Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

December 3, 2010 (Transmitted via E-Mail)

Mr. Jeff Woled, Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives
Proposed Regulations – Post-Hearing Changes, R-2010-05
November 16, 2010

Dear Mr. Woled:

On behalf of the Green Chemistry Alliance ("GCA"), we respectfully submit the following comments relative to the Department of Toxics Substances Control's (DTSC or department) revisions to the proposed Safer Consumer Product Alternatives Regulation ("regulation") of November 16, 2010. GCA acknowledges many of the post-hearing changes made by the department in an attempt to make the proposal more streamlined and workable. Elimination of the troublesome Tier I Alternatives Assessment (which would have had a stifling effect on innovation), and the streamlining of the Tier II Alternatives Assessment process are two of the more notable improvements.

Despite these and other changes, which are discussed in detail within the attached comments, many serious problems remain unresolved or merely deferred to a later time. One of the largest continuing problems is a failure to more clearly enunciate the criteria and process for consistently and systematically identifying and prioritizing *chemicals of concern* and *priority products.* Instead of a process, the regulations focus on three product categories for a five year period and after which time all restraint is lifted.

In posting the 15-Day Notice and Comment Period regarding the post-hearing changes, DTSC writes, "*After January 1, 2016, there is no limitation or specification of the types of products that may be identified as priority products. Even the initial restricted list of possible priority products captures tens of thousands of products. After that, the possible category of priority products grows exponentially.*

The manufacturers and retailers of the broad spectrum of product categories in California's stream of commerce, take little comfort in having avoided selection in the initial round of the revised regulation. Clearly, they will face a regulation in the 2016 and beyond subjecting them to a priority product

selection process which is for all intents and purposes undefined. GCA has stated in its comments of November 1, 2010 that decision criteria and process must be clearly articulated.

Additionally, confidential business information (CBI) must be protected if California is to take full advantage of the public health, environmental, and economic opportunities envisioned by the Governor's Green Chemistry Initiative. For GCA members, CBI issues have been and continue to be major points of contention with the regulations. While admittedly improved, fundamental problems still await resolution.

These persistent ambiguities mean an innovator or manufacturer cannot determine whether a product under development today will in five year's time be subject to regulation or perhaps even prohibition by the DTSC. Moreover, the innovator or manufacturer may not be able to sufficiently safeguard its confidential business information. This lack of clarity cannot help but be a disincentive to the development of new technologies and products in California.

California's embrace of green chemistry is a visionary step that carries the potential to deliver real benefits to consumers and our state. It is too important an idea to receive anything less than the best effort that all involved parties can offer. For our part, the Green Chemistry Alliance will remain focused on participating in the process of establishing a sound, science-based system that will benefit consumers and inspire innovation and investment.

For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. You may also visit the Green Chemistry Alliance website at www.greenchemistryalliance.org. 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
Scott Reid, Cabinet Secretary, Office of the Governor
John Moffatt, Legislative Affairs, Office of the Governor
Maziar Movassaghi, Acting Director, DTSC
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Green Chemistry Alliance Signatories

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Cleaning Institute
American Coatings Association
American Forest & Paper Association
Amway
Association of Home Appliance Manufacturers
Association of International Automobile Manufacturers
Automotive Aftermarket Industry Association (AAIA)
BASF
The Boeing Company
California Aerospace Technology Association
California Automotive Wholesalers' Association (CAWA)
California Chamber Commerce
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
DuPont
Ecolab
Ellis Paint
EPS Molders Association
ExxonMobil
Fashion Accessories Shippers Assoc
Florida Chemical Company, Inc
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Independent Lubricant Manufacturers Association
Industrial Environmental Association
IFRA North America
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 Electrical Manufacturers Association
National Shooting Sports Foundation (NSSF)
Natural Products Association
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Rio Tinto
Rubber Manufacturers Association
SABIC Innovative Plastics
Scott's Miracle-Gro Company
Silicones Environmental Health and Safety Council
Smith & Vandiver
Solar Turbines
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
Synthetic Amorphous Silica & Silicate Industry Assoc.
TechAmerica
The Clorox Company
The Dow Chemical Company
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

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Guide to GCA Comments
regarding
Revisions to the Proposed Safer Consumer Product Alternative Regulations
(R-2010-05; November 16, 2010)

ARTICLE 1 – GENERAL

Section 69301 - Purpose and Applicability

Section 69301.1 – Definitions

Section 69301.3 - Duty to Comply and Consequences of Noncompliance

Section 69301.4 – Information Submission and Retention Requirements

Section 69301.5 – Chemical and Product Information

Chemical Ingredient Information

Market Information

ARTICLE 2 – CHEMICAL PRIORITIZATION PROCESS

Section 69302.2 - Chemicals of Concern Prioritization

Section 69302.3 - Chemicals of Concern Prioritization

ARTICLE 2 & 3 - CHEMICAL & PRODUCT PRIORITIZATION PROCESSES
General Comments

Elimination of Chemicals Under Consideration and Products Under Consideration

Science Based Decisions for Chemicals of Concern and Priority Products.

ARTICLE 3 – PRODUCT PRIORITIZATION PROCESS

Section 69303.2 – Product Lists

Section 69303.3 - Priority Products Prioritization

ARTICLE 5 – ALTERNATIVES ASSESSMENTS

Former Section 69305.1 Alternatives Assessment Notification & Tier 1 AA Reports

Section 69305.1 – Alternatives Assessments: General Provisions

Section 69305.2 – Alternatives Assessment Work Plan

Section 69305.3 – Evaluation and Comparison Process and Factors

Section 69305.4 – Alternatives Assessment Reports

ARTICLE 6 – REGULATORY RESPONSES

Section 69306.2 – No Regulatory Response Required

Section 69306.4 – End of Life Management Requirements

Section 69306.5 – Product Sales Prohibition

Section 69306.7 – Exemption from Regulatory Response Requirements

ARTICLE 7 – DISPUTE RESOLUTION PROCESSES

Section 69307. 1 Informal Dispute Resolution Process

ARTICLE 8 – AUDITS

Previously Section 69308

ARTICLE 9 – CONFIDENTIALITY OF INFORMATION

Section 69309.1: Assertion of a Claim of Confidential Information

Section 69309.1 - Support of a Claim of Trade Secret Protection

Time to Respond

Justification Factors

Substantiating Information

The following are included by reference from the November 1, 2010 Comments

EXHIBITS

1) GCA Regulatory Proposal – June 24, 2009
2) GCA Straw 2 Comment Letter – November 9, 2009
3) GCA "Goal Post" Letter – May 27, 2010
4) GCA Draft Regulation Comment Letter – July 22, 2010
5) GCA OEHHA Pre-Draft Hazard Trait Regulation Comment Letter – September 13, 2010
6) GCA letter to CA Environmental Policy Council (EPC) – November 26, 2010
7) GCA Safer Consumer Product Alternative Regulation Comment Letter – November 1, 2010

ARTICLE 1 – GENERAL

Section 69301 - Purpose and Applicability

Subdivision (b)(4)(A) - As modified in the revised regulations, appropriately focuses the applicability of the regulations on intentional ingredients in consumer products.

Subdivision (b)(4)(B*)* - This paragraph, added in the revised regulations, results in continued significant limitations on intentionally added chemicals. In particular, it excludes from the unintentionally added portion of the regulation chemicals, chemical ingredients, chemicals in recycled feed stock, or a component or processing agent unless there is a lack of awareness of the presence of the chemical after taking reasonably feasible steps.

Additionally, this provision creates ambiguity as to what is required in "taking reasonably feasible steps to obtain knowledge of the chemical." Components of assembled products, like formulated products, may contain both intentional and unintentional ingredients.

From a public policy perspective, this will have the unintended consequence of discouraging the use of recycled feedstock because of the uncertainty about what might be present. Until Chemicals of Concern are removed from primary uses, they have the potential to remain in recycled feedstock. The current iteration of the rule imposes a disproportionate burden on those who use recycled feedstock. To the extent that the regulation achieves its purposes of encouraging manufacturers to consider alternatives, it builds a disincentive to recycle into the regulations, which seems shortsighted at best. GCA opposes these changes and recommends that the recycled feedstock and component exclusions be dropped.

Subdivision (b)(5) – This subdivision is new to the revised regulation. It provides that this chapter does not apply to a chemical or consumer product subject to regulation by one or more federal or other California state regulatory programs or international trade agreements, if the other regulatory program addresses "the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the basis for the product being listed as a Priority Product."

GCA, to the extent that it understands the impact of this provision, supports the revision and the re-articulation of the effect of a chemical or product being subject to other regulatory programs. The language in subdivision (b)(5) refers to "the same public health and environmental threats." Section 69302.3 of these regulations pertaining to chemicals of concern prioritization refers to public health and environmental threats. Specifically, subdivision (a)(1)(A) through (F) refers to the "relative degree of threat posed by each chemical to public health or the environment. The threats listed are physical chemical hazards, adverse public health impacts, adverse ecological impacts, adverse air quality impacts, adverse water quality impacts, and adverse soil quality impacts." GCA assumes, and asks the department to confirm, that the "public health and environmental threats" provision in subdivision (b)(5) of section 69301 are the six threats described in section 69302.3 and listed above in these comments. If so, the provision in subdivision (b)(5) of section 69301 would appear to be consistent with the statutory provisions contained in Health and Safety Code section 25257.1.

GCA also suggests that the reference to "international trade agreements ratified by the United States Senate" is overly limiting. Where international laws are sufficient to address the potential

concerns and California residents are benefiting from manufacturer compliance with those international laws, California's Proposed Regulation should not duplicate those existing requirements. We suggest adding after "international trade agreements ratified by the United States Senate," a reference to "other international laws."

Subdivision (b)(6)(A) – The revision to add "reasonably foreseeable exposure" (in Section 69301 (b)(6)(A)) is a significant improvement to these regulations that will provide an essential criterion for evaluating situations where there is insufficient exposure to a chemical of concern to pose a threat. This criterion builds on federal regulations that rely on the concept of a "reasonable and foreseeable" criterion to evaluate whether or not a product will expose a consumer to a chemical at levels that will cause harm. Thus, it is essential that DTSC maintain this reference to this criterion to provide a protective, yet reasonable standard in the Regulations for determining exposure pathways. This criterion acknowledges the "real-world" planning, design, and control that responsible companies must undertake to prevent exposure to a chemical and the "real-world" use patterns of products.

However, the GCA is adamantly opposed to the inclusion of the concepts of "misuses and abuses" and "improper end-of-life management of the product". The U.S. Environmental Protection Agency (EPA) has embraced this approach of using "reasonable and foreseeable" in the agency's waste management requirements for small and large quantity handlers of universal waste pesticides. See 40 CFR 273.13(b), and 40 CFR 273.33(b). The Federal Hazardous Substances Act also requires that certain hazardous household products bear cautionary labeling to alert consumers tot he potential hazards that those products present. These labels are required when a product may cause "substantial personal injury or substantial illness during or as a proximate result of any customary or reasonable foreseeable handling or use, including reasonable foreseeable ingestion by children." Emphasis added, see, definition of "hazardous substance", 15 USC Section 1261(f)(1)(A).

Regulations incorporating "reasonable and foreseeable" do not suggest that a manufacturer of a consumer product can foresee every hypothetical misuse, abuse, or improper use and management of the product. These concepts are not supported by existing regulatory schemes and threaten to negate the real-world planning for exposure control that this section should address. Beyond product design to prevent concerns, label warnings, together with instructions for use and disposal are directly aimed at assuring safety of use and disposal. To include this language could suggest that any "unreasonable" use of a product as grounds for exposure. This situation would undermine Federal uniformity and necessary understanding of relevant exposures that would be actionable under this regulation.

GCA Recommends that section 69301 (b)(6)(A) be amended as follows:

> "***A determination pursuant to this subparagraph shall be based upon an evaluation of reasonably foreseeable uses~~, misuses and abuses~~ of the product, and reasonably foreseeable ~~proper and improper~~ end-of-life management of the product."***

Subdivision (b)(6)(B) - This paragraph requires a person requesting DTSC to make a determination about exposure to prove by clear and convincing evidence that no exposure posing a threat is reasonably foreseeable. The standard of proof for purposes of Sections 69301(b)(6)(B) and 69306.6(b)(6) should not be artificially elevated. These sections now

require a showing by "clear and convincing evidence" and in the case of Section 69301 "to the department's satisfaction". There is no basis in the authorizing statutes for such a disparity in standards. Indeed, without any empirical basis for such an assessment, establishing such a dichotomy is inherently arbitrary and a violation of the California Administrative Procedure Act. These enhanced standards should be excised. These decisions relate to hazard, exposure and product safety and in the toxicology arena "weight of evidence" is the standard applied to such decisions. If a standard is necessary for this section, GCA recommends "weight of evidence." These decisions relate to hazard, exposure and product safety. In the toxicology arena "weight of evidence based on valid scientific information" is the standard applied to such decisions. GCA recommends the phrasing "*weight of evidence based on valid scientific information*" if a standard is necessary for this section.

Section 69301.1 – Definitions

Subdivision (a) (4-8, 35, 59, 60, and 86) - Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, environmental fate properties, physical hazards and Waste/end-of-life. In general, taken together with the elimination of the 4-5 pages of OEHHA hazard traits, this is an improvement as many of the factors mentioned are traditional endpoints addressed in state, federal and international chemical programs. However, there are a number of concerns in these definitions.

- First, some factors are scientific frontier issues (*e.g.*; epigenetic toxicity), which are not settled science and do not belong in these regulations. In his peer-review, William Farland suggests that "epigenetics" is a valid endpoint as long as it is toxicity-related. However, this makes the implicit assumption that we know which "epigenetic" changes are implicated in the etiology of disease and that is not yet the case. Moreover, the type of information that would satisfy consideration of epigenetics is completely unclear. In addition, the term "organ, tissue or cellular toxicity not otherwise described" is ambiguous and could describe an enormous universe of endpoints. GCA recommends these terms be removed from the current definition of adverse health impacts, or that these terms are more appropriately defined with agreement from multiple stakeholder groups.

- Second is measurement capability—many factors have federal and/or internationally accepted guideline methodologies (e.g. acute toxicity, carcinogenicity), but many do not (e.g. loss of biodiversity, population loss, direct or indirect vegetation contamination). For the many that do not have validated protocols, it will be difficult if not impossible to address those items in DTSC Priority Setting or in Alternative Assessment other than with a "no known impact" statement. Factors within the impact and property definitions that do not have scientifically accepted and validated measurement protocols should be removed.

- Third, some studies are regularly completed to characterize a chemical's hazard traits, (e.g. acute aquatic toxicity, biodegradation), but others are done only when a concern is triggered by concerns identified in lower tier studies (e.g. acute/chronic avian toxicity, reproductive toxicity, bioaccumulation). The listing of all factors that can be measured by accepted and validated protocols must in no way imply that the regulated community should conduct such protocols. Such an approach would be wasteful of resources. In

cases where unavailable information is of interest, tier-based testing and other scientifically sound concepts should be employed.

- Fourth, the adverse water quality impact includes four (4) specific regulatory lists of chemicals as one of the criteria, with no threshold levels. These four (4) lists are not appropriate in the definition of adverse water quality impacts and should be removed from the revision.

- The overriding concern with these adverse impact and chemical property definitions is that there are no threshold levels to provide a context for what is of concern. All chemicals including water have a toxic impact at some level. The absence of thresholds in the regulations suggests that every substance could be a priority Chemical of Concern because it has some impact, no matter how small or large. The definitions should clearly state that the adverse impact occurs when a threshold is exceeded. However, that necessitates thresholds being included in the definition. For the purposes of these definitions, those thresholds may need to be quantified on a case-by-case basis (i.e. "Adverse air quality impacts" means air emissions of any of the air contaminants listed below in quantities that result in an unreasonable public health risk:…"

Subdivision (a) (10) Bioaccumulation - This definition is unchanged and as such, is scientifically inadequate. In GCA's November 1, 2010 comments, we noted that the proposed definition for bioaccumulation was inconsistent with nationally and internationally accepted definitions. Terrence Collins and other peer reviewers commented on this issue. It's not clear why such an important chemical property, with a long history of federal and international standard setting and chemical control actions should be defined with a California-unique approach. This will disconnect the state from the capability to use any existing data or scientific approaches and slow Green Chemistry progress as the department attempts to translate all of the extensive information, learnings, and actions from global programs into a California-unique approach. DTSC has repeatedly failed to justify choosing to adopt a novel definition despite multiple calls from GCA not to do so. GCA reiterates the recommendation that the bioaccumulation definition be changed to be consistent with definitions in the following:

EPA policy statement entitled "Category for Persistent, Bioaccumulative and Toxic New Chemical Substances (64 Fed. Reg. 60194; Nov. 4, 1999)

Stockholm Convention on Persistent Organic Pollutants http://chm.pops.int/default.aspx

Subdivision (a) (11) Carcinogen or reproductive toxin – The definition references toxin. This should be revised to read "…toxicants" as a toxin refers to poisonous substance that is produced by living cells or organisms (*i.e.* protein) and is capable of causing disease when introduced into the body tissues.

Subdivision (a) (11) (F) – GCA accepts the inclusion of the list of chemicals within Annex VI of Regulation (EC) No. 1272/2008 of the European 23 Parliament and the Council. It is the understanding of GCA that this definition specifically covers the list of hazardous substances for which harmonized classification and labeling have been established at Community level. This would consist of Table 3.1 from Annex VI where the classification and labeling are based on the criteria in Annex I to this Regulation, and Table 3.2 where classification and labeling are based

on the criteria in Annex VI to Directive 67/548/EEC. GCA asks the department to confirm this understanding.

Subdivision (a)(12) Chemical – This definition has been altered to remove nanomaterials from the definition of "chemical." GCA supports this change and presents additional comment under the heading Subdivision (a)(50)A through (D). This revision to the definition of "chemical," however, is still defective in as much as it continues to include both chemical substances ***and*** chemicals mixtures. GCA reiterates its earlier comment that we disagree with this approach. [*see GCA's November 1st comment letter, incorporated by reference*] GCA is also concerned with new language in the definition of "chemical," which combines both chemical substance and chemical mixture, is unclear to manufacturers and is not aligned with TSCA. We recommend that chemical be defined the same as chemical substance.

Subdivision (a)(16) and (19) Chemical Substance and Chemical Mixture – While these definitions conformed to the federal definitions in TSCA, they do not include the FDA exemption language.

Specific to the definition "chemical mixture," it is overly confusing and should instead be consistent with the Toxic Substance Control Act (TSCA) definition of chemical mixture. See, 40 CFR 710.2(q). To that end, GCA recommends defining 'chemical mixture' as "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."

Subdivision (a)(20) children's products – The 15-Day Changes Proposal now include a definition of "children's products" as those intended primarily for children 12 years or younger. This definition is divergent from the U.S. Consumer Product Safety Commission's definition of these products; as used under the Consumer Product Safety Improvement Act (CPSIA). The GCA urges DTSC to make the definition of "children's products" consistent with the U.S. CPSC.[1]

Subdivision (a)(22)(B)2 Consumer Product (exclusions) – This paragraph excludes from the definition of a consumer product a chemical that meets the definition of a consumer product, but that is not packaged and placed into the stream of commerce in California as an individual chemical. This articulation presumably of an intermediate is too vague and requires clarity. GCA's concern regarding whether selling a chemical in barrels or in a train car falls within the exclusions from the definition of a consumer product. GCA recommends the subdivision (a)(22)(B)2 be amended to read, "…A chemical that meets the definition of a 'consumer product'', as defined in Health and Safety Code 25251, but that is not packaged for sale at retail, and placed into the stream of commerce in California, as an individual chemical."

Subdivision (a)(25) De Minimis Exemption Notification – While GCA believes the De Minimis Exemption being changed to a "notification" versus the previously proposed "request" is an improvement, GCA still finds the provision troublesome and believes it should be eliminated. Please refer to detailed comments under section 69303.2(d)(3).

[1] U.S. Consumer Product Safety Commission, http://www.cpsc.gov/about/cpsia/faq/children.html

Subdivision (a)(26) De Minimis Level – GCA appreciates the changes made to the de minimis level definition and the acknowledgment that exempting products containing chemicals of concern below a de minimis threshold assists with focusing resources on those products that may pose the greatest risk. However, GCA makes the following recommendation for clarifying the remaining sections related to de minimis and further streamlining the process.

GCA supports the change in the 15-Day Revisions to set the default De Minimis at 0.1%, harmonizing with national and international practices and acknowledging that exempting products containing chemicals of concern below a de minimis threshold assists with focusing resources on those products that may pose the greatest risk.

However, GCA believes that the alternative de minimis level at §69301.1(a)(26)(B), applying hazardous waste regulatory thresholds, is unnecessary and should be eliminated from the regulation.

The 15-day Notice states "This change [application of hazardous waste regulatory threshold] is necessary so that there is no inadvertent conflict between the hazardous waste requirements and these regulations as they may apply to the same product, particularly at the end of the useful life of a product."

GCA is of the opinion that there is no conflict between the regulations—if a product fails the test, it would still be hazardous waste regardless of whether it meets or exceeds the 0.1% de minimis threshold. Further, the application of the hazardous waste regulation thresholds pertains to the end of a product's useful life and its waste management status. It does not pertain to a product's impact on public health and the environment during its useful life. Finally, the threshold is based on a measurement of leachate from the product, which has no correlation with the measurement of concentration in product. As such, it is unnecessary, scientifically unsound and should be removed.

Subdivision (29) Economic Impact Analysis – For clarity, the definition should refer to the impacts in definition (30) rather than 69305.3(f) since that section refers back to definition (30) economic impacts. GCA also suggests below a change to the definition of (30) economic impacts.

Subdivision (30) Economic Impacts – This definition is duplicative because (B) and (C) are the results of the evaluation of (D) – (I). Jobs or businesses in subsection (A) is confusing as it appears that this is meant to be labor costs, but may be interpreted to be the impact on the supply chain from selecting different alternative suppliers. Asking a company to evaluate the impact to jobs or businesses throughout the supply chain is unnecessary and causes an intrusion into the marketplace. GCA's concerns are heightened given the use of the definition in Section 69305.3. Specifically, the economic impact definition may be interpreted by some to be an exhaustive list, but that is not the case. Responsible entities should not be limited to the factors identified in (30) as the only economic impacts that would be relevant to consider. We suggest that economic impacts should be defined as "those costs of bringing the new chemical alternative into the marketplace, removing the existing Chemical of Concern from production, and use of the alternative in the manufacture of the Priority Product." Although not an exhaustive list, some of the factors that would be included in such an evaluation are capital investments, freight, labor, chemical costs, maintenance, packaging, waste disposal, and

others. GCA also notes that much of this information will need to be protected from disclosure and should be carefully considered by DTSC.

Subdivision (a)(31) Economic Interest – The standard of a two thousand dollar interest is unreasonably low and may well have been adopted many years ago. Further, the standard set forth in Section 18703.1 of Title 2 of the California Code of Regulations is intended for application to the interests of government officials, those who have a fiduciary duty to the citizens of the State. Thus there is an increased sensitivity to even the appearance of conflict. That's not the case here. DTSC only needs to assure that an assessor does not have a material economic interest in any particular result and apply a threshold that someone could reasonably be expected to identify in this age of complex investment instruments. GCA recommends subdivision (a)(31)(A) be revised to read "…Has a direct ~~or indirect~~ investment or controlling interest worth ~~two thousand ($2,000)~~ twenty-five thousand ($25,000) or more in the responsible entity…"

Subdivision (a)(41) Functionally Equivalent – The definition for functionally equivalent performance standard is changed to "meets or exceeds" the intended performance of the original. GCA supports this change.

Subdivision (a)(44)(A) Hazard Trait – This defines the source lists for potential chemicals of concern until OEHHA promulgates its initial list of hazard traits. Three sources have been added in paragraphs d-f. These reference EPA's Action Plan chemicals, along with chemicals listed in the Clean Water Act (CWA) sections 303(c) and 303(d). By definition, the chemical in all three of these source lists are regulated by federal agencies and should not be included in the definition of "hazard trait." On the Action Plans, EPA has published extensive plans for regulation under multiple provisions in TSCA. Including EPA Action Plans is an obvious case of regulatory duplication.

Further, reference to 303(d) "chemicals" is disjointed and inappropriate. In general, the CWA regulates "pollutants" – not chemicals. There are many 303(d)-listed pollutants that are NOT chemicals – e.g. sediment, nutrients, temperature, and even trash, which illustrates that this list is completely inappropriate for making it synonymous with "hazard trait".

Beyond that, these additions seem to be at odds with the fundamental approach toward defining chemicals of concern based upon consideration of hazard traits. As noted, the Office of Environmental Health Hazard Assessment is to provide a list of hazard traits, against which chemicals are to be assessed to determine whether they merit evaluation for possible designation as "Chemicals of Concern." These 3 additions are inappropriate in that they do not add or reference hazard traits; they are simply lists of chemicals. To the extent these chemicals do, indeed, possess hazard traits of concern, they would already be considered in the process. To the extent this is documented as the rationale for inclusion on these lists, the referencing of the lists is superfluous and confusing. However, where the traits of concern to California have not been documented for chemicals on these lists, their inclusion is inappropriate. We recommend these three paragraphs be deleted from the proposed regulation.

Subparagraph (a)(44)(A)2:

Item 2.a., The definition references carcinogen or reproductive toxin. This should be revised to toxicant as a toxin only refers to a poisonous substance that is produced by living cells or organisms (*i.e.* protein).
Item 2.c., it should be made clear that the hazard trait is persistence, bioaccumulation and toxicity in combination.
I**tem 2.d**., it should be made clear that the hazard trait is toxicity by virtue of the listing.
Item 2.e, the particular hazard trait that is the basis of the listing, likely toxicity, should be clarified.
I**tem 2.f.**, listing of chemicals as part of the USEPA Existing Chemical Action Plan is not a hazard trait, per se. It may be appropriate to consider the hazards associated with a particular chemical or group of chemicals which were the basis for the Plan. However, the department would need to evaluate the Plans and articulate which hazards are appropriate for designation as a hazard trait. This seems contradictory to the purpose of this provision and would necessitate establishment of a new listing program by the department. As such, this paragraph should be removed.

Subdivision (a)(45) Household Cleaning Products – GCA believes the definition of Household Cleaning Products is less an actual definition and more a listing of product categories which appear to come from the California Air Resources Board's (CARB) program on volatile organic compounds (VOCs) in consumer products. Many of these "cleaning products" are not, in fact, cleaning products (e.g., fabric softener, floor polish) and some are specifically exempted from the regulations (disinfectants).

We recommend that this definition be changed to be composed of two parts. First, "household product" should be defined such that the definition is synonymous with regulations under the Fair Packaging and Labeling Act for a **consumer commodity**[1]. Second, to the extent that the department wants to narrow the universe of household products considered, it should list those particular product categories in Section 69303.3(c)(1) using existing definitions, such as those which already exist under the CARB VOCs in consumer product regulations (17 CCR § 94500-94575). Alternatively, in 2008 the American Cleaning Institute, the Consumer Specialty Product Association and the Canadian Consumer Specialty Product Association developed an ingredient communication initiative (http://www.cleaninginstitute.org/sustainability/ingredient_communication_initiative.aspx) as a

[2] 16 CFR 500.2(c) "The term **consumer commodity** or commodity means any article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use. For purposes of the regulations in this part the term consumer commodity does not include any food, drug, device or cosmetic as defined by section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); any meat or meat product, poultry or poultry product, or tobacco or tobacco product; any commodity subject to packaging or labeling requirements imposed by the Administrator of the Environmental Protection Agency pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.); any commodity subject to the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Virus-Serum-Toxin Act (21 U.S.C. 151-157); any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.); any commodity subject to the provisions of the Federal Seed Act (7 U.S.C. 1551-1610)."157); any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.); any commodity subject to the provisions of the Federal Seed Act (7 U.S.C. 1551-1610)."

way to provide consumers with information about the ingredients in consumer products. This ingredient communications initiative provides the following definitions for cleaning products which

GCA recommends the following: "***Cleaning Product*** *– Soaps, detergents and other chemically formulated consumer products designed for fabric care, dish and other ware washing and/or surface cleaning that are subject to regulation by the Consumer Product Safety Act (15 U.S.C. 2051-2084)."*

Subdivision (a)(50)(A) through (D) Nanomaterial – GCA notes that the revised proposed regulation has removed all specific references to nano materials. GCA fully supports the removal of these references. The text which was deleted was both unnecessary for the effective operation of the regulation and needlessly complicating in the context of nano material policy. GCA refers to the Dec 3, 2010 comments regarding this subject submitted by the California Nano Industry Network (CalNIN) which are hereby incorporated by reference. See also GCA comments above under subdivision (a)(12).

Subdivision (a)(51) Manufacturer – The definition of manufacturer includes a contract manufacturer, even one that manufactures based on the specifications of the client company. So, it would be useful to permit the client company for whom a product is manufactured to have the option to designate itself as "manufacturer" for purposes of the regulations. This would eliminate possible confusion regarding the identity of the responsible entity.

Subdivision (a)(52) Market Presence Information - This paragraph defines market presence information to mean statewide sales by volume, statewide sales by number of units, intended product uses and targeted customer bases. This is a bit of a definitional circle. The statute refers to the volume of a chemical in California. Hence, to define volume, DTSC has introduced the concept of market presence information. Then, to define market presence information, it seeks to collect and examine sales volume. The real problem arises with this definition in its implementation in requiring manufacturers to provide this kind of information. Much of this information is a trade secret and the risk of an inadvertent disclosure is great when DTSC possesses volumes and volumes of this kind of information. In addition, DTSC must be aware that a manufacturer can only report on what it knows, which does not necessarily include what other users of chemicals or manufacturers of similar products are putting into the market.

Subdivision (a)(53)(C) Materials and Resource Consumption - This paragraph defines a nonrenewable resource and previously included in that definition exhausted **renewable** resources. The revision strikes the word renewable. This change lacks clarity (*i.e.*, what are the criteria for identifying an exhausted resource) and fails to address our original objection set out in our comments of November 1st (incorporated by reference). DTSC should broaden its approach towards "materials and resource consumption" by encouraging the Sustainable Development aspects of "consumption" for their overall societal benefits of products and the constituents to produce them. This includes promoting a Life Cycle Assessment perspective along the value chain, which incorporates the use phase of the products being evaluated, rather than simply focusing on renewable versus non-renewable materials. For example, Section (53)(48)(C) defines a nonrenewable resource as resource that is formed over long periods of geologic time and includes petroleum, coal, metals (mined and recycled), minerals, and exhausted ~~renewable~~ resources. But this viewpoint would discourage the use of materials from

these sectors such as the mining industry that contribute to the downstream Sustainable Development aspect of products. For example, Lithium which is produced only through mining is used to make batteries that power electric and hybrid automobiles. Sustainable Development in its various forms is even more important in mining because it is an extractive industry, than for a renewable industry. Thus, the definition of "materials and resource consumption" should encourage and recognized the Sustainable Development aspects of the value chain approach rather than seek to distinguish between renewable and non-renewable resources.

Subdivision (a)(61) Place into the Stream of Commerce in California - GCA supports the revision to the definition of "place into the stream of commerce in California.

Subdivision (a)(70) Reliable Information - We appreciate that subsection (B) has been modified to more clearly specify reliable, validated studies and/or approaches and that subsection (H) has been modified to expressly include programs through which large amounts of information have already (or will continue to be) generated. However, overall, the section fails to address or resolve concerns in GCA's November 1, 2010 letter.

The revised definition identifies a wide variety of sources of scientific information and makes a global determination that they are "reliable". All of the sources mentioned certainly are appropriate for consideration in making decisions. However, defining everything from these sources as *de facto* "reliable" is scientifically bankrupt and will drive controversy into a program that is intended to be science-based.

The need for a mechanism to judge studies for reliability is widely recognized by federal agencies with health and safety responsibilities, and in international for a. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology is used in US and OECD HPV programs and in the REACH regulation for determining data quality and reliability. As discussed below, hundreds of thousands of studies on over 4000 chemicals has now been submitted to REACH and was rated according to this approach as will studies from thousands of additional chemicals in future years. The methodology is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies.[3]

GCA reiterates that the definition of "reliable Information" should be separate from a definition of "information sources" and be based on the internationally accepted OECD methodology.

Subdivision (a)(71) Reliable Information Demonstrating the Occurrence, or Potential Occurrence, of Public Health and/or Environmental Exposures - This paragraph defines "reliable information demonstrated in the occurrence or potential occurrence of public health and/or environmental exposures." GCA recognizes that this is a new definition, and notes that it suffers from the same weaknesses as the definition of "reliable information" per our November 1 comments. In addition, it focuses only qualitative information which, while directionally helpful in indicating the existence of occurrence or presence cannot be used in determining whether the

[3] See http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

occurrence or presence presents a risk (See discussion of Chemical and Product Prioritization on pages 21 and 24 respectively).

Subdivision (a)(72) Responsible Entity - GCA appreciates the changes to the definition of "Responsible Entity," which closely mirrors our recommendation for consistency with the FPLA. By altering the definition in this way, DTSC has taken steps to eliminate tremendous potential for confusion. However, see our comments for Section 69301.2 below.

Subdivision (a)(79) Substance Identification Information - This paragraph defines "substance identification information." It includes, for example, the chemical abstract number and the IUPAC name. However, many substances, especially naturally-derived substances are difficult to chemically characterize. Nonetheless, there are commonly used substance identification systems used for commercial purposes. We recommend these systems be recognized as appropriate by the addition of subparagraph (F) "Other commonly recognized substance identification systems."

Subdivision (a)(81) Threat – This definition lacks clarity. It is more conventional to refer to risks, or the components of risk, hazards and exposures. It is unclear whether the term "threat" is meant to mean hazards only, or risks. Is some portions of the revised regulations, there are references to threats and exposures, which implies that a "threat" is synonymous with a hazard. If that is the case, the use of the terminology is inconsistent with the authorizing statute in places because the objective of the statute is "to limit exposure or to reduce the level of hazard posed by a chemical of concern" and the use of the term "threat" in the revised regulations appears to exclusively focus on reducing hazards. The term should be clarified and made consistent with the authorizing statute.

Section 69301.3 - Duty to Comply and Consequences of Noncompliance

The department has greatly simplified and clarified the Duty to Comply provision of the regulation by identifying the responsible entity as the manufacturer and, in situations where the manufacturer fails to comply, the retailer. This is a significant improvement that removes uncertainty and the potential for duplication and miscommunication in a complex supply chain. In many situations, the manufacturer owns the brand name or trademark and will want to assume the Duty to Comply with regulatory requirements to preserve brand equity and reputation.

In the event the manufacturer who is deemed the responsible entity fails to comply, and the department notifies the retailer of the manufacturer's non-compliance by posting the information on the Failure to Comply List, the retailer should not be responsible for complying with the requirements if they: 1) cease ordering the product no later than thirty (30) days after the department has provided notice to subsection (a) and 2) no later than sixty (60) days after the department has provided notice pursuant to subsection (a) the retailer notifies the department that it has ceased ordering the product and provides specific information requested by the department.

Furthermore, for most retailers, thirty (30) days is not enough time to cease ordering of the product. Many purchasing agreements require more lead time, in excess of thirty (30) days. Without proper notification, retailers may be subject to a compensatory remedy. Given retailers

will have to check the website regularly and then cease ordering, we believe ninety (90) days would be sufficient. In addition, if at some point the manufacturer comes back into compliance the retailer should be able to reorder the product.

GCA continues to urge the department to recognize the manufacturer of a Priority Product as the entity identified on the product label. The provisions of the US Fair Packaging & Labeling Act (FPLA) require all consumer commodities that are legally distributed in US commerce to include the name and place of business of the manufacturer, packer or distributor on the product label in English. For products manufactured in a foreign country and imported into the US, the entity that receives the product shipment in the US must assure there is US-compliant labeling that identifies the entity for which the product is "manufactured for…" or "distributed by…" We believe it is practical for the department to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the Duty to Comply to a foreign manufacturer or retailer.

Subdivision (b) – This section provides a mechanism for manufacturers to demonstrate their product is no longer placed in to the stream of commerce in California in order to relieve themselves of any obligation to comply with the requirements of this chapter. Given the very broad range of activities that is encompassed by the definition of "place into the stream of commerce in California" that could involve a number of other entities in the supply chain over which the manufacturer has no control, it would be impossible for a manufacturer to demonstrate that a particular product is not being placed into the stream of commerce. Instead, the manufacturer should only be required to demonstrate that it no longer manufactures the product for use in California as this is the only activity the manufacturer is able to control.

Section 69301.4 – Information Submission and Retention Requirements

Section 69301.4(a)(1) indicates that a retailer is required to comply only if the manufacturer has failed to comply and the retailer has been notified by DTSC's posting of this information on their web site. The retailer then has 30 days to stop ordering the product and 60 days to provide notice to the agency. However, 69301.4(d) indicates the agency will issue notices of non-compliance to all responsible entities known to DTSC which could include not only manufacturers but also retailers and that DTSC will post information concerning the non-compliance to their web site as soon as 45 days but no later than 90 days after issuing the notice. Presuming that upon receiving a notice of non-compliance directly from DTSC (rather than being informed by a posting to DTSC's web site) a retailer decides to take the actions outlined in 69301.4(c) and provide notice to the agency within 60 days, it is conceivable that they would be listed as failing to comply on the DTSC web site before their notice pursuant to 69301.49(c) is submitted to the agency. Since there are two potential mechanisms for retailers to become informed that a manufacturer has not complied with requirements of this chapter, the timeframes for agency to post information to their Failure to Comply list should be adjusted to align particularly if the retailer has no obligation to comply until they are notified by the agency that the manufacturer has failed to comply.

Subdivision (d)(3)(D) – This section appears to include an old reference to distributors that should have been deleted along with the changes to the definitions of "responsible entity." The distributor of a product should not be listed on the Failure to Comply List. GCA recognizes that

this is a technical change that may have been overlooked but would be necessary for consistency based on the revised definition of "responsible entity" and the structure of the duty to comply section. It is our understanding that distributors do not have compliance obligations under the revised Proposed Regulations.

Section 69301.5 – Chemical and Product Information

In the initially noticed version, this section was numbered 69301.6. In addition to renumbering this section, the department made a number of substantive changes to the requirements for information imposed on manufacturers of consumer products containing chemicals of concern. It should be noted at the outset, however, that the changes do not remove GCA's objections to the provisions of this section.

GCA objected first on the grounds that the department has no authority to require manufacturers of products to submit the information detailed in this section. Neither AB 289, codified at Health and Safety Code section 57019, or AB 1871, specifically Health and Safety Code sections 25252 and 25253, provide that authority.

Further, GCA objected on the grounds that the section lacked clarity in that the department reserved the right to require information "including but not limited to" specified information. In the revised version, the department continues to provide in subdivision (d)(3) that it may also request any data and information "that is pertinent to chemicals contained in products placed into the stream of commerce in California, and that the department determines is necessary to implement [the law]." While the verbiage is different, the lack of clarity is just as blatant.

Chemical Ingredient Information

Subdivision (c)(1)(D) of section 69301.5 requires the manufacturer of a product containing a chemical of concern to identify all intentionally added chemicals and chemical ingredients in the product and the quantities of the chemical in the product. The department lacks authority to impose this requirement on product manufacturers. The purpose of AB 1879 is for the department to establish a process to identify and prioritize chemicals of concern, to establish a process for evaluating chemicals of concern in consumer products and their alternatives, and to specify a range of regulatory responses. Nothing in the law requires the disclosure of every ingredient in a product simply because it contains a chemical of concern.

Further, the department has failed to demonstrate the necessity for imposing on manufacturers the obligation to identify and quantify every ingredient simply because a product contains a chemical of concern. Certainly, nothing in the Initial Statement of Reasons or in the 15-day notice provides necessity for requiring the disclosure of chemical ingredients and certainly not the scores of ingredients in confidential fragrance formulas. The Initial Statement of Reasons simply states that the "information is necessary to ensure that decisions made by DTSC in carrying out its responsibilities under Chapter 53 and Health and Safety Code section 25252 are fully informed and based on sound science and other relevant information." That is a conclusory statement. No effort was made to link the imposition of detailed ingredient and quantity information with any tasks imposed on the department by the green chemistry law. As noted above, the tasks are to establish a process to (1) identify and prioritize chemicals of concern, (2) evaluate chemicals of concern in consumer products and their alternatives, and (3) specify a range of regulatory responses. The department has not, and, in fact, cannot, demonstrate a need for detailed ingredient and quantity information to implement those tasks. It

can seek information about chemicals of concern, but not information about every ingredient in a product simply because it contains a chemical of concern.
The absence of authority and necessity to require manufacturers to identify all ingredients and the quantity of each is highlighted best by the issue of fragrances. How are fragrances to be addressed in the context of this regulatory requirement that all chemicals and all chemical ingredients have to be identified and quantity provided.

Fragrances are particularly important in personal care and cleaning products. Fragrances themselves may consist of 200 or more ingredients. Fragrance formulas are highly-protected trade secrets. The formula of the fragrance is often not even known by the product manufacturer. Even if it is possible for a product manufacturer to provide that information, the department lacks authority and it is not necessary to do so to implement the provisions of the green chemistry law.

Market Information

The department modified subdivisions (c)(1)(D) and (E) of section 69301.5 specifying the information that it may require. GCA objected that requiring this information from product manufacturers is unnecessary. The revisions to this subdivision, while narrowing the types of information, are still unnecessary.

The department struck the specific provisions in subdivision (c)(1)(D). However, it indirectly added the same types of data when it revised the section to include subdivision (c)(1)(E), Market Presence Information. That term is newly defined in section 69301.1(52) to include much of the same information struck from subdivision (c)(1)(D).

Further, substantial public information exists to provide data for the department to prioritize chemicals on the basis of volume, exposure, and exposure to sensitive populations without requiring manufacturers of products to provide substantial trade secret information.

In 2006, EPA collected data from US chemical manufacturers and importers on U.S. chemical volumes and uses under the Inventory Update Rule (IUR). All organic and inorganic chemicals were subject to the reporting requirement of manufacturers and importers where volumes at a manufacturing or import site were more than 25,000 pounds. Use information was required to be reported where volumes were more than 300,000 pounds. Use information was reported across a number of industrial and consumer/commercial product "use categories."

A total of 6200 chemicals were reported as manufactured or imported by over fourteen hundred companies. Volumes from multiple companies and sites are aggregated and reported in ranges to provide public information while protecting CBI. A total of 2264 chemicals were reported as having consumer/commercial product uses, and many chemicals are reported in multiple use categories. Consumer/commercial chemicals reported represent a very large spectrum of industrial and specialty chemicals, in use across 20 reporting categories.

Inventory Updates are done every 5 years and the next one is scheduled for mid-2011. Based on EPA's announced plans (http://www.epa.gov/iur/pubs/guidance/aboutsub.html), this Update will collect more complete Use and Exposure information. Chemicals above 25,000 pounds will be subject to reporting and more detailed Use Categories will be employed, providing much more detailed information. Reporting will be done via standardized electronic methods, enabling EPA to more quickly summarize and share the results publicly.

The production volume and product category information can be useful in the initial round of priority setting for California's Safer Alternative Regulations. It provides a significant database of confirmed production/import of 6200 chemicals and details on the use of over 2200 chemicals in consumer/commercial products that can be matched up with chemicals listed by DTSC's identified authoritative bodies. DTSC can use this information as a useful starting point in priority setting. DTSC can screen the listed chemicals using the 2006 IUR information to determine:

- Which listed chemicals were produced/imported in the 2006 IUR.
- Which listed chemicals were HPV in the 2006 IUR.
- Which listed chemicals were HPV and reported as used in Consumer/Commercial products in the 2006 IUR.
- Which listed chemicals were HPV and reported as used in more than 1 Consumer/Commercial product category.
- Which listed chemicals were HPV and reported as used in more than 2 Consumer/Commercial product categories.

Volumes of additional relevant public data are available. See the following databases:

- FDA has a cosmetics reporting system VCRP (Voluntary Cosmetics Reporting Program) http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/default.htm.
- National Library of Medicine has a Household Products database within its Hazardous Substances Data Base. http://hpd.nlm.nih.gov/about.htm.
- ACI and CSPA have a Consumer Product Ingredient initiative (http://www.cleaninginstitute.org/ingredientcentral/ and http://www.cspa.org/public/media/info/cpici.html).
- SRI Chemical Economics Handbook (http://www.SRIconsulting.com/CEH)

ARTICLE 2 – CHEMICAL PRIORITIZATION PROCESS

Section 69302.2 - Chemicals of Concern Prioritization

The opportunity to provide public comment on the proposed Chemicals of Concern List (69302.2 (b))is an important step in keeping an open dialog among stakeholders during the regulatory process.

Section 69302.3 - Chemicals of Concern Prioritization

GCA expressed its support for the revision to the applicability of section 69301 with respect to the changes made dealing with chemicals and products subject to regulation from other regulatory programs. The articulation of the provisions in that section makes clear that chemicals and products subject to such regulation for the same threat and exposure pathway are **not** covered by these regulations.

Unfortunately, new language added in subdivision (a)(4) of section 69302.3 creates ambiguity. That subdivision lists as a priority factor "the scope of federal and/or California State regulatory programs, and any applicable international trade agreements ratified by the United States

Senate, under which the chemical is regulated, and the extent to which these other regulatory requirements address the same public health and environmental threats and exposure pathways that are being considered as a potential basis for the chemical being listed as a Chemical of Concern."

The fact that the same language is used to articulate a prioritization factor as is used in concluding that the regulations do not apply to a particular chemical is confusing. The question is, What circumstance does the department have in mind where the applicability provision does not remove a chemical from consideration, leaving it subject to prioritization based on the extent to which the other regulatory requirements address the same public health and environmental threats?

It occurs to GCA that the other regulatory program might specifically address one of the six listed threats and, in doing so, has an impact on the threat that is the basis for the chemical being considered as a chemical of concern. An example will illustrate this concept.

The California Air Resources Board regulates volatile organic compounds in consumer products to address "adverse air quality impacts." At the same time, those regulations have an impact on addressing adverse public health impacts. The CARB regulations reduce the precursors for smog, improving air quality; thereby, improving public health.

If this is the type of circumstance that the Department has in mind in listing other regulatory programs as a priority factor versus an applicability factor, it should confirm that and consider revising the language in subdivision (a)(4) of section 69302.3 to reflect that concept. One suggestion is to make a minor revision to the language in subdivision (a)(4) so that it reads, "the extent to which these other regulatory requirements affect the same public health and environmental threats." In addition, the Department needs to make clear that repeating the same language in the prioritization factors does not diminish in any way the effect of the applicability provisions in section 69301.

Subdivision (b)(2) discusses the chemical prioritization process. This subdivision provides that the Department "shall then determine which of these threats and exposures are addressed by consideration of subsection (a)(4), and adjust the prioritization accordingly." Once again, that language gives rise to the same confusion discussed with respect to subdivision (a)(4) of section 69302.3 above. Again, the department should more clearly articulate the concept it envisions whereby regulation by other agencies would be a priority factor and not simply an applicability factor.

ARTICLE 2 & 3 - CHEMICAL & PRODUCT PRIORITIZATION PROCESSES General Comments

Elimination of Chemicals Under Consideration and Products Under Consideration

Sections 69301.1, 69302 and 69303 – In the Revised Proposed Regulations, the concepts of Chemicals Under Consideration and Products Under Consideration have been eliminated, dramatically shortening the prioritization process for chemicals and products. While this has the public policy benefit of accelerating the timeline in making the initial finalized chemical of concern and priority product decisions, it has several negative effects. As noted in GCA's 11/1/2010 comments, these concepts play an important role in gathering information from the

public and sending a signal to the marketplace for manufacturers and users as they make production and formulation decisions. Â We are concerned that with the resulting compressed process, stakeholders will not have sufficient time and opportunity to provide complete information to ensure good decision-making by the Department. The Revisions add the requirement that the Department conduct one or more workshops, which will help in the understanding of the rationale for proposed lists. However the preparation of public comments for these proposals will require the assembly and communication of significant scientific information. Should the Department proceed with the Revised approach, it will be critical that comment periods be sufficient – 120 to 180 days – to ensure adequate time for quality responses.

Science Based Decisions for Chemicals of Concern and Priority Products.

GCA supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of DTSC scientists. In its comments of November 1, 2010, GCA said that the Proposed Regulation language provides workable direction for making such decisions in a scientifically credible and defensible manner. This was based on the fact that the proposal was clear that the prioritization process required the department to make quantitative comparisons of hazard and exposure in setting priorities and to focus on those situations with the greatest potential for harm.

The revisions include a number of changes that further strengthen this approach and that GCA supports as well as some changes that raise concerns. The key regulatory language has been changed to direct the department to focus on those situations "…for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts." (69302.3 (b)(1) and 69303.3(b)(1)). GCA supports this articulation.

GCA is concerned about the deletion of the statement in 69302.3 (b)(1) and 69303.3(b)(1) that "The department shall consider both the potential for exposure to the chemical and the potential harm resulting from potential exposures", and requests that it be reinstated, with the substitution of "impact" for "harm" to conform with the Revision language. This provides clear direction and is consistent with the Revision's prioritization approach thus it is not clear why it was removed.

69302.3 (b)(2) and 69303.3(b)(2) relate to the prioritization processes and are improved over the Proposed Regulation. However, the provisions introduce a lack of clarity when, having identified the threats and potential exposures for each chemical, the department must then determine which of these threats and exposures are addressed by other state or federal regulatory programs and "adjust the prioritization accordingly." A clarification is needed to make clear that if the same threat and exposure is already being regulated, it is exempt from the regulation, but if not, then it should be taken into account to adjust the prioritization.

69302.3(b)(3) and 69303.3(b)(3) further address prioritization decisions and introduce an inconsistency with a new term, "Reliable information demonstrating the occurrence, or potential occurrence, of public health and environmental exposures." As discussed in the comment on the definition of this term in 69301.1(a)(71), the criteria are all limited to qualitative exposure information. Qualitative information while directionally helpful in indicating the existence of occurrence or presence cannot be used in determining whether the occurrence or presence presents a risk. Presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern must be the primary driving factor in priority

setting decisions. As such employing Qualitative indicators in (b)(3) is inconsistent with (b)(1) on lines 39-41 of the previous page that calls for the department to prioritize based on the *"greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in adverse public health or environmental impacts*" which is clearly a Quantitative approach.

This concern can be addressed and the provisions made consistent by adding the following statement, "*Reliable information demonstrating the occurrence, or potential occurrence, of public health and environmental exposures in quantities that can result in adverse public health or environmental impacts."* Alternatively, the (b)(3) provisions could be deleted since they are fundamentally restatements of 69302.3 (b)(1) and 69303.3(b)(1).

ARTICLE 3 – PRODUCT PRIORITIZATION PROCESS

Section 69303.2 – Product Lists

The GCA strongly opposes the current structure of Section 69303.2 and the de minimis provisions within (Pages 49-52) and how it addresses formulated products and assembled products differently. The de minimis level (0.1%) – while appropriate and consistent with REACH – should be applied to the total product by weight; and not to components.

Neither "formulated products" nor "assembled products" are defined and classifying these products will be difficult; given that products might span both product areas. Additionally all products have "components" regardless of whether they are "assembled" or "formulated". Finally, determining what is component and a sub-component will also be very difficult and it will be very difficult for the department to determine.

The result of the assembled products provisions in this Section is to lower the de minimis for assembled products to a component level, not a total product weight level. This is in stark contrast with REACH Article 7 that articulates that the 0.1% de minimis level applies to the total product by weight. In fact, recent REACH legal guidance indicates, *"an article is to be understood as the article as produced or imported. It may be very simple, like a wooden chair but could also be rather complex, like a computer, consisting of several parts, which are also considered articles when produced or imported."*[4] *[1]*

The key impact of establishing the de minimis level is to establish a level below, which exposure to a CoC is not relevant for regulatory action. Therefore exposure should be the key determinant to applying the de minimis provision. Application of the de minimis level to components ignores the fact that it is aggregate exposure to a total product (not a specific component) that should be the drive for the de minimis level – below which exposure is not a concern. Application of the de minims to components distorts the aggregate exposure of a product. The de minimis should apply to the total exposure and threat of adverse impact from the entire product.

[4] European Commission. Ref. Ares(2010)826118 - 17/11/2010, http://chemicalwatch.com/downloads/Opinionofthelegalservice-Article7and33REACH.pdf

The GCA recommends: *For all products, the de minimis level should be applied by weight to the total product, which accounts for total exposure to a product and is consistent with international guidance under REACH.*

Subdivision (b) - There is an unspecified time period for notice and comment on Priority Product listings. It is critical that manufacturers have adequate time to respond to this, for instance to provide information on the typical levels of the CoC in product, what exposures result from those levels as a result of reasonable and foreseeable use and abuse and how those exposures compare with the hazard of the CoC. GCA recommends DTSC provide a 120 day notice and comment period. Additionally, a Public Workshop is added in these Revisions, which seems unnecessary.

Subdivision (d)(1) – According to this Subdivision, all products in the category are presumed to be priority products. To be consistent with the purpose of this provision, DTSC should clarify that only those products in the category containing a chemical of concern are considered to be Priority Products.

Subdivision (d)(2) - This subdivision provides for a Chemical Removal Notice, slightly modified from the Proposed Regulations. GCA reiterates concerns raised in our November 1, 2010 letter that this provision is not necessary or authorized and will create a significant paperwork burden. If DTSC retains the notification requirement, we suggest clarifying and streamlining the information requested to avoid a deluge of information being provided that is unnecessary and potentially subject to confidential business information protections. One element of accomplishing the streamlining is to delete "all" in both paragraphs of Section 69303.2 (d)(3)(A)4.a. and b. The requirement for "all data and other information used by the manufacturer to determine and substantiate this concentration" is unclear and unnecessary. It is reasonable that information be provided to substantiate the level at which a CoC is added below the de minimis level. However to require "all" data and information will be confusing for the responsible entity to comply with the provisions, and will result in the department receiving data and information beyond that necessary to support the de minimis exemption.

Subdivision (d)(3) – This subdivision is made operable on the basis of the definition of "De Minimis Exemption Notification" in section 69301(a)(25). In GCA's November 1, 2010 comments, incorporated herein by reference, GCA writes, "….The de minimis exemption should be self-implementing, requiring no submission to the department. For compliance and enforcement reasons, manufacturers could be required to maintain records supporting their actions."[5] Also suggested in GCA's November 1, 2010 comments, this requirement is unnecessary, unauthorized and bureaucratically burdensome. GCA recommends that DTSC remove the requirement for a de minimis notification. A product containing a Chemical of Concern below the de minimis level should not be considered for the Priority Products list.

The requirement for "all data and other information used by the manufacturer to determine and substantiate this concentration" is unclear and unnecessary. It is reasonable that information be provided to substantiate the level at which a CoC is added below the de minimis level. However to require "all" data and information will be confusing for the responsible entity to comply with

[5] GCA Comment Letter to DTSC regarding Proposed Safer Consumer Product Alternative regulation, November 01, 2010, p. 21

the provisions, and will result in the department receiving data and information beyond that necessary to support the de minimis exemption.If DTSC retains the notification requirement, we suggest clarifying and streamlining the information requested to avoid a deluge of information being provided that is unnecessary and potentially subject to confidential business information protections. One element of accomplishing the streamlining is to delete "all" in both paragraphs of Section 69303.2 (d)(3)(A)4.a. and b.

Subdivision (d)(3)(A) - This subdivision should be re-written to read "An individual manufacturer's product shall not be considered a Priority Product if the product meets the criteria specified in subparagraph (D)" and the corresponding subsections 1-4 should be deleted.

Subdivision (d)(3)(D) – This provision would require that the sum of all Chemicals of Concern (in a product/component) that are a basis for a Priority Product listing and that exhibit the same hazard not exceed the de minimis level. This provision lacks clarity in that the implementation and enforcement would be extremely difficult as the nature of "the same hazard" will be difficult for the department and the regulated community to interpret. While it may be desirable to control for Chemicals of Concern that have toxic activity via the same mode of action, those are not aligned with the proposed hazard traits. For example, not all carcinogens operate according to the same mode of action; in fact, there are a wide variety of cancers that might be elicited by different chemical carcinogens. To consider them as similar for the purpose of aggregation by virtue of the classification as "carcinogens" is not scientifically valid. The inconsistencies of the approach proposed are more stark when one considers the Hazard Trait definition proposed in Section 69301.1 (44); the multiple listing provisions proposed (2.c-f) for designating a hazard trait have no necessary commonality among the chemicals that populate each list. The arbitrary grouping of chemicals resulting in regulatory action is not valid or necessary. As such, this provision should be deleted.

Section 69303.3 - Priority Products Prioritization

Subdivision (a)(1)(A) – For prioritizing products, the 15-Day Revision states that until 2016, the department shall only consider Personal care products, Household cleaning products and Children's products designed or intended primarily for children 12 years or younger. While the statutory criteria of volume in commerce and potential for exposure to the chemical in a product and potential effects on sensitive subpopulations are mentioned in the 15-Day Notice, it is not clear whether other product categories were considered and how the criteria were applied to result in these selections. Nor is there a discussion about what criteria and approach will be used in 2016 for adding categories, or whether products from all categories would be added to the scope at that time. The department should address these questions in the Final Statement of Need and Reasonableness.

Subdivisions (a)(1)(B)3, subdivision (a)(3), and subdivision (b)(2) introduce the same ambiguity raised above with respect to section 69301.3. GCA incorporates its comments with respect to that section and urges the department to revise the regulation to make clear the circumstances when other regulatory programs are prioritization factors.

Subdivision (b)(1), (b)(2), and (b)(3) set out the prioritization standard and process for products containing chemicals of concern that pose "the greatest threat of adverse public health and environmental impact." (See discussion ARTICLE 2 & 3 – CHEMICAL & PRODUCT PRIORITIZATION PROCESSES – General Comments)

Subdivision (b)(3) is similar to the (b)(3) provision in chemical priority setting and the use of the phrase potential for harm or potential occurrence and lack of consistency by DTSC in the use of various terms. Like above, there is a clarity/inconsistency issue with the new phrase, "Reliable information demonstrating the occurrence, or potential occurrence, of public health and environmental exposures". As mentioned in the definition comment, this is restricted to Qualitative exposure information. As such employing it in (b)(3) makes it inconsistent with (b)(1) on line 40-42 of the previous page that calls for the department to prioritize based on the "greatest potential for consumers or environmental receptors to be exposed to the Chemical of Concern chemical in quantities that can result in adverse public health or environmental impacts." which is clearly a Quantitative approach. In (C) of this subdivision, consideration of frequency of use and product concentration could be viewed as either Qualitative or Quantitative, thus is unclear. This needs to be consistently Quantitative.

With regard to Section 69303.3(d)(3)(A), GCA is of the opinion that a product that does not contain a Chemical of Concern above the de minimis level should not be considered to be a Priority Product. In addition, the De Minimis Exemption Request has been changed to a Notification. While this is a notable improvement, GCA continues to object to the excessive testing and administrative costs represented by this requirement. To address this concern, the provision should be re-written to read: *"An individual manufacturer's product shall not be considered a Priority Product if the product does not exceed the criteria specified in subparagraph (D)."*

Subdivision (c)(1) Selection of Cleaning, Personal Care and Products for Children 12-years and initial focus - As amended the 15-Day Revision states that until 2016, the department shall only consider Personal care products, Household cleaning products, and Children's products designed or intended primarily for children 12-years or younger.

GCA understands that the statutory criteria of volume in commerce, potential for exposure to the chemical in a product, and potential effects on sensitive subpopulations are referenced in the 15-Day Notice; however, it is not clear whether other product categories were considered and if so how the criteria were applied that resulted in the these particular selections. Neither is there a discussion regarding what criteria and approach will be used for adding product categories in 2016 and beyond, or whether products from all categories would be added to the scope of the regulation at that time. DTSC's 15-Day Pubic Notice states,

> *"After January 1, 2016, there is no limitation or specification of the types of products that may be identified as priority products. Even the initial restricted list of possible priority products captures tens of thousands of products. After that, the possible category of priority products grows exponentially."*

The membership of the GCA, representing the broad spectrum of product categories in California's stream of commerce, takes little comfort in having avoided selection in the initial round of the revised regulation. Clearly, they will face a regulation in the 2016 and beyond subjecting them to a priority product selection process which for all intents and purposes is

undefined. GCA has clearly stated in its comments of November 1, 2010 that decision criteria; as they relate to exposure must be clearly articulated. GCA believes the department must identify within the regulation its decision-making rationale for priority product selection. We further believe DTSC has an obligation to identify in the Final Statement of Need and Reasonableness its rationale used to select the enumerated classes of products for this initial round. Specifically, DTSC must indicate how exposure was evaluated for the enumerated products in making these selections and how exposure will continue to be used in future prioritizations.

GCA further notes, that the Administrative Procedures Act says that no change can be adopted "from which was originally made available to the public unless the change is . . . (2) sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action." Such a change can be made only after providing 15 days for additional comments. If it is not sufficiently related, the change is viewed essentially as a new regulation, requiring 45 days.

ARTICLE 5 – ALTERNATIVES ASSESSMENTS

Former Section 69305.1 Alternatives Assessment Notification & Tier 1 AA Reports

GCA is pleased with the removal of the Tier 1 Alternatives Assessment process. This would have been an onerous and burdensome process that would have resulted in the stifling of innovation.

Section 69305.1 – Alternatives Assessments: General Provisions

GCA supports the revisions in Article 5 that eliminate the process and requirements to obtain certification by the department as a qualified third party assessment entity, qualified in-house assessment entity, accrediting body, or lead assessor. We also support the flexibility for a "consortium, trade association, public-private partnership, or similar organization with which a responsible entity is affiliated" (§69305.1(c)(1)) to perform an AA.

GCA is unequivocally opposed to ***mandatory*** third party verifiers for every AA, as they do not have an in-depth appreciation and understanding of the product development science and engineering used in the manufacture of consumer products. A Research and Development (R&D) scientist must consider a variety of factors in the selection of chemical ingredients for a consumer product. Hazard traits of an individual chemical and life cycle analysis are only pieces of the equation. Chemical ingredients often serve multiple functions in a consumer product formulation rather than provide a single benefit. Therefore, Alternative Assessment is a broad process that must evaluate a number of holistic considerations for any potential chemical alternative, including impact on product performance, potential interaction with other formula components, useful life, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right targeted balance of chemical ingredients for consumer product formulations. It is unreasonable to expect third party verification firms to fully appreciate the intricate R&D science invested in consumer product formulations or share the in-depth understanding of consumer behavior and preferences to adequately verify that an AA is complete.

Additionally, requiring third party verification for *every* AA will be costly and hinder timeframes for completion of the AA given our understanding of the finite supply of third parties to accomplish this work. Given the concerns by other stakeholders regarding the timeframes associated with the green chemistry processes, the verification steps will only serve to delay the process further for no benefit.

For those instances when third party assistance is either voluntarily sought by the manufacturer or where the company clearly lacks the in-house expertise to conduct the assessment, DTSC should establish grievance and dispute resolution procedures for parties who believe their AAs have been improperly denied verification.

Under the proposed regulation in §69305.1(c)(1) the verifying third-party must "have no economic interest in the responsible entity." "Economic interest," as currently defined in §69301.1(a)(31)(A), is an impossibly low threshold in this era of mutual funds and other broad and sophisticated economic investments wherein a verifying third-party may not easily or readily determine if s/he has any economic interest in any particular entity. We encourage the department to recognize the "economic interest" threshold in accordance with the recommended language provided by GCA for this definition See also Section 69301(a)(31**)**.

Section 69305.2 – Alternatives Assessment Work Plan

Much of the data previously required, such as the supply chain information and specific life cycle segments have been deleted. GCA supports these changes.

Section 69305.3 – Evaluation and Comparison Process and Factors

GCA supports the change in this section to create a more streamlined approach and to maintain flexibility to focus the AA on "pertinent" factors and the flexibility to use different AA methodologies. Additionally, in Subdivision (a)(1) the AA report is now a single document covering the important factors (hazard, exposure, lifecycle/resources, function/performance, and economic impact).

Subdivision (a)(2)(A and B) dramatically expands the Chemical Hazard Assessment to require comparisons of all chemicals contained in the priority product and in the alternative. This is also the case for the Exposure Potential Assessment. This is a massive burden and unnecessary change—the AA should focus on the chemical of concern.

With regard to the implementation of the assessment, there is further room for simplification that would assist both the party conducting the assessment. Specifically:

While it is common for AA methodologies to take a modular approach to documenting information, in practice, real world R&D considers all these factors simultaneously in the product development process. This is usually done by means of a series of screening steps, with each step doing a more detailed level of investigation and analysis of all pertinent factors for all alternatives and each step selecting alternatives to go forward and discarding alternatives that do not meet the criteria.

The evaluation modules included in this proposed regulation show some confusing overlap. Both the Chemical Hazard Assessment and the Life Cycle Assessment include evaluations of adverse impacts to air, water and soil.

Rather than including a prescriptive methodology in the regulations when the science of Alternatives Assessment is still evolving, we recommend the regulation more generally cite the evaluation factors of importance to California and allow the implementation detail to be developed in a collaborative fashion with various stakeholders through the preparation of guidance materials per section 69305 (a).

Section 69305.4 – Alternatives Assessment Reports

GCA supports DTSC removing language that would have created separate hazard and exposure reports. The revised draft regulation clearly describes a single document where all factors considered in the alternatives assessment are presented in proper, complete context. However, there are a couple of aspects of Section 69305.4 with which we still have additional concerns.

Subdivision (b)(3 and 4) requires supply chain information in the AA Report providing the name of, and contact information, for all persons in California to whom the manufacturer directly sold the product within the prior twelve (12) months; and identification and location of t retail sales outlets where the manufacturer sold, supplied or offered for sale the product in California. This is needlessly burdensome for products that are not imminent risks.

Subdivision (n)(1) requires the AA report to include an executive summary that is sufficient to convey to the public a general understanding of the scope, goals and results. The problematic portion goes on to say, "...and sufficient to allow a technically qualified person to make an independent assessment of the findings presented in the AA report." We question whether one executive summary can meet the needs of both the general public and a technical expert looking to make "an independent assessment of the findings." Moreover, it is likely that the amount of information needed to make "an independent assessment of the findings" will be significant, and well beyond what is traditionally contained in an executive summary. It would also likely include CBI information. GCA strenuously objects to this as a standard for what is required in the executive summary.

ARTICLE 6 – REGULATORY RESPONSES

Section 69306.2 – No Regulatory Response Required

The significance here is that the de minimis level is calculated by looking at the total concentration of all the chemicals of concern. As discussed, we should object to this "add up of de minimis". It could make sense on a case-by-case basis if the chemicals of concern have the same mode of action.

Section 69306.4 – End of Life Management Requirements

A financial guarantee is impractical and neither authorized nor necessary to implement the goals of the Statute. (See section 69306.4(a)(2)(A)(6).)

Section 69306.5 – Product Sales Prohibition

The product recall program established in section 69306.5 of the Revised Draft Regulation exceeds the authority granted to the department and the regulatory responses permitted under the Statute.

Section 69306.7 – Exemption from Regulatory Response Requirements

GCA remains concerned that the exemption process applies once a notice is provided that a manufacturer is subject to a regulatory response. While useful, it fails to be incorporated at an earlier point to avoid needless work by the regulated community and by the department.

ARTICLE 7 – DISPUTE RESOLUTION PROCESSES

Section 69307. 1 Informal Dispute Resolution Process

The responsible entity only has 15 days following notice or website posting of the department's decision to file an informal dispute resolution request. If the responsible entity does not request the informal dispute resolution within this timeframe, then they lose any opportunity for additional dispute resolution. Fifteen (15) days is too short a period for this important opportunity to informally settle disputes and we recommend a period of 90 days to file an informal dispute.

ARTICLE 8 – AUDITS

Previously Section 69308

These revisions eliminate Lead Assessor, Accreditation, Qualified Entities, and Accrediting Bodies. GCA strongly supports all of these revisions to the proposed regulation.

ARTICLE 9 – CONFIDENTIALITY OF INFORMATION

This Article was initially noticed as Article 10, having been renumbered as Article 9 in the revised regulation. GCA supports many of the changes made to this Article. Specifically, GCA supports the elimination of the up-front substantiation, the elimination of a separate claims index, the reduction of the number of factors for substantiating trade secrets, the elimination of the section on process, and narrowing the provision relating to hazard trait information.

In addition, the department added subdivision (d) to section 69309.1 defining the term "confidential information." GCA agrees with the department's reasons for adding this provision, and supports this addition.

Section 69309.1: Assertion of a Claim of Confidential Information

GCA previously objected to the requirement that a person claiming a trade secret shall provide a redacted copy of the document being submitted to the department, excluding the claimed confidential information. That provision, subdivision (b)(2) of section 69309.1, also provides that the department may make the redacted copy available to the public. The department added at the end of that latter provision in section 69309.1(b)(2) the phrase "at its discretion." The addition of this phrase creates uncertainty.

The provisions of AB 1879 make it clear that the department is to release non-confidential information only upon a request made pursuant to the California Public Records Act. Hence, the phrase "at its discretion" cannot mean that the department may release the redacted copy of information absent such a request. Moreover, AB 1879 provides that unless the information is confidential, it is to be released. Hence, it is unclear what circumstance the department has in mind giving rise to the exercise of its discretion.

Under the Public Records Act, the department is to provide the information requested if it can reasonably segregate out the confidential information. Does the department intend by the phrase "at its discretion" to provide that it may make available either a redacted copy of the documentation, or the original documentation after segregating out the confidential information? If so, that intent demonstrates why a redacted copy should not be required. A redacted copy is unnecessary since the original document, after segregating the confidential information, can be provided. Moreover, if a redacted copy is in the possession of the department and a Public Records Act request is made for it, the department is obligated to provide it. The law controls what the department is required to make available and to hold confidential. Accordingly, subdivision (b)(2) of section 69309.1 is unnecessary.

Section 69309.1 - Support of a Claim of Trade Secret Protection

Time to Respond

Subdivision (a) of section 69309.1 provides that a person who asserts a claim of trade secret and receives a request from the department to support the claim shall, within 10 days, provide the following substantiating information. This provision was amended by the department by adding after the 10-day time period, "or within a longer period negotiated with the department."

No necessity has been demonstrated for requiring the person making a trade secret claim to respond with substantiating information within 10 days. Certainly neither the Initial Statement of Reasons nor the 15-day notice provides a justification for providing such a short amount of time to provide substantial information in response to the regulatory requirements.

Further, the statute, AB 1879, Health and Safety Code section 25257(d), allows the department 60 days to respond to a request for public information. The statute further requires the department to give the provider of the information immediate notice. Why then is the department limiting the provider of the trade secret information to 10 days to respond and

reserving for itself up to 50 days to make a determination? No necessity has been shown, nor can it be shown for providing such a short amount of time. The added provision "or within a longer period negotiated with the department" does not cure this lack of necessity.

In addition to the timing issue, the revision fails to indicate what event would trigger the department requesting substantiation of a CBI claim. The department should be consistent with AB 1879 and only request substantiation information if a third party requests CBI information and challenges the claim of protection. GCA also suggests that the contact information for the requester be provided to the claimant of the CBI protection. The parties may be able to identify information that would satisfy the requester's needs while at the same time protecting the information claimed as CBI without having to involve the department in that process. This is a process that has been working in Canada under the CEPA implementation and should be considered for purposes of implementing the proposed regulation.

Justification Factors

As noted above, GCA supports the department's elimination of some of the factors to be addressed in substantiating a trade secret claim. GCA continues to object to subdivision (a)(5), (6), and (7) of section 69309.1.

Subdivision (a)(5) requires the person who claims information to be a trade secret to provide "the value of the information to the person and to the person's competitor." Subdivision (a)(6) requires the person claiming information to be a trade secret to provide information about "the amount of effort or money expended by the person in developing the information." Subdivision (a)(7) requires the person claiming information to be a trade secret to provide information on "the ease or difficulty with which information can be properly acquired or duplicated by others."

The department revised each of those paragraphs by striking the word "estimated" from each of them. The purpose in striking "estimated" from each of those three paragraphs is unclear. Is the intent to now require a precise value or amount, or a precise description of the ease in acquiring or duplicating the information by others?

Certainly, striking the word "estimated" does not remove GCA's objection to these provisions on the grounds that they are inconsistent with the Uniform Trade Secret Act. Civil Code section 3426.1(d). The department has adopted the Civil Code definition as its definition of trade secret. See section 69301.1(a)(83). The statutory definition of trade secret means information that "derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy."

The test is whether the information derives economic value. It is not as subdivision (a)(5) requires the value of the information. Further, nothing in the definition of a trade secret raises an inference that a showing has to be made of the amount of effort or money expended in developing the information as required by subdivision (a)(6). Also, the statutory definition refers to efforts to maintain the secrecy of the information. Nothing inherent in that provision justifies the requirement in subdivision (a)(7) that a person claiming information to be a trade secret has to demonstrate the ease or difficulty with which the information can be properly acquired or duplicated by others.

The department, in its 15-day notice, seeks to justify the imposition of these three factors as the basis for asserting a trade secret claim. The department relies on what it cites as Restatement,

Torts 2d, section 727, and *Futurecraft Corp. v. Clary Corp.* (1962) 205 Cal.App.2d 279 at 289. It should be noted that the *Futurecraft* case was decided in 1962. The court references Restatement of Torts section 757.

It is important to note that in the Restatement of Law 2d, Torts, the Reporter highlights that the rules relating to liability or harm caused by unfair trade practices developed initially in the law of torts. Hence, the original Restatement of Torts included trade secret infringement in its discussion. More than 40 years later, tort law was less relevant and Unfair Competition and Trade Regulation are independent areas of the law. As a consequence, the section relied on by the department and the court in *Futurecraft*, has been superseded. Today the applicable Restatement is Restatement 3d of Unfair Competition, section 40.

Restatement 3d, Unfair Competition, section 40 is predicated on the Uniform Trade Secret Act, which is the basis of California's Civil Code provision. The factors previously considered relevant when trade secret infringement was viewed as a tort are not to be found. Evaluations of trade secrets today are predicated on the elements in the Civil Code Section 3426.1. See for example, *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443 (2002).

Since the rationale provided by the department for including subdivision (a)(5), (6), and (7) is no longer applicable law, those provisions should be struck in their entirety.

Substantiating Information

Subdivision (c) of section 69309.1 provides that if the substantiating information contains information that is itself subject to a claim of trade secret protection; such substantiating information shall also be separately supplied in both complete and redacted forms. The explanation for this provision provided in the 15-day notice states that the purpose is to ensure that justification information is treated properly and with minimal administrative burdens. It specifically states that the idea is to avoid an infinite substantiation loop.

The ambiguity of subdivision (c) and the lack of clarity of the explanation set out in the 15-day notice gives rise to a significant question. How is the substantiating information treated if the department makes a decision that the substantiation is inadequate to protect the initial information submitted? Will the department conclude that the substantiating information also lacks substantiation for being claimed as a trade secret and release it? The department needs to address how substantiating information will be handled and when substantiating information will be necessary.

OTHER ISSUES OF SIGNIFICANCE

An Effective, Less Burdensome Alternative to the Proposed Action Exists

The department, in the notice announcing its intent to adopt these regulations, stated that it must determine that no other alternative would be as effective and less burdensome to affected parties than the proposed action. In fact, the department cannot make that determination in good faith. In June, 2009, GCA submitted a comprehensive set of regulations that would have been as effective, or even more effective, than the proposed action and would have been significantly less burdensome.

The regulations submitted by GCA would have resulted in a process that would have fully identified chemicals of concern and would have prioritized those chemicals in accordance with the statutory priority factors, focusing on those chemical uses that pose real risks. The GCA proposal set out in detail a process for evaluating the current use of chemicals of concern in consumer products and their alternatives. Also, the GCA proposal provided for the imposition of regulatory responses based on specified outcomes flowing from the alternatives assessments. Moreover, the GCA proposal protected trade secrets as provided by the green chemistry law, contrary to the proposed action that puts confidential information at risks.

A copy of GCA's proposal is attached to these comments to make an effective and less burdensome alternative part of the record.

The Proposed Action Constitutes a Technical Barrier to Trade

Moreover, it is indisputable that the Proposed Regulations reach far beyond California's borders to regulate the global supply chain of nearly every major consumer product company. This broad reach will likely have significant implications on interstate commerce and international trade. As currently drafted, the Proposed Regulations exceed the statutory and constitutional limits on California's regulatory authority. First, California law is presumed "not to have 'extraterritorial' effect unless specifically provided by the Legislature or 'such intention is clearly expressed or reasonably to be inferred' from the language of the act or from its purpose, subject matter or history." Opinion of the Attorney General No. 87-207, 70 Op. Atty Gen. Cal. 187, 1987 Cal. AG LEXIS 24, quoting *North Alaska Salmon Co. v. Pillsbury* , 174 Cal. 1, 4 (1916) (internal quotation omitted). Second, "[a] state cannot regulate or proscribe activities conducted in another state or supervise the internal affairs of another state in any way, even though the welfare of its citizens may be affected . . . ." *Archibald v. Cinerama Hawaiian Hotels, Inc*., 73 Cal. App. 3d 152, 159 (1977). Finally, the Proposed Regulations include requirements that would unduly burden interstate commerce, and may stand as an obstacle to Congress's purpose in enacting TSCA, the CPSA, as amended, the FFDCA, the FHSA, and the other federal statutes that govern consumer products, chemicals and chemical handling, exposure and management. We urge DTSC to expressly acknowledge the existing federal authority governing consumer products and chemical management and provide for an appropriate exemption that does not give DTSC the authority to create conflicting and duplicative standards.

By casting a unjustifiably wide regulatory dragnet, and including draconian regulatory responses ranging from California-specific formulations and risk communication to consumer product sales bans, the Proposed Regulation poses a unlawful Technical Barrier to Trade, as that term is defined in the Agreement on the Technical Barriers to Trade ("TBT Agreement"), a WTO agreement to which the U.S. is a party. Both federal and state governments of signatory parties have an obligation to ensure that their regulations do not constitute TBTs. Even assuming that the Proposed Regulation is not a TBT, the enactment requires notification to the World Trade Organization through the National Institutes of Standards and Technology, the U.S. enquiry point, and a meaningfully opportunity for Member States to comment. We believe that the NIST acknowledged these potential impacts and their notification obligation, but failed to provide a proper notification until on October 26, 2010, *three business days* before the comment period closed. At a minimum, we would expect DTSC to extend the comment period so that the WTO Member States and their respective stakeholders may have the opportunity to comment on the Proposed Regulations, as required by U.S. law.

The Department is Obligated to Comply with CEQA

Alston & Bird previously submitted substantial comments demonstrating the environmental impact that these regulations will have. In addition, those comments demonstrate that no exemption exists to excuse the department from conducting an initial study at once, and based on that study, prepare an environmental impact report. Rather than duplicate an exposition of the applicable law, GCA incorporates by reference the comments and exhibits submitted by Alston & Bird.

Concern Regarding Adoption of Environmental Policy Council (EPC) Resolution

Recognizing the far-reaching impact of the Green Chemistry laws, the Legislature directed the Department to conduct, as part of its rulemaking process, a multimedia evaluation of adverse impacts the proposed regulations could have on public health or the environment (Health & Safety Code Section 25252.5). In its effort to comprehensively regulate products sold in California to keep consumers of those products safe, the Department must also consider the possible impacts such expansive regulations could have on other media such as air, water, waste disposal, or public health. The Legislature did not leave responsibility for this important holistic analysis to the Department alone, however, but specifically drafted the new law to expand the role of the Environmental Policy Council, thereby enlisting the expertise of the directors of the state's key environmental agencies.

Despite the Legislature's express direction that the Council consider potential adverse impacts from this far-reaching, largely unprecedented new regulatory scheme, the Department recommended and the Council simply accepted the determination that the process could not possibly result in significant adverse impacts to public health or the environment.

The Council's acceptance of the Department's determination and adoption of the Resolution without regard for the comments provided in writing less than 24 hours prior and the public comments provided during the public hearing on November 27, 2010 is unacceptable. Adoption of such a resolution should not have been considered at all prior to reviewing and considering public comments on the Department's determination that a thorough multimedia evaluation was not necessary.

Even though the proposed regulations are designed to benefit public health and the environment, they may result in significant adverse impacts. These significant adverse impacts may be offset by benefits, but should not have been discounted by the Council in making their determination regarding any possibility of a significant adverse impact. The Council cannot conclusively determine that the proposed regulations will not, in any way, adversely impact public health or the environment. We are highly concerned with the Council's action to affirm the Department's determination that a full multimedia review is unnecessary. This action fails to meet the requirements of Health and Safety Code Section 25252.5 and should be revisited. (see GCA's Letter to the Environmental Policy Council – November 26, 2010)

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