department may take following the completion of the alternatives analysis.

In meeting the challenges of those charges, DTSC must also satisfy the provision of the statute for "reference and use, to the maximum extent feasible, [of] available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes." There are extensive bodies of public information currently available through the US EPA, Environment Canada and Health Canada, the OECD and the European Union, and California may also be able to access information which is not otherwise publicly available. In addition, vast amounts of data on chemicals will be available beginning next year through the EU's REACH program.

Finally, DTSC's regulation should be a catalyst for the advancement of Green Chemistry and further consumer product innovation. As currently proposed, the regulations would serve merely as a burden that would force businesses to leave the market in California and manufacturers in the state to move out.

SDA would like to express once again its appreciation in being able to comment on the straw proposal and the DTSC staff presentations. SDA would be happy to further assist DTSC in your development of regulations for the implementation of AB 1879 and SB 509 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@sdahq.org.

Sincerely,



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

Enclosure

cc: Michael O'Docharty, DTSC
The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
John Moffatt, Legislative Affairs, Office of the Governor
Victoria Bradshaw, Cabinet Secretary, Office of the Governor
The Honorable Joe Simitian, California State Senate
The Honorable Sam Blakeslee, Assembly Republican Leader
The Honorable Mike Feuer, California State Assembly

ATTACHMENT 5

June 24, 2009 Comprehensive Proposal for the Implementation of AB 1879 from the Green Chemistry Alliance

Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

June 24, 2009

Maziar Movassaghi,
Acting Director
Department of Toxic Substances Control
California Environmental Protection Agency
1101 I Street, 25th Floor
Sacramento, CA 95814

Re: Comprehensive Proposal for the Implementation of AB 1879 (2008)

Dear Director Movassaghi:

On behalf of the numerous trade associations and individual companies which comprise the Green Chemistry Alliance (GCA), we are pleased to submit the following proposal regarding the implementation of AB 1879 (Feuer) which together with its companion bill SB 509 (Simitian) was signed into law by Governor Schwarzenegger in September of 2008. GCA believes this comprehensive proposal, if adopted, will enable the Department of Toxic Substances Control (DTSC) to fully and successfully implement the subject legislation which will in turn enhance public health and environmental protection while respecting confidential business information and promoting principles of sustainable development.

The GCA has its roots in a group of business trade associations and companies that lobbied effectively during the closing weeks, days and hours of the 2008 California legislative session in support of bi-partisan measures to create a new science based framework for chemicals management. The driving force behind the legislation was a broad based desire for state regulators, rather than the legislators, to exercise their expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting *chemicals of concern in consumer products*. In the wake of this groundbreaking legislation, the GCA was formalized for the purpose of constructively informing the implementation effort such that the promulgated regulations remain true to the objective and scientific ideals of the authorizing legislation.

The following conceptual regulatory proposal by the Green Chemistry Alliance represents hundreds of hours of focused effort over a period of months by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national, and international chemical management policy. The proposal is a forward looking approach to identify, prioritize, evaluate and regulate the highest priority *chemicals of concern in consumer products*; and to promote truly safer

alternatives on the basis of comparative multi-media life-cycle evaluation. The proposal consists of a comprehensive set of regulatory concepts which GCA believes fully satisfy the substance and intent of legislation; and will allow timely implementation in an orderly and economically responsible manner.

The Green Chemistry Alliance believes the concept regulatory proposal detailed on the following pages is consistent with the guiding principles of the Alliance (attachment 1), and will fully and successfully implement the goals of AB 1879 and Governor Schwarzenegger's California Green Chemistry Initiative. This proposal if adopted will enhance public safety and environmental protection, and effectively promote the development of green products.

The task of chemicals management is a long-term endeavor driven by ever changing developments in science. Regardless of the resources directed toward development of data, there will always be more questions to ask and more data to gather – it is after all the nature the scientific process. The issue is not whether there is a data gap; but rather, how can the state manage its finite resources to best identify and prioritize the uses of the chemicals of greatest concern in consumer products? In the current and foreseeable economic climate, Californian must adopt regulations that focus on exposures to substances in consumer products sold or used in the state. The regulatory concept proposed by GCA "casts a wide net" which will result in an initial set of more than 2,000 chemicals for consideration and further evaluation.

These proposed regulations will drive California's economy toward the development of safer alternatives for consumer products while simultaneously providing a balanced and sustainable approach. We thank you for your consideration and we urge the department to adopt this framework.

Sincerely,

Green Chemistry Alliance Steering Committee
(Alphabetical order)

Curt Augustine
Alliance of Automobile Manufacturers

Joe Gregorich
TechAmerica

Sande George
California Paint Council

Dawn Koepke, Co-Chair
McHugh & Associates Government Relations

Gene Livingston
The Soap and Detergent Association

Laurie Nelson
Consumer Specialty Products Association

Eric Newman
KP Public Affairs

Randy Pollack
Personal Care Products Council

Mike Rogge
CA Manufacturers & Technology Association

Jeff Sickenger
Western States Petroleum Association

Caroline Silvera
Grocery Manufacturers Association

Jason Schmelzer & Robert Callahan
California Chamber of Commerce

Tim Shestek
American Chemistry Council

John Ulrich, Co-Chair
Chemical Industry Council of CA

Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

Alliance of Automobile Manufacturers

American Chemistry Council

American Forest & Paper Association

California Chamber of Commerce

California League of Food Processors

California Manufacturers & Technology Association

California Paint Council

California Restaurant Association

California Retailers Association

Can Manufacturers Institute

Chemical Industry Council of California

Citizens for Fire Safety Institute

Consumer Specialty Products Association

Grocery Manufacturers Association

Industrial Environmental Association

Metal Finishing Associations of Northern and Southern CA

National Paint and Coatings Association

Personal Care Products Council

Plumbing Manufacturers Institute

Soap & Detergent Association

TechAmerica

Toy Industry Association

Western Plant Health Association

Western States Petroleum Association

PRINCIPLES

The members of the Green Chemistry Alliance (GCA) hold that regulations promulgated by the Department of Toxic Substances Control for the purpose of implementing the Green Chemistry legislation of 2008 (AB-1879 and SB 509) conform to the following:

- Promote safe and sustainable products through the application of sound scientific methods of review;
- Avoid duplicative and conflicting regulatory and reporting requirements;
- Ensure protection of Confidential Business Information (CBI);
- Use a systematic approach in which chemicals, their uses, and potential alternatives are first prioritized based on hazard and exposure;
- Ensure balanced consideration of the unique applications, intended function, performance, and useful life of the product in question as well as other lifecycle factors required by statute;
- Impose only cost-effective, sustainable, technologically and commercially feasible requirements;
- The implementation of such regulation should minimize compliance costs and administrative burdens, and protect California jobs and consumers; and
- Support a transparent process in accordance with the California Administrative Procedures Act

* * * * *

Green Chemistry Alliance
Comprehensive Proposal for the Implementation of AB 1879

Attachment 2

The Green Chemistry Alliance regulatory proposal consists of the following sections:

- **Definitions:** Careful consideration was given in crafting definitions to ensure that data used in identifying chemicals of concern and safer alternatives is based on sound science from reliable studies and authoritative bodies. The definitions provided in the GCA regulatory proposal refer to terms within AB 1879 (Feuer, 2008). GCA does not propose to alter the definition of *consumer product* as defined in SB 509. Nevertheless, a definition of *consumer product* which includes with few exception every chemical item which is brought, sold, or leased within California (from the largest building structure to the smallest consumer retail item) begs for focus and direction. Through definitions of *consumer*, *person*, and *product* GCA's proposal seeks to provide the necessary focus which will subsequently lead to the identification and prioritization of the highest risk uses of chemicals of concern in consumer products.

- **Identification of Chemicals for Consideration:** The initial screening of a chemical will determine if it exhibits one or more of the following characteristics. Is the material: carcinogenic, mutagenic, developmentally and reproductively harmful, and/or persistent, bioaccumlative and toxic (CMR/PB&T)? If so, the chemical would be identified as a *chemical for consideration* and subject to further review. The proposal also stipulates that the department (DTSC) can identify the chemical as a *chemical for consideration* if one or more authoritative bodies, as defined, find the chemical meets the CMR/PB&T criteria. Opportunity is also provided for reconsideration based on new data.

- **Identification and Prioritization of Chemicals of Concern:** Once identified as a *chemical for consideration* the chemical undergoes additional evaluation based on the severity of the risks associated with the chemical prior to identifying the chemical as a *chemical of concern*. During this evaluation consideration will be given to the chemical's hazard exposure, volume in commerce in California, potential effects on sensitive subpopulations, and the potential for adverse impacts on the environment. The department will prioritize chemicals into high, medium, or low categories from which the high category shall be identified as *chemicals of concern. Chemicals of concern* designations may be revised periodically by the department as new data from authoritative bodies are published. A notice and comment opportunity is provided prior to a material being formally identified as a *chemical of concern.*

- **Evaluation of Consumer Products Containing Chemicals of Concern:** Upon identifying chemicals as *chemicals of concern*, the department (DTSC) will evaluate consumer products containing these chemicals, taking into consideration data from various authoritative bodies and industry trade associations or industry consortia. The consumer products containing *chemicals of concern* will be evaluated based upon the volume of the product for sale in California; the concentration of the *chemical of concern in the consumer product*; the use of the consumer product by sensitive subpopulations; potential for exposure; design features and handling recommendations for the consumer product; and environmental impacts from releases and exposures of the chemical of concern in the consumer products. Official notice and comment opportunity is provided prior to assigning high, medium, and low priorities for the uses of *chemicals of concern*

in consumer products. The department will subsequently publish a list of high priority uses of chemicals of concern in consumer products to which the department may thereafter apply the alternatives analysis.

- **Alternatives Assessment:** This framework provides for public engagement relative to identifying alternatives to a particular *use of a chemical of concern in a consumer product*. Under the GCA proposal, it is incumbent upon the stakeholders suggesting alternatives to conduct the alternatives assessment on the basis of guidance materials developed by the department. The proposal provides the option for manufacturers to conduct an assessment of the chemical in question compared to the proposed alternative, with the information being provided to the department under the confidential business information protections afforded by the legislation. Under the assessment framework, the proposed alternative(s) will be evaluated based on performance, environmental impacts; health and safety impacts, and economic impacts and feasibility. The department is then required to assess the evaluation and may request third party independent review. In a manner to be prescribed, the associated costs of the third party review would be recoverable by the department. Notice and comment opportunity is provided relative to decisions stemming from the alternatives evaluation(s). Also included are incentive and partnership opportunities relative to alternatives or the lack thereof.

- **Multi-Media Analysis:** Pursuant to the GCA proposal, a decision by the department to restrict or prohibit the *use of a chemical of concern in a consumer product*, must be supported by a multimedia life cycle evaluation based on scientific data that addresses air, water, end-of-life, worker safety, and other environmental impacts. Notice and comment opportunity is provided relative to decisions stemming from the multimedia evaluation. Upon the completion of the department's evaluation and the public comment opportunity, the evaluation would be submitted to the Environmental Policy Council for review prior to taking official action on the chemical of concern in a consumer product.

- **Regulatory Enforcement Provisions:** AB 1879 (Feuer, 2008) identifies a range of possible enforcement actions. The GCA proposal provides opportunity to employ control measures to significantly mitigate the adverse impacts from the use of a chemical of concern in a consumer product. The proposal also provides a transition period; and prohibition against a universal ban of all uses of a chemical of concern. In the case of significant regulatory action as specified, the GCA proposal calls for the department to adopt a regulation and to provide the basis for the specified regulatory actions. The proposal also provides an opportunity for an external scientific peer review prior to final adoption a proposed regulation of the use of a chemical of concern in a consumer product. The entire cost of the peer review would be borne by the requesting party.

# # # # #

GCA DRAFT REGULATION IMPLEMENTING AB 1879 (FEUER)

Section 1. Definitions.

For purposes of this article, the following definitions shall apply:

(a) "Authoritative body"[1] means a government agency or formalized scientific organization that satisfies all of the following requirements:

1. It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.

2. It is widely perceived to be objective, scientifically based, and does not engage in advocacy.

3. It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.

4. It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

(b) "Chemical of concern" means a chemical designated as such according to section 3(d).

(c) "Chemical for consideration" means a chemical designated as such pursuant to section 2.

(d) "Chemicals that cause cancer in humans" means chemicals that have been classified in (i) the International Agency for Research on Cancer ("IARC") category 1, 2a or (ii) an equivalent category in a similar classification system promulgated by another authoritative body such as US EPA, California Proposition 65, the National Toxicology Program Report on Carcinogens, or the European Union.

(e) "Chemicals that cause mutagenic effects in humans" means chemicals classified in (i) the European Union Category 1A or 1B under Annex VI, part 3 of Regulation (EC)

1272/2008 or (ii) an equivalent category in a similar classification system promulgate by another authoritative body.

(f) "Chemicals that are persistent in the environment, bioaccumulate and are toxic"[2] means chemicals that meet all of the following standards.

1. Persistent in the environment means the chemical has a half-life, as measured by reliable studies, equal to or greater than 180 days in water, or 180 days in soil, or 180 days in sediment, or 2 days in air.

2. Bioaccumulate means the chemical has a bioaccumulation factor (BAF) or bioconcentration factor (BAF), as measured by reliable studies, greater than 5000.

3. Toxic means a chemical has, as measured by repeat dose studies for mammalian toxicity or by acute or chronic studies for aquatic organisms, a subchronic oral value less than or equal to 10 mg/kg-bw/day for mammals; or, LC50 or EC50 less than or equal to 1.0 mg/L (for acute toxicity) or a No Observed Effect Concentration (NOEC) less than or equal to 0.1 mg/L (for chronic toxicity) for aquatic species.

(g) "Chemicals that cause reproductive harm" means chemicals that have been classified as reproductive or developmental toxicants by an authoritative body such as US EPA, California Proposition 65, the National Toxicology Program Center for Evaluation of Risks to Human Reproduction, or the European Union.

(h) "Clearinghouse" means the Toxics Information Clearinghouse established pursuant to Section 25256.

(i) "Consumer" means a person who used, bought, or leased for use a consumer product. The consumer of a consumer product is not the manufacturer, distributor, reseller, or retailer of a consumer product.

(j) "Consumer product"[3] means a product or part of the product that is used, brought, or leased for use by a person for any purpose. "Consumer product" does not include any of the following:

1. A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.

2. Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.

3. A device as defined in Section 4023 of the Business of Professions Code.

4. A food as defined in subdivision (a) of the Health and Safety Code Section 109935.

5. The packaging associated with any of the items specified in subparagraph (1), (2), or (3).

6. A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).

7. Mercury-containing lights defined as mercury-containing lamps, bulbs, tubes, or other electric devices that provide functional illumination.

(k) "Council" means the California Environmental Policy Council established pursuant to subdivision (b) of Section 71017 of the Public Resources Code.

(l) "De minimis"[4] means the concentration of the chemical is less than 0.1% by weight in the consumer product.

(m) "Department" means the Department of Toxic Substances Control.

(n) "Independent third party" means any party designated by the department pursuant to section 5 (e) for purposes of evaluating potential alternatives to a use of a chemical of concern in a consumer product characterized as a high priority. It is widely perceived to be objective, scientifically based, and does not engage in advocacy.

(o) "Multimedia life cycle evaluation"[5] means the identification and evaluation of any significant adverse impacts on public health or the environment, including air, water, or soil, that may result from the production, use, or disposal of a consumer product or consumer product ingredient.

(p) "Office" means Office of Environmental Health Hazard Assessment.

(q) "Panel" means the Green Ribbon Science Panel established pursuant to Section 25254.

(r) "Person"[6] means any person, firm, association, organization, partnership, business trust, corporation, limited liability company, or company and also includes any city, county, district, commission, the state or any department, agency, or political

subdivision thereof, any interstate body, and the federal government or any department or agency thereof to the extent permitted by law.

(s) “Product” does not include raw materials, feedstock, intermediates, byproducts, permitted releases, or processing aids. A product acquired for resale is not a consumer product.

(t) "Reliable studies”[7] are studies or data generated according to valid accepted testing guidelines in which the test parameters documented are based on a 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 validated in keeping with OECD principles of validation for regulatory purposes, may be considered. Those studies or data which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable may also be considered reliable studies. The methodology used by the Organization for Economic Cooperation and Development (OECD) in their *Manual for Investigation of HPV Chemicals* (OECD Secretariat, July 2007) will be acceptable for the determination of reliable studies as well as methods used in the U.S. EPA's High Production Volume Challenge Program.

(u) "Sensitive subpopulations" means subgroups of the general population, including, but not limited to, infants, children, pregnant women, the elderly, and individuals with a history of serious illness that comprise a meaningful portion of the general population and are identifiable as being more susceptible to adverse health effects than the general population.

(v) “Weight-of-evidence approach” means a transparent, criteria-based, methodological evaluation to review and interpret all available and relevant scientific research for a given issue.

Section 2. Chemicals for Consideration.

(a) The department shall compile a list of chemicals for consideration as chemicals of concern for which reliable studies conducted in accordance with good laboratory practices or data from accepted and validated models demonstrate that a chemical meets at least one of the following five criteria:

1. The chemical causes cancer in humans.

2. The chemical causes mutagenic effects in humans.

3. The chemical causes developmental harm in humans.

4. The chemical causes reproductive harm in humans.

5. The chemical is persistent in the environment, bioaccumulates and is toxic.

(b) In preparing the list required by subdivision (a), the department may include chemicals identified as meeting these criteria by one or more authoritative bodies. The department may periodically review chemicals identified by authoritative bodies and determine whether these chemicals should be evaluated as possible chemicals for consideration.

Section 3. Chemicals of concern.

(a) The department shall evaluate the chemicals on the list of chemicals for consideration for possible listing as a chemical of concern. The department may request information from the chemical manufacturer in making its determination which the department shall protect as confidential business information to the extent requested by the manufacturer. The department shall make its determination of chemicals of concern by taking into account the following factors:

1. The severity of the hazard property of the chemical in meeting the criteria under subsection (a), such as a Category 1 is more severe than a Category 2 mutagen and higher Persistence and Bioaccumulation values are more severe than lower values, and like considerations designed to indicate levels of severity;

2. The number of criteria under subdivision (a) of Section 2 that the chemical meets;

3. The production volume of the chemical in California produced annually, or if statistics are unavailable for California, the national volume of the chemical produced annually;

4. Whether the chemical is intentionally added and has a functional purpose in a consumer product versus an impurity or contaminant present in the consumer product at a de minimis level. Chemicals that are not intentionally added and have no functional purpose shall be excluded from the department's determination;

5. Whether the chemical satisfies one or more of the following factors:

A. The intended use of the consumer product containing the chemical results in repeated and substantial exposure to the chemical to sensitive subpopulations

in California through a plausible pathway, such as ingestion,dermal, or inhalation exposures;

B. The chemical used in the consumer product has been shown to be present in humans through biomonitoring performed by the federal Centers for Disease Control; the California Environmental Contaminant Biomonitoring Program, or other biomonitoring, or environmental monitoring program, performed by an authoritative body, provided the levels of the chemical detected in any one of the programs set forth above are determined by reliable studies to pose or potentially pose a significant risk to public health.

C. The use of the chemical of concern in consumer products that results in a release of a chemical of concern in an amount that results in significant adverse impacts to the environment in California.

(b) The department shall prioritize chemicals for consideration with the factors set out in subdivision (a) above based on a qualitative weight of evidence approach into "high", "medium" and "low" priority. Greater weight shall be given to human toxicity characteristics as compared to persistence and bioaccumulation; chemicals that elicit toxic effects at lower doses or have greater carcinogenic potency; chemicals found in consumer products sold at retail; and, chemicals that are intentionally added ingredients in consumer products that have the greatest potential for exposure to sensitive subpopulations.

(c) The department shall provide at least 45 days notice by publishing in the California Regulatory Notice Register the chemicals for consideration it proposes as high, medium and low priority and shall provide in a detailed statement the specific factors set out in subdivision (a) that the department relied on in making its priority decisions. The department shall also make the list and proposed priorities available on its website. Interested parties may submit written comments during the notice period. The comments may address the factors cited by the department as the basis for assigning a high, medium or low priority to a specific chemical. The department shall give good faith consideration and respond to all comments within a reasonable time.

(d) The department shall reconsider its decision to assign a priority to a specific chemical on the basis of an application supported by reliable studies and submitted by an interested party. The department shall provide at least 45 days notice of the application for reconsideration by publishing it in the California regulatory Notice Register. The department shall also make the application and the scientific support for the application available on its website. During the notice period, interested parties may submit comments in support of or in opposition to the application, relying on reliable studies. The department shall give good faith consideration to the written comments submitted, may obtain additional information or analysis to more fully inform its decision

to assign a priority to a specific chemical and shall respond to all comments within a reasonable time.

(e) A chemical on the list for consideration assigned a "high" priority shall be considered a "chemical of concern."

(f) DTSC shall make information obtained pursuant to the above available to the Division of Occupational Safety and Health for purposes of providing for its consideration in matters relating to workplace exposure to the chemicals of concern.

(g) If insufficient data exists for a specific chemical to characterize it's hazard adequately, the Department may require the chemical manufacturer to provide additional information about the chemical pursuant to Health and Safety Code section 57019, provided the Department's data needs analysis follows tiered testing procedures as used in US EPA regulatory programs and considers animal welfare interests in finding other options to testing on animals wherever possible.

Citations:

US EPA Pesticide Regulatory Requirements, 2007

US EPA Antimicrobial Data Requirements, 40CFR Part 158

Section 4. Evaluation of Consumer Products Containing Chemicals of Concern.

(a) The department may evaluate consumer products intentionally using chemicals of concern for purposes of taking the actions set forth in Sections 5 and 7.

1. In identifying consumer products using chemicals of concern, the department may consider all of the following:

    A. The U.S. Environmental Protection Agency's ("EPA's") Inventory Update Report ("IUR") database to determine an initial list of product categories with reported uses of a chemical of concern and also information on whether there are reported uses of the chemical of concern in products intended for sensitive subpopulations.

    B. The National Library of Medicine's Hazardous Substances Data Bank, the Chemical and Economics Handbook, trade association databases, chemical manufacturer and distributor sales literature, and consumer product manufacturer ingredient information.

    C. Information provided, pursuant to Health & Safety Code Section 57109, in which product manufacturers indicate whether a chemical of concern is used in any of the manufacturer's

products. Information provided shall be treated as confidential business information pursuant to Health and Safety Code section 25257 to the extent requested by the manufacturer.

D. Trade associations or consortia of manufacturers that provide aggregated data which indicates whether a chemical of concern is used in any of the associations' or consortias' member manufacturer's products. Information provided shall be treated as confidential business information pursuant to Health and Safety Code section 25257 to the extent requested by the producer of the information.

2. The department shall consider all of the following factors using a weight-of-evidence approach to determine which uses of chemicals of concern in consumer products are of low, medium, or high priority:

A. The estimated volume of sales of the consumer product in California or if statistics are unavailable for California, the national volume of sales of the consumer product produced annually;

B. The concentration of the chemical of concern in the consumer product is de minimis and is not intentionally added to serve a functional purpose in the consumer product

C. The probable route of human exposure to the chemical of concern in the consumer product that may result from reasonable and intended uses of the consumer product;

D. The use of the consumer product resulting in exposure to sensitive subpopulations;

E. The consumer product design features that eliminate or significantly minimize exposure to the chemical of concern in the consumer product;

F. Whether use of protective equipment or other mitigation measures are recommended to the consumer when using the consumer product;

G. The probable releases and exposure to the environment of the chemical of concern in the consumer product; and

H. Whether environmental releases of the chemical of concern have an adverse impact on water quality or air quality.

3. The department may also request, pursuant to Health and Safety Code section 57019, that consumer product manufacturers provide information regarding the characteristics listed under paragraph 2 of subdivision (a). Information provided

shall be treated as confidential business information at the request of the provider pursuant to Health and Safety Code section 25257.

4. The department may also request trade associations or consortia of manufacturers to provide data for the characteristics listed under paragraph 2 of subdivision (a). Information provided shall be treated as confidential business information at the request of the provider pursuant to Health and Safety Code section 25257.

(b) The department shall provide at least 45 days notice by publishing in the California Regulatory Notice Register the list of uses of the chemicals of concern in consumer products it proposes to assign as high, medium and low priority, and shall set out in a detailed statement the specific factors that the department relied on in making its priority decision. The department shall make the list of uses and the factors considered available on its website. Interested parties may submit written comments during the notice period. The comments may address the factors cited by the department as the basis for assigning a priority to a specific consumer product. The department shall give good faith consideration and respond to all comments within a reasonable time.

(c) Following the notice period and after the department responds to comments, the department shall publish its list of high priority uses of chemicals of concern in consumer products to which the department may thereafter apply the alternatives analysis set forth in section 5, and the regulatory enforcement options set forth in section 7.

(d) The department shall reconsider its decision to include or omit a specific use of a chemical of concern in a consumer product on the list of high priority uses of chemicals of concern in a consumer product on the basis of an application submitted by an interested party and supported by reliable studies. The department shall provide at least 45 days notice of the application for reconsideration by publishing it in the California Regulatory Notice Register. The department shall make the application and scientific support for the application available on its website. During the notice period, interested parties may submit comments in support of or in opposition to the application for reconsideration, basing its comment on reliable studies. The department shall give good faith consideration to the comments, may obtain additional information or analysis to inform fully its decision on the application for reconsideration and shall respond to all comments within a reasonable time.

(e) The department shall not designate a use of a chemical of concern as a high priority if the use is already regulated by another agency to address the same characteristics that would otherwise result in designation of that use as a high priority pursuant to this section.

Section 5. Alternatives Assessment.

(a) To identify potential alternatives to the use of a chemical of concern in a consumer product characterized as a high priority, the department shall publish a notice in the California Regulatory Notice Register that it is soliciting alternatives to a particular use of a chemical of concern in that consumer product. The notice shall provide that alternatives may include drop-in chemical substitutes, material substitutes, changes to manufacturing operations, changes to component/product design, or other technological solutions. Interested parties shall submit proposed alternatives within the time period set by the department in the notice.

(b) Persons proposing an alternative shall provide information on all of the criteria set forth in (c) with respect to the alternative proposed in comparison to the use of the chemical of concern in the consumer product under consideration. The department may prepare a guidance document to assist in the evaluation of viable alternatives that satisfy the requirements of this section. The information provided in this section shall be treated as confidential business information pursuant to Health and Safety Code Section 25257 to the extent requested by the producer of the information.

(c) An evaluation of alternatives to the use of a chemical of concern in a consumer product shall be conducted taking into account the following factors:

1. Performance -- Does the proposed alternative meet the performance requirements and benefits of the use of the chemical of concern in the consumer product under review? These also include but are not limited to useful life, durability, materials and resource consumption, production, in-use and transportation energy inputs and energy efficiency.

2. Environmental Impact -- Does the alternative persist and bio-accumulate and is toxic? Has the alternative been identified as meeting these criteria by one or more authoritative bodies? What impact does the alternative have on the environment from production or extraction through disposal in terms of water use, water pollution, air emissions, energy use involved in production or extraction, production, transportation, and use, greenhouse gas emissions from production or extraction through end of life? Does it have significantly less impact on the environment than the use of the chemical of concern in the current product? What are the benefits to the environment of the chemical of concern in the consumer product? An exposure assessment of the use of the chemical of concern and proposed alternatives shall be prepared regarding impacts to the environment under this paragraph.

3. Health and Safety Impact -- Does the alternative cause cancer, mutagenic effects, developmental harm, or reproductive harm? Has the alternative been identified as meeting these criteria by one or more authoritative bodies? Is it significantly less toxic to human health and safety than the use of the chemical

of concern in the current product? Does the alternative have any adverse impacts to sensitive subpopulations, including infants and children? What are the benefits to the public health and safety of the chemical of concern in the consumer product? An exposure assessment of the use of the chemical of concern and proposed alternatives shall be prepared regarding impacts to public health under this paragraph.

4. Economic Impact and Feasibility -- Is the alternative commercially available in the volumes needed to address the use of a chemical of concern in the current consumer product ? Is the cost of the alternative the same or less than the chemical of concern used in the current consumer product? Is the cost the same or less, taking into account the production or extraction of the raw materials, processing, storage, handling, use, and disposal of the alternative? What economic impacts are likely to occur to the state, the country and globally from the use of the alternative in place of the consumer product or the chemical of concern in the consumer product under review? Are there any pending or existing restrictions on the use of the alternative that might affect the ability of an industry to market its products internationally?

5. Other -- What other criteria does the alternative possess that may render it superior or inferior to the use of the chemical of concern in the consumer product under review?

(d) The manufacturer of the consumer product under review, associated trade association or similar entity, may conduct an evaluation of the alternatives in comparison to the use of the chemical of concern in a consumer product, pursuant to subdivision (c). If the manufacturer, trade association or similar entity chooses to conduct such an alternatives evaluation it shall submit the evaluation to the department according to the schedule set forth by the department and the department shall consider the evaluation as confidential business information pursuant to Health and Safety Code Section 25257, to the extent requested by the producer of the information.

(e) The department shall assess whether the evaluation is adequate for the purposes of this Act. If the department determines the evaluation is not adequate, the department may request additional data.

(f) In the absence of an evaluation by the manufacturer, trade association, or similar entity, the department shall conduct its own evaluation or commission an independent third party evaluation. In a manner to be prescribed, the associated costs of the third party review may be recoverable by the department from the manufacturers or importers of the subject materials under review pursuant to subdivision (a). Other parties independently submitting potential alternatives pursuant to subdivision (a) will be solely responsible for the department's recoverable costs associated with the third party review of their proposed alternatives.

(g) In designating an independent third party pursuant to subdivision (e), the department shall consult with affected chemical and product manufacturers and other interested parties to identify entities with the capabilities and expertise necessary to adequately and objectively evaluate potential alternatives to the use of a chemical of concern in a consumer product according to the criteria established in subdivision (c).

(h) The department shall provide at least 45 days notice by publishing the results of its alternatives review in the California Regulatory Notice Register. The department shall also make the results of its review available on its website. During the notice period, interested parties may submit comments. The department shall give good faith consideration and respond to all comments within a reasonable time.

(i) The department shall reconsider the results of its alternatives review on the basis of an application submitted by an interested party. The department shall provide at least 45 days notice of the application for reconsideration by publishing it in the California Regulatory Notice Register. The department shall make the application and the basis for its review available on its website. During the notice period, interested parties may submit comments in support of or in opposition to the application for reconsideration. The department shall give good faith consideration to the comments, may obtain additional information or analysis to inform fully its decision on the application for reconsideration and shall respond to all comments within a reasonable time.

(j) After the completion of the alternatives analysis conducted pursuant to section 5, the department may promote the use of alternatives to chemicals of concern in consumer products characterized as a high priority in any of the following ways:

1. Disseminate information about the outcome of the alternatives analysis.

2. Provide incentives to a company selecting the alternative.

3. Encourage other state agencies to make purchases of the alternative.

(k) When the department determines that no feasible alternatives exist to a chemical of concern in a specific consumer product category, the Department may take the following actions:

1. Establish voluntary public-private partnership programs to research alternative chemicals.

2. Provide incentives for the development of commercially viable alternatives for a chemical of concern in a consumer product category.

3. Provide grants to researchers for development of alternatives.

(l) Absent extraordinary circumstances, such as a major scientific breakthrough, alternatives analysis for a use of a chemical of concern in a consumer product may be conducted no sooner than five years after the last alternatives evaluation for a uses of a chemical of concern in a particular consumer product.

Section 6. Multimedia Life Cycle Evaluation

(a) Except as provided in subdivision (g), the department, in proposing a regulation restricting or prohibiting the use of a chemical of concern in a consumer product characterized as a high priority pursuant to Section 7, either based on known alternatives identified and evaluated pursuant to section 5 or in the absence of known alternatives, shall prepare a multimedia life cycle evaluation conducted by affected agencies and coordinated by the department, and shall submit each proposed regulation and multimedia life cycle evaluation to the council for review.

(b) The multimedia life cycle evaluation shall be based on the best available scientific data, written comments submitted by interested persons, and information collected by the department in preparation for adopting the regulation, and shall address, but is not limited to, impacts associated with all of the following:

1. Emissions of air pollutants, including ozone forming compounds, particulate matter, toxic air contaminants, and greenhouse gases.

2. Contamination of surface water, groundwater, and soil.

3. Disposal or use of the byproducts and waste materials.

4. Worker safety and impacts to public health.

5. Other anticipated impacts to the environment.

(c) Prior to providing formal notice of a proposed regulation in accordance with subdivision (e) of section 7, the department shall publish in the California Regulatory Notice Register notice that it is submitting to the council a regulation described in subdivision (a) of this section and a multimedia life cycle evaluation for review. The department shall also make the draft regulation and multimedia life cycle evaluation available on its website. Interested parties may submit written comments to the multimedia life cycle evaluation during its review by the council. The department shall make the written comments available to the council and shall consider the comments in revising the draft regulation. The department shall maintain for public inspection a record of any relevant materials submitted from any state agency and any written public comments received during the multimedia life cycle evaluation.

(d) The council shall complete its review of the multimedia life cycle evaluation within 90 calendar days following notice from the department that it intends to adopt regulations. If the council determines that the proposed regulation will cause a significant adverse impact on the public health or the environment, or that alternatives exist that would be less adverse, the council shall recommend alternative measures that the department or other state agencies may take to reduce the significant adverse impact on public health or the environment. The council shall make all information relating to its review available to the public.

(e) Within 60 days of receiving notification from the council of a determination of significant adverse impact, the department shall adopt revisions to the proposed regulation to avoid or reduce the adverse impact, or the affected agencies shall take appropriate action that will, to the extent feasible, mitigate the adverse impact so that, on balance, there is no significant adverse impact on public health or the environment.

(f) In coordinating a multimedia life cycle evaluation pursuant to subdivision (a), the department shall consult with other boards and departments within the California Environmental Protection Agency, the State Department of Public Health, the State and Consumer Services Agency, the Department of Homeland Security, the Department of Industrial Relations, and other state agencies with responsibility for, or expertise regarding, impacts that could result from the production, use, or disposal of consumer products and the ingredients they may contain.

(g) Notwithstanding subdivision (a), the department may adopt a regulation pursuant to Section 7 restricting or prohibiting the use of a chemical of concern in a consumer product characterized as a high priority either based on known alternatives identified and evaluated pursuant to Section 5 or in the absence of known alternatives, without subjecting the proposed regulation to a multimedia life cycle evaluation if the council, following an initial evaluation of the proposed regulation, conclusively determines that the regulation will not have any significant adverse impact on public health or the environment.

Section 7. Regulatory Enforcement Provisions

(a) Following the completion of an alternatives analysis as described in Section 5 and any multimedia life cycle evaluation required by Section 6, the department, acting pursuant to Government Code section 11340 et seq., with the exception of the provisions of paragraphs 1 and 2, may propose one or more of the following alternative enforcement requirements by regulation as necessary to mitigate the adverse environmental or public health impacts, or both, associated with a chemical of concern in a consumer product designated as a high priority pursuant to section 4:

1. Not requiring any action.

2. Imposing requirements to provide additional information needed to assess the chemical of concern in the consumer product and its potential alternatives.

3. Imposing requirements on the labeling or other type of consumer product information not conflicting with those of the Federal Government or other State agencies.

4. Imposing requirements for the manufacturer of the consumer product to manage the consumer product at the end of its useful life, including recycling or responsible disposal of the consumer product.

5. Imposing requirements that control access to or limit exposure to the chemical of concern in the consumer product.

6. Imposing a restriction on the use of the chemical of concern in the consumer product.

7. Imposing a requirement to fund green chemistry challenge grants where no feasible alternative exists.

8. Prohibiting the use of the chemical of concern in the consumer product.

(b) The department shall not prohibit the use of the chemical of concern in a consumer product, if control measures can be imposed which would significantly mitigate adverse impacts on human health and the environment.

(c) Any action by the department pursuant to subdivision (a) shall include a plan for a transition period, allowing manufacturers to procure alternative materials, change plant equipment and procedures and sell through and replenish existing inventories through the value chain.

(d) The department may not impose a universal prohibition or ban on all uses of a chemical of concern.

(e) The department shall adopt a regulation pursuant to Government Code section 11340 and following as the means for taking enforcement actions pursuant to this section. The department shall set out in its Initial Statement of Reasons the basis for its proposed enforcement action. The proposed action shall address the specific hazard causing the chemical to be characterized as a chemical of concern and the specific use of that chemical of concern that was characterized as a high priority. The department shall make findings, supported by substantial evidence, for the following enforcement actions:

1. To prohibit the use of a chemical of concern in a consumer product, the department shall find that the use poses a high probability of severe, irreversible risk to public health, safety, or to the environment such that urgent action is required; the risk of the use outweighs its benefits; and, none of the actions set out in paragraphs 2 through 7 of subdivision (a) of this section is sufficient to mitigate the risk to an acceptable level.

2. To restrict the use of, control access, or limit exposure to a chemical of concern in the consumer product, the department shall find that the risk of the use outweighs its benefits under certain circumstances or to certain sensitive subpopulations; that the risk can be mitigated to an acceptable level by the specific restriction; and that none of the actions set out in paragraphs 2 through 4 of subdivision (a) of this section is sufficient to mitigate the risk under those circumstances or to those sensitive subpopulations to an acceptable level.

3. To require the manufacturer of the consumer product to manage the consumer product at the end of its useful life, the department shall find that the product is a unique waste that cannot be more efficiently managed through the existing waste management systems; that users of the product can and will participate in the manufacturer's waste management program easily and efficiently; and that no adverse changes occur in any of the life cycle factors set out in Health and Safety Code section 25253.

4. To require additional labeling on the use of a consumer product, the Department shall find that the risk posed by the specific use can be mitigated to an acceptable level by further directing consumers on how to use the consumer product.

5. To require additional information about the use of a chemical of concern in a consumer product, the Department shall find that the hazard characteristics of the chemical of concern and the exposure profile of the use is more likely than not to pose a significant risk to human health and safety or to the environment, and that the risk has not been adequately characterized.

6. To require the funding of a green chemistry challenge grant, the Department shall find that no feasible alternative has been identified pursuant to the process set out in section 5; that the risk to human health and safety or to the environment posed by the use is significant; and is more likely than not that an alternative to the use can be developed within a reasonable time period and at a reasonable cost, and states the basis for that finding.

(f) Any person may, within 15 calendar days of the date of the public workshop on a proposed regulation of a chemical of concern in a consumer product characterized as a high priority, request the department to submit the proposed regulation, including any

related alternatives assessment and multimedia life cycle evaluation, to external scientific peer review prior to its adoption. If the department receives such a request, the department shall submit the proposed regulation, including any related alternatives assessment and multimedia life cycle evaluation, for review in accordance with subsection (g) if the person requesting the external scientific peer review enters into an enforceable agreement with the department within 15 calendar days of making the request that requires the person requesting the submission for review to fully reimburse the department for all of the costs associated with conducting the external scientific peer review.

(g) Upon entering into an agreement pursuant to subsection (f), the department shall assemble an expert panel to conduct the external scientific peer review. The department shall select individuals with expertise relevant to the potential human health and environmental impacts associated with the use of a chemical of concern in a consumer product characterized as a high priority that is the subject of the proposed regulation, including, but not limited to the pool of applicants to the Green Ribbon Science Advisory Panel. No person may serve as an external scientific peer reviewer if that person participated in the development of the proposed regulation or any related alternatives assessment or multimedia life cycle evaluation.

(h) For any proposed regulation subject to an external scientific peer review pursuant to subsection (f), the department shall not take any action to adopt a final regulation unless all of the following conditions are met:

1. The department submits the proposed regulation, along with a statement of the scientific findings, conclusions, and assumptions on which the proposed regulation is based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review panel for its evaluation. Information provided shall be treated as confidential business information at the request of the provider pursuant to Health and Safety Code section 25257.

2. The external scientific peer review panel, within the timeframe agreed upon by the department and the external scientific peer review panel, shall prepare a written report that contains an evaluation of the scientific basis of the proposed regulation. If the external scientific peer review panel finds that the department has failed to demonstrate that the proposed regulation is based upon sound scientific knowledge, methods, and practices, the report shall state that finding, and the reasons explaining the finding, within the agreed-upon timeframe. The department may accept the finding of the external scientific peer review panel, in whole, or in part, and may revise the proposed regulation accordingly. If the department disagrees with any aspect of the finding of the external scientific peer review panel, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final

regulation, including the reasons why it has determined that the proposed regulation is based on sound scientific knowledge, methods, and practices.

(i) The department shall not regulate any use of a chemical of concern characterized as a high priority if that use is already regulated by another agency to address the same characteristics that would otherwise result in regulation of that use pursuant to this section.

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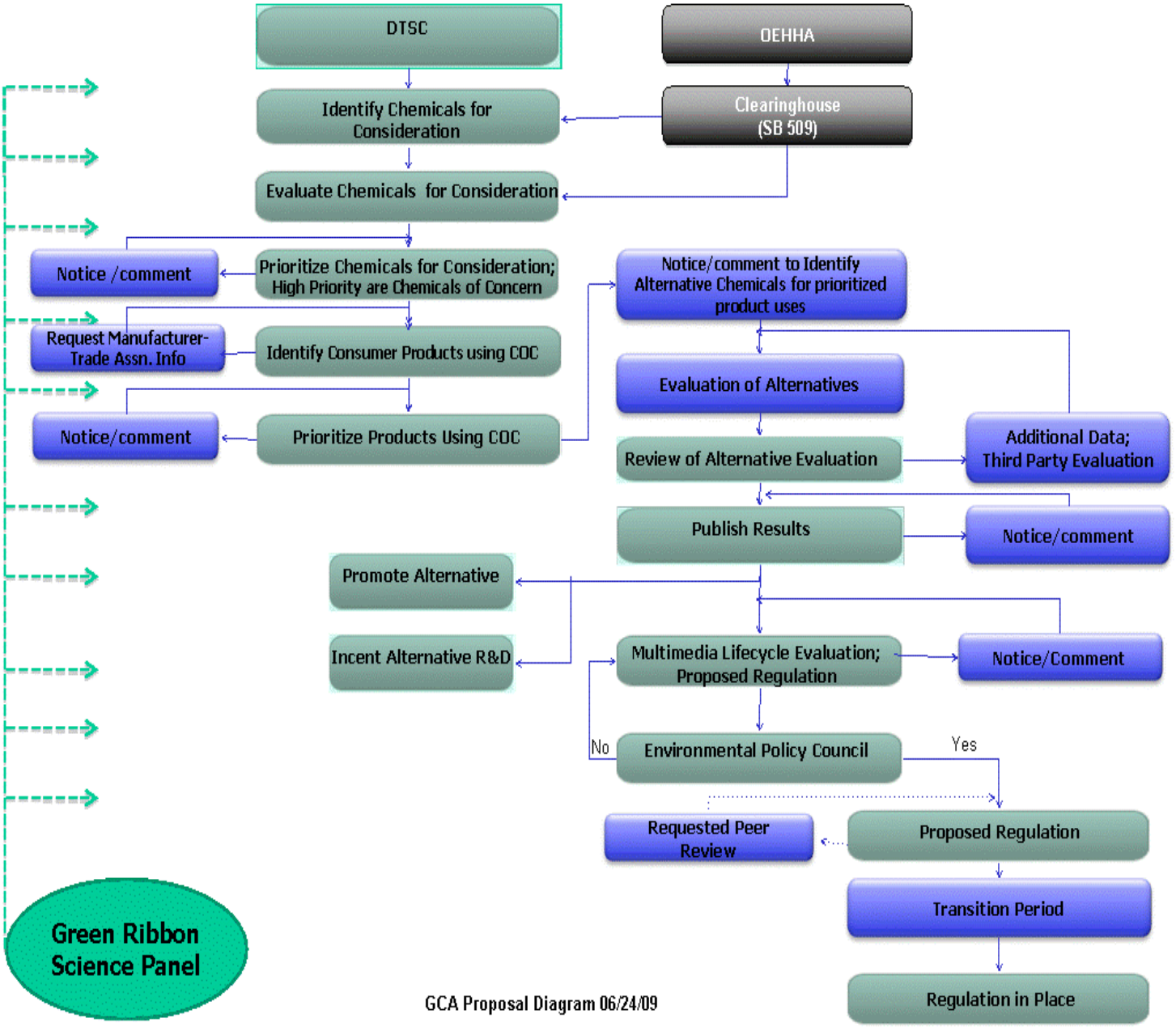
[1] IARC – http://monographs.iarc.fr/ENG/Classification/index.php
EU Annex VI, part 3 of Regulation (EC) 1272/2008 – http://ec.europa.eu/enterprise/reach/ghs/legislation/index_en.htm
California Proposition 65 – http://www.oehha.ca.gov/prop65.html
National Toxicology Program, Biennial Report on Carcinogens – http://ntp.niehs.nih.gov/?objectid=72016262-BDB7-CEBA-FA60E922B18C2540
National Toxicology Program, Center for Evaluation of Risks to Human Reproduction – http://cerhr.niehs.nih.gov/index.html
Canada DSL Categorization and Screening – http://www.chemicalsubstanceschimiques.gc.ca/categor/index_e.html

[2] Stockholm POPs – http://chm.pops.int/
US EPA EPCRA 313 PBT Rule – http://www.epa.gov/tri/lawsandregs/pbt/pbtrule.htm
US EPA Sustainable Futures/P2 Framework Program and Interpretive Guidance – http://www.epa.gov/oppt/sf/
Canadian DSL Categorization Criteria for PBT – http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria_process.cfm
Canadian DSL Categorization Criteria for Human Health – http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/categor/approach-approche-eng.php
[3]
SB 509 [Simitian, 2008], HSC 25256
[4] REACH Article 7
[5] AB 1879 [Feuer, 2008], HSC 25252.5
[6] Derived from HSC 7150.10
[7] Reliable Studies, OECD Manual for In
http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

Green Chemistry Alliance
Comprehensive Proposal for the Implementation of AB 1879

Figure 1



ATTACHMENT 6

September 13, 2010 comments from the American Cleaning Institute on *Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints* from the California Office of Environmental Health Hazard Assessment (OEHHA) released on August 11, 2010

american cleaning institute℠
for better living

September 13, 2010

Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812
(via e-mail: fkammerer@oehha.ca.gov)

Re: ACI comments on OEHHA Pre-Regulatory Proposal

Dear Ms. Kammerer:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints* released on August 11, 2010 by the California Office of Environmental Health Hazard Assessment (OEHHA) for the implementation of SB 509.

ACI is a trade association representing the $30 billion U.S. cleaning products industry. 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. 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. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate. We hope by sharing our insights from these experiences we can enhance OEHHA's implementation of SB 509.

We have a number of detailed comments below, but would like to share perspective on some more general considerations in your draft regulations.

California's identification of hazard traits and endpoints should be harmonized with other existing global systems defining those traits and endpoints.
There has been a global movement for several decades to standardize the way in which human health and environmental data are reported in order to provide global utility of that data. There are a number of harmonized systems which are being used to report data and the Toxics Information Clearinghouse (TIC) should be capable of leveraging data available in those formats. Examples include the OECD Screening Information Data Set (SIDS), the IUCLID format for reporting data under REACH, and US Occupational Safety and Health Administration (OSHA) Hazard Communication regulations which will shortly utilize the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) including its standard definitions for

hazard traits and endpoints, and standard formats for reporting hazard information. California should designate hazard traits and endpoints in such a fashion as to allow the TIC to take advantage of existing data and future data that will be generated and reported using such formats consistent with SB 509 and AB 1879.

The categories of "Toxicological Hazard Traits" in Section 3 are inconsistent with chemical human health hazard categories widely recognized and implemented internationally.
The categories of "toxicological hazard traits" described on pages 5-14 of the proposal are inconsistent with other widely recognized and implemented international categories. For example, updated hazard communications regulations recently proposed by OSHA utilize the GHS principles which include criteria for identifying hazard traits that are commonly used around the globe. Similarly, the member countries of the OECD have developed the Screening Information Data Set (SIDS) to understand chemical hazard, which is used broadly by OECD member states and others as a basis for developing information on and making regulatory decisions about chemicals. It is not clear why OEHHA failed to incorporate any aspects of these widely used and agreed upon systems in the TIC discussion document. The OSHA GHS and OECD hazard traits are ones typically encountered in discussions of chemical hazard and are based on the types of data routinely gathered in toxicity testing. In contrast, the OEHHA hazard traits classification system is overly specific. There is no need to break out systemic toxicity or target organ toxicity by specific systems (e.g., cardiovascular, gastrointestinal, liver, renal, etc.) when the goal is hazard identification. Instead, use of the OSHA GHS or OECD approaches, listing target organ effects, is more than adequate to describe a chemical's hazard.

OEHHA should seek scientific consensus on the description of "emerging" hazard trait and endpoints.
For "emerging" traits like endocrine toxicity and epigenetic toxicity, OEHHA should seek scientific consensus on the description of the trait and the appropriate endpoint(s). OEHHA should be able to show that scientific consensus exists, or they should be establishing the process for reaching that consensus where none exist, but they should not be unilaterally establishing new hazard traits.

Exposure potential is not a hazard trait.
Hazard traits are *intrinsic properties* of a chemical that may lead to adverse effects. As part of the proposed regulation, OEHHA has invented the novel "Exposure potential hazard trait." A number of physical-chemical attributes (e.g., particle size, persistence, global warming potential) have been defined as hazard traits without any scientific basis or precedent to support them. In fact, the notion of exposure potential as a hazard trait is contrary to well established principles of risk assessment, where risk is a function of hazard and exposure. Hazard and exposure are entirely separate contributing factors to risk and they should be treated as such. The individual "traits" described may be valuable physical-chemical data that could be included in the TIC as Other Relevant Data, but they are not hazard traits. The entire section should be struck from the regulation.

Environmental hazard traits should be greatly simplified to reflect the availability of the vast majority of relevant information.
The proposed regulations include, in Section 3b, an exhaustive accounting of potential biological responses in wildlife related to chemical exposures. While there are internationally harmonized test guidelines for pesticide testing, the vast majority of environmental data on non-pesticide chemicals will be aquatic toxicity data (acute, chronic and subchronic) for (freshwater species of)

algae, invertebrates (e.g., *Daphnia)* and fish. It would be the most economical use of State resources, and the best value for potential users of the TIC for environmental hazard traits to be focused on aquatic toxicity data initially, with an opportunity for the addition of other traits and endpoints as the TIC grows.

OEHHA should reconsider what "other relevant data" may be easily accessible and valuable within the context of the Toxics Information Clearinghouse.
The notion of other data that might be relevant within the use parameters of the Toxics Information Clearinghouse go beyond that of hazard traits. To the extent that the TIC is intended for businesses and consumers to understand more about chemicals and products in commerce, information regarding the market volume of chemicals, their uses and monitoring data may all be useful in the TIC. OEHHA should consider where such data may exist in standardized formats and the feasibility of incorporating it into the TIC.

California should not implement a new chemical hazard classification system.
The classification proposal should be abandoned entirely. SB 509 does not give California either the mandate or the authority to create a new hazard classification system. The classification system is a significant overstep of authority. Moreover, the entire classification provision is pejorative, unrealistic, and unhelpful. The proposal does not bring clarity to chemical information. Indeed, it increases opacity on all dimensions, as evidenced by the following:

- It inappropriately combines lack of information and a determination of no effect into a single result, "unclassifiable." This is not reflective of the real world and is of no utility to TIC users.
- It muddies the waters by lumping distinctions made in existing systems (e.g., IARC as just one example) for no apparent reason, actually decreasing information available on chemicals.
- Clearly there are chemicals where the scientific data has demonstrated that the chemical lacks certain hazard traits, including some of the most important concerns such as carcinogenicity and reproductive and developmental toxicity.
- Without identifying a class for hazard traits that recognizes the lack of activity for a chemical, rather than the lack of data, the system used to classify chemicals is flawed.
- It would be impossible to identify "non-toxic" chemicals using OEHHA's proposed classification scheme. Even the "greenest" of chemicals will be classified as hazardous or "unclassifiable." Clearly this is unhelpful.
- Finally, it appears that, a chemical is categorized as having many of the toxicities listed until such time as OEHHA or DTSC determines otherwise. Again, this is less than helpful.

In addition to the general comments above, please find a number of detailed comments on the language of the proposed regulations below:

Section 2. Definitions

Adverse effect – the definition is overly broad and without context for the purpose of defining chemical hazard traits. The definition proposed is inclusive of every degree of

perturbations without consideration of a threshold for "adverse effect." OEHHA should reconsider this definition using widely held precedents as a guide for seeking broad scientific consensus on a definition.

Adverse environmental effect – this definition suffers from the same deficiencies as the definition of "adverse effect." OEHHA should reconsider this definition.

Authoritative organization – the criteria for accepting findings from "non-governmental entities" should be reconsidered. We propose the following definition and criteria:

> "Authoritative body/organization" means a government agency or formalized scientific organization that satisfies all of the following requirements:
>
> - It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
> - It is widely perceived to be objective, scientifically based, and does not engage in advocacy.
> - It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
> - It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

Chemical substance – this definition is not harmonized with the Safer Consumer Product Alternative regulations being developed by the Department of Toxic Substances Control. At a minimum, this definition should be consistent with the DTSC definition.

Class One chemical – this definition, and Section 4, should be deleted. The statute does not give the authority for California to be classifying chemicals, and the State does not have the resources or expertise to embark on a new chemical classification program.

Class Two chemical – delete this definition.

Exposure potential characteristic – this definition, and Section 3c, should be deleted. The notion of "exposure potential" as an inherent property of a chemical is not scientifically valid and is contrary to the tenets of risk assessment. Exposure will always be a function of the use conditions of a chemical.

Not Classifiable – delete this definition.

Other relevant data – the notion of other data that might be relevant within the use parameters of the Toxics Information Clearinghouse go beyond that of hazard traits. To the extent that the TIC is intended for businesses and consumers to understand more about chemicals and products in commerce, information regarding the market volume of chemicals, uses and monitoring data may all be useful in the TIC.

Well conducted scientific studies – limiting the definition of "well conducted scientific studies" to published studies assumes that all published studies are good, and those that are not published, are bad. The scientific literature is rife with studies that are not repeatable and have not been conducted using good methods. Similarly, there are a host of "no effects" studies that are well conducted, but will never be published. The definition may be sufficient if simply stated as: "*well conducted scientific studies" means studies conducted using methods and analyses which are scientifically valid according to generally accepted principles.*

Section 3. Specific Hazard Traits, and Endpoints and Other Relevant Data

3.a.i. **Carcinogenicity** is a generally accepted hazard trait within all existing hazard identification systems. However, OEHHA should seek to harmonize their definition with those used by other widely accepted authoritative bodies (e.g., EPA, IARC, OSHA GHS, etc.).

3.a.iii. **Dermatotoxicity** is not a trait commonly addressed through standard toxicity testing. Instead, various testing batteries include studies examining endpoints of dermal toxicity such as skin sensitization, phototoxicity, and dermal irritation.

3.a.xiv. **Ocular toxicity** is an endpoint commonly addressed through testing for eye irritation and damage in standard acute toxicity tests. Since testing for eye irritation, for example, is commonly included within standard toxicity testing batteries, it is unclear why OEHHA has chosen to deviate from the standard approach to identifying hazards to the eye.

3.a.xvi. **Reactivity in biological systems** is an overly broad "trait" that is not useful for hazard evaluation since all chemicals could be considered to "react" with biological systems simply by being absorbed into a cell. The related endpoints appear to fit more easily within other hazard trait categories as underlying mechanisms or modes of action. This trait should be eliminated.

3.a.xvii. **Reproductive toxicity** is a generally accepted hazard trait within all existing hazard identification systems. However, some reproductive system changes observed in toxicity studies are produced only when doses exceed a maximum tolerated dose for the parental test animals and thus are not relevant for chemical hazard assessment. The omission of any discussion or consideration of exposure or dose levels when assessing the reproductive toxicity hazard trait is a significant flaw in the document.

3.b.vi. **Loss of genetic diversity** occurs based on site-specific conditions within any ecosystem. It is not an inherent chemical trait and should not be included as a hazard trait. Even the most innocuous chemicals (e.g., table sugar) could be considered hazardous based on this definition. This trait should be eliminated.

3.b.vii. **Eutrophication** occurs based on site-specific conditions within any ecosystem. It is not an inherent chemical trait and should not be included as a hazard trait.

3.c. **Exposure potential hazard traits -** The notion of "exposure potential" as an inherent property of a chemical is not scientifically valid and is contrary to the tenets of risk assessment. Exposure will always be a function of the use conditions of a chemical. As such, Section 3c should be eliminated. However, a number physical-chemical parameters mentioned which may be "other relevant data" that could be included within the TIC;

e.g., bioconcentration factors (BCF), bioaccumulation factor (BAF), half-life, water solubility, pharmacokinetic data.

3.c.x. Toxic environmental transformation – The concept proposed in this section is seriously flawed. For degradation of organic compounds, it is generally considered desirable for those compounds to be completely mineralized to carbon dioxide. However, CO_2 would likely be more persistent than many organic compounds resulting in irrelevant hazard identification. This is but one example if this ill-conceived concept.

3.d. Physical hazard traits – Any identification of physical hazard traits should be consistent with terminology used by the Department of Transportation (OSHA) and the Occupational Safety and Health Administration (OSHA).

3.d.iii. Nanomaterial hazard trait – Recently, the International Standards Organization (ISO) Technical Committee (TC) 229 Nanotechnologies achieved the first international consensus definitions for core terms like nanotechnology and nanomaterial, as well as engineered nanomaterial and manufactured nanomaterial. ISO has established designated series number 80004 to facilitate the distribution and usage of consensus terms. California should harmonize their "nano" definitions to be consistent with other international bodies such as ISO.

While chemicals may exhibit different properties based on their relative size, to identify a chemical as hazardous based on this phenomenon is contradictory to chemical identification and hazard identification. The more appropriate approach to handling this phenomenon is to identify chemicals uniquely based on various structures, when appropriate, and to conduct hazard screening on the unique chemical.

Section 4. Sources and methodologies for identifying toxicological and environmental hazard traits.

This section should be eliminated entirely. SB 509 does not give California either the mandate or the authority to create a new hazard classification system. Moreover, the entire classification provision is pejorative, unrealistic, and unhelpful. The proposal system does not bring clarity to chemical information.

ACI would like to express once again its appreciation in being able to comment on the pre-regulatory draft regulations. We would be happy to further assist OEHHA in your development of regulations for the implementation of SB 509 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

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