Alliance of Automobile Manufacturers

American Chemistry Council

American Cleaning Institute

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 Healthcare Products Association

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

TechAmerica

Toy Industry Association

Western Plant Health Association

Western States Petroleum Association

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:

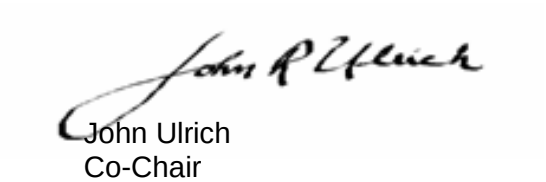
- Absence of clear and workable science-based standards to support priority decisions - language such as, "pose threats" and "adverse impacts to public health and the environment" are not specific enough to be workable;
- *De minimis* as an all or nothing proposition and the expansion of scope beyond 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.

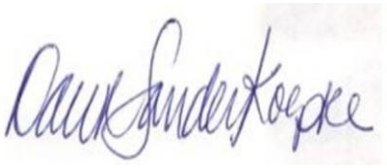
GCA and its members appreciate the work DTSC and other interested stakeholders have invested in this process. And while GCA remains highly concerned about the direction of the draft regulation, we remain committed to working with DTSC and other stakeholders to finalize reasonable and effective regulations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

# # #