Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

November 1, 2010

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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 R-2010-05 (September 13, 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) Safer Consumer Product Alternatives Regulation ("regulation") of September 13, 2010.

While GCA and its members appreciate the complicated nature of drafting the Safer Consumer Product Alternatives regulation, we are incredibly dismayed with the proposal that is before us for consideration. Rather than narrowing the list of outstanding issues, the overall scope and details of the regulation of September 13, 2010 have expanded dramatically leaving a regulatory proposal that is completely unworkable and that will have seriously detrimental impacts on California's economy, public health and the environment. This expanded regulatory scope leaves DTSC without the ability to articulate a meaningful basis for exempting this regulation from environmental review.

For years, GCA stakeholders have lobbied in support of bi-partisan measures to create a science based framework for chemicals management. This was particularly evident in 2008 with the passage of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008), the enabling legislation for the regulation. The driving force behind industry's efforts has been a broad based desire for state scientists, rather than legislators, to exercise their expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting chemicals of concern in consumer products.

GCA has strongly advocated for crafting regulations that enable the DTSC to fully and successfully implement the enabling legislation, which would in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development. In a proactive fashion and in response to DTSC's requests for comments, GCA stakeholders have invested countless hours over the last two years developing regulatory text (June 24, 2009, incorporated by reference) and comments for drafting implementing the regulation (May 27, 2010; November 9, 2009; and July 22,

2010; incorporated by reference). This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy.

When GCA began this process and called upon experts to become engaged, we were hopeful that the regulation would be forward looking to identify, prioritize, evaluate and regulate the highest priority chemicals of concern in high priority consumer products; promote truly safer alternatives on the basis of comparative multi-media life-cycle evaluation; consist of a comprehensive set of regulatory concepts that are within the authority of and fully satisfy the substance of the enacting legislation; allow for a clear and timely implementation in an orderly and economically responsible manner; and provide clarity regarding compliance and enforcement (May 27, 2010). What we have before us accomplishes none of these goals.

In the current and foreseeable economic climate, California must adopt balanced regulations that focus on the highest risk exposures to substances in consumer products sold or used in the state. Nowhere else in the world is there a regulatory process to manage chemicals in consumer products as aggressively as that which is being proposed. The Green Ribbon Science Panel upon reviewing earlier draft proposals cautioned against trying to do too much too soon.

The proposed regulation has not heeded the Panel's recommendation to take it slow; rather, the scope of the regulations has been expanded from everyday consumer products on store shelves to intermediate and bulk chemicals in the workplace; increased public participation and oversight at every step that will without question stifle the very innovation the regulation is supposed to promote; required costly and unnecessary third party certification; and circumvented protections against access to legitimate confidential business information and trade secrets. And all of this occurs in the absence of a science-based showing of true hazard to public health or the environment and with total disregard to the economic viability of the regulated entities and the state's economy. Such provisions will only serve to impede progress rather than stimulate it. Most unfortunate of all, the proposed regulation would have questionable value in improving the safety of consumer products in California.

Despite countless conversations highlighting the issues, the proposal fails to recognize that the regulated community can only act as quickly as the regulators can put systems in place to perform their regulatory functions (the more complicated and unclear the regulation, the slower the progress.) The proposal will not stimulate product innovation, growth, and green job creation in California; rather, it applies last century's command and control regulatory regime to what was to be a 21st century approach to consumer products. The only alternative products resulting in larger number in less time will be lawsuits.

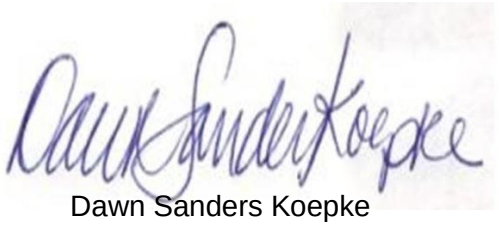
Given the current economic challenges to the state and its business community, the regulation must be realistic and pragmatic rather than assigning costly responsibilities that provide little or no benefit. At a time when California needs desperately to kick-start its economy by creating jobs, the proposed regulation imposes layer upon layer of additional cost on companies, impedes innovation and technology transfer, and will ultimately drive product development out of the state when California can least afford it. This is not the scenario the Governor enunciated during the signing ceremony for AB 1879 and SB 508. The proposed regulation fails to address these components in a clear and consistent manner that would enable the regulated community to comply with the requirements in the regulation. Moreover, much of what is proposed is well beyond the authority provided to the department under the provisions of AB 1879, SB 509 and federal laws and regulation.

While GCA appreciates the opportunity to have engaged DTSC on numerous occasions and provided detailed comments and solutions (June 24, 2009; November 9, 2009; May 27, 2010; and July 22, 2010, incorporated by reference), we are highly dismayed with the department's proposed regulations which fall far short of adequately addressing the concerns raised by GCA. These proposed regulations if adopted will have very serious and detrimental impacts on the regulated community and the state's economy. In this regard, GCA respectfully submits the following comments and related concerns regarding the Safer Consumer Product Alternatives Regulation (September 13, 2010).

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 www.greenchemistryalliance.org.

Sincerely,

John Ulrich
Co-Chair
Chemical Industry Council of California



Dawn Sanders Koepke
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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
Jeff Wong, Chief Scientist, DTSC
Odette Madriago, Chief Deputy, DTSC
Hank Dempsey, Special Advisor, DTSC

Encl: GCA Regulatory Proposal – June 24, 2009
GCA Straw 2 Comment Letter – November 9, 2009
GCA Goal Post Letter – May 27, 2010
GCA Draft Regulation Comment Letter – July 22, 2010
GCA OEHHA Draft Hazard Trait Regulation Comment Letter – September 13, 2010
GCA letter to CA Environmental Policy Council (EPC) – November 26, 2010

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 Association
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
Motor and Equipment Manufacturers Association
National Aerosol 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

Proposed Safer Consumer Product Alternative Regulations

(R-2010-05; September 2010)

PROLOGUE

- The regulations are inconsistent with the underlying statutes.
- The regulations contain numerous provisions that are either counterproductive or inefficient to the achievement of the statutes' purposes.
- The draft regulations undermine the goals of green chemistry.

ARTICLE 1 – GENERAL

§ 69301 – Purpose and Applicability

- Subdivision (b)(1) expands the scope of the green chemistry law, and contradicts the department's mandate to propose regulations which minimize its costs and maximize its benefits for the state's economy.
- Subdivision (b)(2) unnecessarily duplicates the green chemistry law and creates the potential for confusion.
- Subdivision (b)(3) expands the scope of the green chemistry law, and contradicts its purpose to regulate consumer products used in California.
- Subdivision (c), in Its Entirety, Is Inconsistent with the Green Chemistry Law and Contradicts Other Existing Law.
- Subdivision (c), and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations.
- Subdivision (c)(1) and (c)(2) Are Unclear and Appear To Be in Conflict.

§ 69301.1 – Guiding Principles

- Section 69301.1 Is Unnecessary and Goes Far Beyond the Department's Authority to Implement the Green Chemistry Law.

§ 69301.2 – Definitions

- Bioaccumulation & Persistence
- Carcinogen or Reproductive Toxin
- Chemical, Chemical Substance, Chemical Mixture
- Chemical Hazard Assessment
- Chemical/Product Removal Notifications & Tier I AA Notifications
- De Minimis
- Economic Impacts
- Financial Guarantee
- Functionally Equivalent
- Hazard Traits
- Intentionally Added Chemical or Chemical Ingredient
- Intermediate Manufacturing Materials & Processes
- Multimedia
- Nanomaterials
- Place into the Stream of Commerce
- Product Stewardship
- Reliable Information
- Responsible entity
- Unreasonable Compliance Options for Non-Manufacturer Responsible Entities
- Safer
- Sensitive Subpopulations
- Threat
- Trade Secret

§ 69301.4 – Duty to Comply and Consequences of Non-compliance

§ 69301.5 – Information Submission and Retention Requirements

§ 69301.6 – Chemical and Product Information

- The Department Lacks the Authority to Request Data From Manufacturers
- Fails to Provide Clarity and Certainty
- The Department Has Not Shown Why the Suggested Information is Necessary For Prioritization
- Lacks Necessity

ARTICLE 2 & 3 – CHEMICAL/PRODUCT PRIORITIZATION PROCESS

§ 69302 – Chemical Prioritization Process

§§ 69302.1 and 69303.1 – Applicability: Duplication

- The Proposed Regulation Attempts to Supersede Other Agency Authorities and/or Duplicate Existing Regulations
- Particular Concerns Associated with Intermediate Manufacturing Materials & Processes

§§ 69302.1 and 69303.1 – Applicability: "Reasonable & Foreseeable" Exposure

§ 69302.1 and 69303.1 – Applicability: Science Based Decisions

§§ 69302.2 and 69303.2 – Chemicals/Products Lists: Hazard & Exposure Info

§ 69302.3 – Chemicals Under Consideration

- Subdivisions (a) Through (g), and Many of Their Subparts, Are Unclear and Fail To Meet the Necessity Standard for Proposed Regulations.
- Subdivision (b)(25) and (d)(5) are unclear.

Using Regulatory Duplication as a Priority Factor Is Inappropriate

ARTICLE 3 – PRODUCT PRIORITIZATION PROCESS

§ 69303.1 – Applicability: Intermediate Manufacturing Materials & Processes

§ 69303.2 - Product Lists

- Subdivision 69303.2(d) Fails To Meet the Necessity Standard for Proposed Regulations.
- Subdivision 69303.2(d)(3) Goes Beyond the Department's Authority to Implement the Green Chemistry Law.
- Subdivision 69303.2(e) Is Inconsistent with the Green Chemistry Law, Contradicts Other Existing Law and Fails To Meet the Necessity Standard for Proposed Regulations.

§ 69303.3 – Products under Consideration: Exposure

- Intermediate Manufacturing Materials & Processes
- Fails To Meet the Necessity Standard for Proposed Regulations.
- Subdivision (c)(5) Is Inconsistent With, and Exceeds the Department's Authority Under, the Green Chemistry Law.

§ 69303.4 – Priority Products

- § 69303.4 Fails To Meet the Necessity Standard for Proposed Regulations.

ARTICLE 4 – PETITION FOR INCLUSION OF A CHEMICAL OR PRODUCT IN THE PRIORITIZATION PROCESS

- **§ 69304 – Applicability and Petition Contents**

ARTICLE 5 – ALTERNATIVES ASSESSMENTS

- **§ 69305 – Alternatives Assessments**
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- **§ 69305.3 – De Minimis Level (0.1%) & Exposure**

ARTICLE 6 – REGULATORY RESPONSES

- **No clarity that Regulatory Responses must be proportional to the degree of risk**
- **§ 69306.2 – No Regulatory Response Required**
- **§ 69306.3 – Product Information to Consumers**
- **§ 69306.4 – End-of-Life Management Requirements**
- **§ 69306.5 – Product Sales Prohibition**
- **§ 69306.6 – Other Regulatory Responses**
- **§ 69306.9 – Regulatory Response Report and Notifications**

ARTICLE 7 – DISPUTE RESOLUTION PROCESSES

ARTICLE 8 – ACCREDITATION AND QUALIFICATION REQUIREMENTS FOR PERFORMANCE OF ALTERNATIVES ASSESSMENTS

§§ 69308, 69308.1, and 69308.2 – Requirements for Qualified Third-Party Assessment Entities, In-House Assessment Entities, and Designated Accrediting Bodies

- Article 8, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations.
- Subdivision (a)(4)(A) Exceeds the Department's Authority, Conflicts With Other Law and Is Unclear.

§ 69308.2 - Requirements for Designated Accrediting Bodies

- Subdivision (g)(2) Conflicts With Substantive and Procedural Due Process Protections and Is Unclear.

§ 69308.3 – Lead Assessor Accreditation

ARTICLE 10 – CONFIDENTIALITY OF INFORMATION

GCA Asserts Article 10 Is Not Necessary and Should be Struck In Its Entirety

§ 69310 – Confidential Business Information

§ 69310.1 – Assertion of A Claim of Confidential Business Information

- The Duplicative Portions of This Section Are Unnecessary
- Portions of This Section Are Inconsistent and Expand the Scope of the Underlying Law

§ 69310.2 – Marking and Indexing of Documents

- The Duplicative Portion of This Section Is Unnecessary
- The Portion of This Section Is Inconsistent and Expands the Scope of the Underlying Law
- The Requirement for a Claims Index Threatens the Security of Trade Secrets

§ 69310.4 – Support of a Claim of Trade Secrets Protection

- A Portion of **§** 69310.4 Lacks Clarity
- Requiring Extensive Substantiating Information Within Ten Days Is Infeasible, Unnecessary, and Inconsistent with Existing Law
- Significant Portions of § 69310.4, Requiring Substantiating Information, Are Unnecessary and Inconsistent with the Statutory Definition of a Trade Secret

§ 69310.5 – Departmental Review of Trade Secret Claims

- Subdivision (a) of § 69310.5 Is Inconsistent With Underlying Law
- Subdivision (b) of § 69310.5 Duplicates **§** 25257 and Is Unnecessary

§ 69310.6 – Hazard and Trait Submission

- The Portion of § 69310.6 That Duplicates Existing Law Is Unnecessary
- The Balance of § 69310.6 Is Inconsistent With the Underlying Law

Summary of Comments on Article 10

ARTICLE 11 – SMALL BUSINESSES

- Article 11, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations.

OTHER ISSUES OF SIGNIFICANCE

- An Effective, Less Burdensome Alternative to the Proposed Action Exists
- The Proposed Action Constitutes a Technical Barrier to Trade
- The Department is Obligated to Comply with CEQA

CONCLUSION

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, 2
6) GCA letter to CA Environmental Policy Council (EPC) – November 26, 2010

PROLOGUE

After careful review and consideration, The Green Chemistry Alliance (GCA) has conclusively determined that the draft regulations do not promote our shared goals for numerous reasons. The regulation is fundamentally inconsistent with the underlying statutes. It contains numerous provisions that are either counterproductive or inefficient to the achievement of the shared goals. And, most ironically, it undermines the goals of green chemistry. We discuss each of these three issues in this section. More detailed analysis is provided in the comments that follow.

1. The regulations are inconsistent with the underlying statutes

- AB 1879 calls for the adoption of regulations to identify and prioritize chemicals in consumer products. Health & Safety Code (H&S Code) § 25252(a). The proposed regulations go well beyond the regulation of chemicals in *everyday* consumer products, which are the focus of nearly every presentation by DTSC. These regulations if adopted would encompass such complex items as buildings, vehicles of all shapes and sizes, aircraft, and even tank car quantities of chemical raw materials and intermediates.

- The statute requires that the department not duplicate or adopt regulations for product categories subject to other similarly intentioned regulations. H&S Code § 25257.1(c). The flow chart developed to summarize the conclusions of the Green Chemistry Initiative Final Report also shows exemptions for chemicals and products "regulated by others." However, the proposed regulations will not provide exemptions as contemplated by the flow chart or the statute. Clear exemptions must be included to implement the statutory requirement.

- AB 1879 calls for the protection of trade secrets, consistent with provisions in the Government and Evidence Codes. H&S Code § 25257. However, the draft regulations provide for trade secret protection that is less protective than provided for in current California law. The department does not have the authority to erode the trade secret protections set forth in California statute. See discussion re: Article 10, p. 54.

2. The regulations contain numerous provisions which are counterproductive and/or inefficient to the achievement of the statutes' purposes

- It was the intent of the Legislature that the regulations be structured to allow maximum use of information from other nations and other states to leverage work already completed and to minimize costs. H&S Code § 25252(b)(2). Notwithstanding this clear direction, most of the definitions and applicability of terms in the draft regulations that are also used in federal and international protocols deviate from the accepted international and federal definitions and standards (*e.g.,* the definitions of bioaccumulation, chemical, chemical hazard assessment, *de minimis,* nanomaterials, reliable information, reasonable and foreseeable in product safety laws, and responsible entity). An inconsistent regulatory program will make the sharing and comparing of information among California, national and international agencies difficult and inefficient because California refuses to "speak the same language."

- Prioritization of risks is a critical element of the statute. *See*, H&S Code § 25252(a). A number of provisions in the regulations are counter-productive to establishing an efficient prioritization process. For example: 1) there is no exemption for products where the reasonable or foreseeable risk of exposure is low or even inconsequential thus sweeping a large number of low-risk products into the regulatory universe; and 2) the definitions of "hazard trait," "reliable information" and "threat," and the related definition of "adverse effect" in the OEHHA draft regulations, cast the net so broadly that virtually every chemically-formulated product will be subject to some form of regulation. This latter point will result in significant regulatory and economic uncertainty for those potentially subject to the regulation.

- The regulations require mandatory third-party verification for ***all*** Tier II alternatives assessments. While appropriate in some instances, third party involvement in all cases is not justified. GCA supports the use of third parties under certain circumstances, however, the provision to subject ***all*** Tier II assessments to third party review is unnecessary in light of the department's direct role in reviewing alternatives assessment work plans and reports,. Third-party assessments will increase the bureaucracy and delay the completion of alternatives assessments. In the case of particularly complex assessment, third-party assessments are also likely to be less reliable than work done by in-house assessors who intimately understand the full range of factors that must be considered. Third-parties simply cannot duplicate the in-house expertise necessary to conduct complex assessments. Significantly, it must be noted that AB 1879 neither addresses nor mandates third-party verification.

3. The draft regulations undermine the goals of green chemistry

- The Green Chemistry Initiative Final Report envisioned a process in which the universe of chemicals would be prioritized in a two-step process—by identifying "*Chemicals under Consideration*" from the entire universe of chemicals and then further identifying a subset of "*Chemicals of Concern*." Consumer products that contained this narrower category of "*Chemicals of Concern*." would then enter the assessment process The draft regulation ignores this prioritization process and subject consumer products containing one or more of the much broader set of *"Chemicals under Consideration"* to burdensome regulatory requirements. This destroys the prioritization process, which was a foundational element of the product evaluation process and subjects potentially low-risk products to the same level of scrutiny as potentially high-risk products. Without effective prioritization, the goal of addressing the highest risks first is lost.

- Green Chemistry envisions that chemists will play a fundamental role in reducing risks by synthesizing new safer chemicals and designing products that are more benign. Regulations that promote innovation and target regulatory activities to where they are most needed will spur innovation. The draft regulations, which feature extensive oversight, third-party verification, a much larger number of required assessments, and unprecedented restrictions on protection of trade secret information, will stifle innovation rather than promote it.

GCA and its members have worked diligently with other stakeholders for more than two years to promote the Green Chemistry Initiative and the associated regulations. Our goal has been to help develop a set of regulations that would identify the highest priority chemicals of concern, focus on consumer products using the chemicals of concern that present the greatest risks, and promote safer alternatives by challenging and bringing out the best in our research chemists.

Unfortunately in the roughly 8-week interval between the time the discussion draft regulation were released (June 23, 2010) and the more recent official notice of the formally Proposed Regulations (September 13, 2010) the language in the proposed regulation has been altered so significantly that it is now fundamentally unworkable. The proposed regulation undermines the chemical and product prioritization process such that resources will not be focused where real risk reductions may be possible. Instead, the focus will be expanded to encompass a larger number of chemicals and products, many of which will offer marginal risk reduction possibilities, but with significant costs to the department and the regulated community.

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ARTICLE 1 - GENERAL

§ 69301 - Purpose and Applicability

Subdivision (b)(1) expands the scope of the green chemistry law, and contradicts the department's mandate to propose regulations which minimize its costs and maximize its benefits for the state's economy: Section 69301(b)(1) declares the scope of the proposed regulations to include all consumer products placed into the stream of commerce in California. However, Health and Safety Code **§** 25257.1 limits the department's authority by proscribing regulation of product categories that are already regulated, or subject to pending regulation consistent with the purposes of the green chemistry law. Thus, the proposed language exceeds the authority given the department by statute. Moreover, to the extent subdivision (b)(1) includes consumer products that are already regulated it is inconsistent with Health and Safety Code **§** 25252(b)(2), which requires the department to minimize costs and maximize benefits for the state's economy when adopting regulations to implement AB 1879 and SB 509 ("the green chemistry law"). Finally, the Initial Statement of Reasons ("ISOR") provided by the department as justification for adopting this subdivision fails to explain the problem, administrative requirement, or other condition or circumstance which it is intended to address, or explain why it is necessary to encompass consumer products that are already subject to regulation to accomplish the purpose of the green chemistry law.

For the reasons above, subdivision (b)(1) fails to meet the authority, consistency and necessity standards set out in Government Code **§** 11349.1 and 1 CCR §10.

Subdivision (b)(2) unnecessarily duplicates the green chemistry law and creates the potential for confusion: This subdivision does nothing more than exempt consumer products, and parts of consumer products, that are already specifically exempted from the definition of consumer product in Health and Safety Code **§** 25251. Moreover, the proposed language creates the potential for confusion because it uses different terms than **§** 25251. To the extent the use of those terms is intended to make the statutory exemptions more clear or specific, the ISOR

completely fails to explain the reasons or necessity for doing so. The statutory exemptions speak for themselves and there is no need for them to be repeated in the regulation.

For the reasons above, subdivision (b)(2) fails to meet the nonduplication, clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision (b)(3) expands the scope of the green chemistry law, and contradicts its purpose to regulate consumer products used in California: On its face, **§** 69301(b)(3) appears to limit the scope of the proposed regulations by excluding consumer products manufactured, stored or transported in California solely for use outside of the state. Such a limitation is appropriate and consistent with the Commerce Clause of the federal Constitution, which precludes California from regulating foreign or interstate commerce. In effect, however, subdivision (b)(3) establishes a presumption, albeit implicitly, that any product present in California is within the California stream of commerce and, therefore, subject to the proposed regulations. Subdivision (b)(3) goes further, explicitly, and imposes a burden on the "manufacturer" of the product to establish that it is manufactured, stored or transported solely for use outside of California. Manufacturer is defined elsewhere in the proposed regulations, in § 69301.2(a)(47), to include the producer of a consumer product or the person who owns or licenses the brand name or trademark of the consumer product.

Subdivision (b)(3) runs afoul of Government Code § 11349.1 for several reasons, not the least of which is the fact department has no authority under the green chemistry law to establish a presumption or allocate the burden of proof with respect to the intended use of products within California but destined for interstate or foreign commerce. Even if the department has authority to make such a rule, it cannot use that authority to regulate a manufacturer, brand owner or trademark owner who has no presence in California and has no responsibility for the presence of a product within California. As noted above, such a rule is inconsistent with the limits on the state's authority established by the Commerce Clause, not to mention inconsistent with the green chemistry law itself, the purpose of which is to identify and limit exposure to chemicals of concern in consumer products "used" in California, as defined by Health and Safety Code § 25251(e).

Finally, the ISOR fails to explain the necessity of this provision to implement the green chemistry law. Reduced to its essence, the ISOR does nothing more than restate what the provision does and then conclude that the provision is necessary to do what it does. Such a tautology in no way explains the problem, administrative requirement, or other condition or circumstance which it is intended to address, much less why it is necessary to do so.

For the reasons above, subdivision (b)(3) fails to meet the authority, consistency and necessity standards set out in Government Code § 11349.1.

Subdivision (c), in Its Entirety, Is Inconsistent with the Green Chemistry Law and Contradicts Other Existing Law: Taken as a whole, the provisions of subdivision (c) exempt from regulation consumer products which only contain unintentionally added chemicals or chemical ingredients if the producer of the product: (1) exercises due diligence to identify the presence of such ingredients by taking reasonable steps to become knowledgeable about the source, composition and types of chemicals used to make the product, and about the manufacturing process itself, including likely chemical reactions during that process; and (2) the producer cannot reasonably be expected to know of the presence of the unintentionally added chemical

or chemical ingredient under all of the facts and circumstances. Subdivision (c) is inconsistent with the green chemistry law, specifically Health and Safety Code § 25257.1, which precludes the department from superseding the regulatory authority of any other department or agency, or adopting duplicative or conflicting regulations for already regulated products. In particular, California's Proposition 65 initiative passed by the voters already regulates the presence of naturally occurring or unintentionally added chemicals or chemical ingredients in consumer products. Even more, subdivision (c) conflicts with Proposition 65 because it would make the presence of any naturally occurring or unintentionally added chemical or chemical ingredient actionable under the proposed regulations even though no action would be required under Proposition 65. Finally, to the extent subdivision (c) regulates chemicals or chemical ingredients that are the subject of Proposition 65 but would require no action under that law, the regulation is inconsistent with Health and Safety Code § 25252(b)(2), which requires the department to minimize costs and maximize benefits for the state's economy when adopting regulations to implement the green chemistry law.

For the reasons above, subdivision (c) fails to meet the consistency standard set out in Government Code § 11349.1.

Subdivision (c), and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations: With respect to the provisions of § 69301(c), the ISOR does nothing more than describe what the individual provisions do, in large part by simply restating the provisions themselves. However, to demonstrate the necessity of these provisions the ISOR must explain the problem, administrative requirement, or other condition or circumstance which each provision is intended to address, and explain why the provision is necessary to do so. In this instance, as is true in many instances throughout the ISOR, the explanation provided by the ISOR is not just insufficient, it is completely nonexistent.

The reasons for excepting non-intentionally-added ingredients are obvious, to focus application of the green chemistry law on real risks and product design that can be addressed. However, it is not obvious why the benefit of such an exception is then conditioned with virtually impossible hurdles. Certainly, no necessity is demonstrated in the ISOR for imposing the limiting conditions set out in subdivision (c).

For the reasons above, subdivision (c) and each of its subparts fails to meet the necessity standard set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision (c)(1) and (c)(2) Are Unclear and Appear To Be in Conflict: Subdivision (c)(1) specifies the first of four conditions that must be met for a product which includes unintentionally added chemicals or chemical ingredients to be exempt from the proposed regulations. Specifically, it requires the "producer" of the product to exercise "due diligence" to identify the presence of such ingredients in the product by taking "reasonable steps" to become knowledgeable about the source, composition and types of chemicals used to make the product, and about the manufacturing process itself, including likely chemical reactions during that process. Although "producer" is defined elsewhere in the regulations, "reasonable steps" and "due diligence" are both left undefined. As a result, producers who are subject to the regulation are left in the dark about what actions are necessary to meet the requirements of this provision.

Subdivision (c)(2) specifies the second of the four conditions that must be met for a product which includes naturally occurring or other unintentionally added chemicals or chemical ingredients to be exempt from the proposed regulations. It requires that the producer cannot reasonably be expected to know of the presence of the unintentionally added chemical or chemical ingredient in the product under all of the facts and circumstances. What is unclear is how a producer can possibly satisfy subdivision (c)(1) but not satisfy subdivision (c)(2).

For the reasons above, subdivisions (c)(1) and (c)(2) fail to meet the clarity and consistency standards set out in Government Code § 11349.1.

§ 69301.1 - Guiding Principles

§ 69301.1 Is Unnecessary and Goes Far Beyond the Department's Authority to Implement the Green Chemistry Law: This section would establish guiding principles the department and those who fall under the regulation must follow to comply with its provisions. The green chemistry law does not provide authority for the department to adopt such principles, much less impose them on those it regulates. Moreover, as elsewhere, the ISOR utterly fails to explain the necessity for any one of its requirements.

For the reasons above, § 69301.1 and each of its subparts fail to meet the authority and necessity standards set out in Government Code § 11349.1.

§ 69301.2 - Definitions

GCA is concerned that having a set of new California-only definitions as proposed under the regulation is inefficient, duplicative, and will make it unnecessarily difficult to leverage existing information. DTSC should harmonize as much as possible with existing international and national definitions that are already in place and use under other chemical and product regulations (*i.e.,* OECD, EPA, GHS, TSCA, etc.).

Bioaccumulation & Persistence

In § 69301.2, the definitions for "bioaccumulation" and "persistence" are not consistent with nationally and internationally accepted definitions. Besides ignoring the statutory mandate to incorporate existing approaches, novel definitions will make implementation of the regulations more complex and will slow it down as the department attempts to translate all of the extensive information, teachings and actions from global programs into a California-unique approach. GCA suggests that the Proposed Regulation definitions be deleted and changed to be based on definitions in the following:

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

Chemical, Chemical Substance, Chemical Mixture

In § 69301.2, the term "chemical" is defined as chemical substances, chemical mixtures, and nanomaterials. Separately, chemical mixtures are defined as a mixture or solution of two or

more chemical substances. This is confusing and circular, does not properly distinguish the situation in the real world and will create substantial issues in implementation. The definition of "chemical mixture" should be written to distinguish intentionally engineered and manufactured formulations from blends of distinct chemical substances that might occur naturally or as a result of standard processing of industrial chemicals. More specifically, DTSC should revise the definition to exclude "chemical mixtures" from the definition of chemical. Doing so would avoid undermining the proposed regulation's step-wise architecture of first focusing on chemicals and then moving on to products (mixtures and articles) that contain particular chemicals.

Commonly recognized products, such as paints, are carefully engineered and manufactured "chemical mixtures" designed to have certain performance characteristics. On the other hand, "chemicals" are individual substances defined by a Chemical Abstract Services ("CAS") number. There are many mixtures that are defined by TSCA as chemical substances because these mixtures are a result of nature and/or standard chemical processing reactions. These mixtures are assigned a single CAS number for listing on the TSCA Inventory.

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

As recommended in prior GCA comments submitted on July 22, 2010, GCA urges DTSC to include the following language consistent with TSCA:

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

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

(B) Such term does not include—
(I) any mixture,
(ii) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. §§ 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide,
(iii) tobacco or any tobacco product,
(iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. §§ 2011 et seq.] and regulations issued under such Act),
(v) any article the sale of which is subject to the tax imposed by § 4181 of the Internal Revenue Code of 1954 [1986] [26 U.S.C. § 4181] (determined without regard to any exemptions from such tax provided by § 4182 or 4221 [26 U.S.C. § 4182 or 4221] or any other provision of such Code), and
(vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

The term "food" as used in clause (vi) of this subparagraph includes poultry and poultry products (as defined in Sections 4(e) and 4(f) of the Poultry Products Inspection Act [21 U.S.C.

Section 453(e) and 4(f)]), meat and meat food products (as defined in Section 1(j) of the Federal Meat Inspection Act [21 U.S.C. Section 601(j)]), and eggs and egg products (as defined in Section 4 of the Egg Products Inspection Act [21 U.S.C. § 1033]).

The term "mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include any combination which occurs, in whole or in part, as a result of a chemical reaction if none of the chemical substances comprising the combination is a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined.

Subdivision (a)(10)(c) Exceeds the Departments Authority Under the Green Chemistry Law: Subdivision (a)(10)(c) would include "nanomaterial" within the definition of chemical notwithstanding that the green chemistry law provides no authority for the department to regulate nanomaterial other than to the extent such material can be considered a chemical or chemical ingredient. In fact, the term nanomaterial cannot be found in either SB 509 or AB 1789.

For the reasons above, subdivision (a)(10)(c) fails to meet the authority standard set out in Government Code § 11349.1.

Chemical Hazard Assessment

Section 69301.2(a)(12) defines "chemical hazard assessment" as an approach to assessment of pertinent hazards of the chemical of concern in the priority product in comparison to the alternatives. This is a critical component in Alternative Analysis. Unfortunately, the regulation is employing a term that is used nationally by EPA and internationally by OECD, the EU, Japan and others to describe the approach for consolidating and assessing all of the hazard information on a single chemical. Use of this term in the Green Chemistry context is confusing and unclear. To avoid confusion and to be more descriptive and clear, we recommend using a term such as "*comparative hazard assessment*."

Chemical/Product Removal Notifications & Tier I AA Notifications

In § 69301.2 and § 69305.1, the department would require any manufacturer of a consumer product containing a *Chemical of Concern* (either a *Priority Chemical* or a *Chemical Under Consideration*) to comply with burdensome reporting requirements, including Chemical/Product Removal Notifications or Tier I AA Notifications and Reports, prior to placing redesigned products on the market or removing products from California commerce. The Removal Notifications are doubly burdensome in requiring submission first of an Intent Notification and then a Confirmation Notification. They will truly stifle innovation and present a significant hurdle to doing business with California consumers. These provisions are completely counter to the stated purpose of the Safer Consumer Product Alternatives regulations, namely to bring safer products to the market quickly and efficiently. The purpose of these requirements seems to be solely to educate the department regarding product design; the department's conceptual flow chart shows this as a dead-end of information to be collected and posted, not cycling back to any critical decision-making process. The Initial Statement of Reasons states, "The AA

Notification is necessary so that DTSC can keep an eye out for any regrettable substitutions." In doing this, the department puts itself in the position of being the gatekeeper and scorekeeper for any change to any product coming on the market in California. This establishes a *de facto* pre-market registration system for products in California, a completely unjustified burden that is unnecessary, unauthorized and unworkable. In particular, the Tier I AA notification process in § 69305.1 discourages companies from reformulating products containing a *Chemical of Concern* until it is identified by the state as a *Priority Product* containing *Priority Chemicals*. This will freeze innovation in California. Due to paperwork and market delay burdens that have very real effects on the cost of doing business, the state will be the last place to see introductions of safer and more sustainable products.

Sections § 69301.2, § 69305.1 and § 69305.3 should be amended so these are voluntary submission processes, unrelated to the timing of product introductions into California commerce and the department should provide incentives for participation so that safer products are brought to the market quickly.

GCA recommends that the Removal Notification be a single voluntary submission. If the department needs to develop its knowledge base in the arena of product development, it should find a more effective approach. Also, the scope of these provisions should be limited to *Chemicals of Concern*[1] in *Priority Products*. If a manufacturer removes a *Chemical of Concern* from a *Priority Product* and does not replace it with a *Chemical of Concern*, there should be no further regulatory requirements.

De Minimis

GCA has consistently advocated for the inclusion of a *de minimis* threshold in the implementing regulation (June 24, 2009; November 9, 2009; May 27, 2010; and July 22, 2010). GCA supports the inclusion in these proposed regulations of a *de minimis* exemption with a default level of 0.1%. This is consistent with numerous state, federal and global regulations, including the European Union's implementation of the Globally Harmonized System (GHS) for product classification. In addition to applying a default threshold of 0.1% by weight, the EU GHS establishes chemical-specific thresholds that may be lower or higher than 0.1% based on sound science and reliable information. The Proposed Regulation gives DTSC the authority to adopt a similar approach.

However, the remainder of the definition is a presentation of "safe" levels in existing regulations that are inherently based on risk, use, application, and to some extent policy. To make those other regulatory thresholds relevant to these regulations, DTSC would need to establish the appropriate intake or exposure level (as the SCPA threshold), taking into consideration the facts of the specific public health regulation. For example, drinking water MCLs are based on risk and assume a drinking water ingestion rate of 2 liters/day. Thus the MCL level is not directly relevant to a consumer product. Nor are the thresholds from other cited regulations consistent with the exposure that results from contact with a consumer product, with the exception of Proposition 65 MADL's. An additional concern is that the MCLG "safe" level for a carcinogen is equal to zero and is stated as a goal, not a standard. Thus, the direct re-application of

[1] Note: GCA strongly recommends the term "Priority Chemical" be eliminated and restored to its previous identifier, namely, "Chemical of Concern." It is in this context and this context only that the above GCA recommendation references "Chemical of Concern" rather than "Priority Chemical."

thresholds from the regulations cited in this section is not consistent or appropriate for SCPA. The current approach fails to connect the scientifically appropriate levels to designated products. If DTSC wants to re-apply the science in these regulations, we suggest that they be clarified and re-applied to SCPA on the basis of intake levels to be scientifically consistent with the other regulations.

The Proposed Regulations also continue to contemplate situations where "0" is an appropriate *de minimis*. Zero ("0") is a technically impossible to measure regulatory standard that provides no additional benefit to public health and the environment. As described below, the inability for a manufacturer to seek a *de minimis* exemption for nanomaterials is especially problematic. In a situation where DTSC scientists believe 0.1% is not appropriate as a *de minimis* concentration, they should calculate an alternative threshold concentration—either higher or lower – considering detection limits (which are not the same as zero) and taking into account the ability to reliably and accurately measure the analyte in the product matrix using commercially available analytical equipment and methodologies. Experience in the European Classification and Labeling system (EC No. 1272/2008) is that for 85% of the over 3300 chemicals with classified hazards the *de minimis* is 0.1%; for the remaining 15% the EU has determined a different level—sometimes lower and sometimes higher.

In § 69305.3, a notification to the department is required to apply the *de minimis* exemption to a *Priority Product*. This requirement is unnecessary, unauthorized and bureaucratically burdensome. 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.

Finally, as outlined in the proposed regulation, the *de minimis* seems only to apply to Priority Products. That is appropriate, but there are other items to which the *de minimis* should also apply--Chemical/Product Removal Notifications, and Tier I AA Notifications. While GCA does not believe that there is a necessity for, nor is there authorization for supporting the burden imposed by any of these, it would be appropriate to include the *de minimis* in determining when they are required.

The reason for establishing a *de minimis* level is obvious, to focus application of the green chemistry law on real risks and product design that can be addressed. Moreover, the reason for setting 0.1% as the de minimis standard is also obvious. It is the standard that is virtually established universally in regulatory programs around the world and certainly in those programs with features similar to the California green chemistry law. However, the necessity for selecting standards unrelated to such programs as the mandated exceptions to the *de minimis* standard is non existent. As noted above, such standards are unrelated to the anticipated exposures resulting from use of consumer products. Certainly, no explanation or rationale is given setting out the standards to be imposed as exceptions to the 0.1% *de minimis* standard.

For the reasons above, subdivision (a) (24) fails to meet the necessity standard set out in Government Code § 11349.1.

<u>Economic Impacts</u>

Subdivision (a)(27) Is Unclear and Duplicative: Subdivision (a)(27) defines "economic impacts" as an increase or decrease in jobs or businesses, the costs of doing business, the cost of goods to consumers, or other economic impacts including, but not limited to, economic impacts

specified in § 69305.5(d)(4). This definition is unclear because it defines economic impacts using the term itself. It is also unclear because it is made completely open ended by use of the phrase "including, but not limited to" and provides no criteria by which one might understand its limits. Finally, it is duplicative because the same term is defined elsewhere in the regulations, § 69305.5(d)(4).

For the reasons above, subdivision (a)(10)(c) fails to meet the standards for clarity and non-duplication set out in Government Code § 11349.1.

Financial Guarantee

The definition included in the Proposed Regulations fails to explain what DTSC plans to require for a financial guarantee. It is unclear from this definition how the regulated community would determine how much guarantee is needed, for how long the guarantee would be needed, as well as what mechanisms would be acceptable to satisfy the financial guarantee responsibility. Many financial institutions are becoming uncomfortable issuing the letters of credit or guarantees due to the vagueness of the obligations such as the one suggested in the Proposed Regulations. This concept of requiring a financial guarantee should be eliminated from the Proposed Regulations, both in the definition and in the requirements for an end of life management program in Section 69306.4.

Functionally Equivalent

There is an inconsistency in the regulation relating to judging comparative product performance. In § 69301.1(c) Guiding Principles, the goal of the program is stated as "…encouraging the redesign of consumer products and manufacturing processes and approaches, while maintaining or enhancing product function and performance." However, in § 69301.2(36) an inconsistent view for judging performance "functionally equivalent" is introduced that considers performance adequate when it "substantially satisfies the intended performance and functionality of the original product." This latter approach is carried through the balance of the regulation. GCA objects to this second definition in the strongest possible terms. Alternatives must be developed that "meet or exceed" current function and performance, not "substantially satisfy" the current function and performance. Californians will not accept products that perform worse or "almost as good." GCA requests that these provisions be made consistent by changing the terms from "substantially satisfies" to "meets or exceeds" in the definition for functionally equivalent.

Hazard Traits

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

On October 1, 2009, DTSC published a "Straw Proposal" for the implementation of the GCI. This proposal established a series of hazard categories for the evaluation of chemicals of concern. These criteria were: (1) acute toxicity, (2) eye irritation, (3) genetic toxicity and

mutagenicity, (4) reproductive toxicity, (5) carcinogenicity, (6) endocrine disruption, (7) respiratory sensitization, (8) skin sensitization, (9) bioaccumulation, (10) acute aquatic toxicity, and (11) hazards to the ozone layer. GCA provided detailed comments critiquing this proposal (November 9, 2009). But in general, these criteria follow the internationally accepted system of nomenclature on hazard traits used by EPA, the OECD and in REACH.

However, in § 69301.2(a)(39) and § 69302.3, the Proposed Regulation unfortunately incorporates a uniquely California system and approach to hazard traits proposed by OEHHA in its pre-draft regulation. GCA and its stakeholders filed extensive comments critiquing this proposal (September 13, 2010, incorporated by reference). The proposed system is completely unnecessary—it ignores national and international approaches to identifying hazard traits, to determining the reliability of information and to classifying levels of hazard. The entire proposed system should be scrapped and California should adopt approaches in concert with national and internationally accepted systems. Not doing so will dramatically slow progress on advancing Green Chemistry in California. Just to cite one example—by March 2011, the hazard, use and exposure information on over 4,000 high volume chemicals plus CMR's and high ecotoxicity chemicals submitted in the first phase of REACH will be publicly available. This will provide hundreds of thousands of toxicology and exposure studies. All of these studies will be presented in the internationally accepted approaches noted above. Because OEHHA's proposed system ignores those approaches, Californians will have to wait years before the REACH information is converted to this California-unique system. Why would the department accept this tragic waste of time and money, disregarding the statutory mandate to make use of existing systems, and foreclose any chance of fully achieving the goals of the Green Chemistry Initiative? Doing so is absolutely inconsistent with the authorizing statute's mandate to utilize information generated in other systems.

Intentionally Added Chemical or Chemical Ingredient

GCA appreciates that the definitions of intentionally added and unintentionally added are in line with the recommendations we provided in our previous comments. § 69301.2(a)(41) and § 69301.2(a)(82). However, the manner in which these terms are used in the "Applicability" section create confusion and problems. In § 69301 (Applicability) unintentionally is further narrowed to "an ingredient that is not known by the producer to be present in the product". This provision suggests that anything present in the product that the manufacturer knows or should have known about is subject to the regulations and only a substance that the manufacturer cannot reasonably be expected to know about is exempt. Therefore, an exemption for unintentionally added substances only applies to substances that are completely unexpected surprises. Although the exemption may be applicable in the case of tainted products or supply chain mistakes, it is of little applicability to most products, for example, those incorporating natural materials or recycled content.

The only other instance of these concepts being incorporated is the use of "intentionally added" as used is in § 69301.6 (Chemical and Product Information) where the department requests information to identify "intentionally-added chemicals and chemical ingredients in specified products." The GCA's interest in this concept was to use it together with the *de minimis* concept to exempt products from the burdens of the regulation related to unintentional constituents that pose less potential risk than intentionally added ingredients. Instead, the draft uses various forms of the term "contain" such as "…threat to public health and/or the environment due to the. Priority Chemical contained in the product". Therefore the Proposed Regulation applies to every molecule that manufacturers know or should have known is in a product, including trace level

contaminants from water, air, etc. As outlined in GCA's comment letter dated July 22, 2010, GCA urges the department to limit the applicability of the proposed regulation to only those chemicals that are intentionally added above the relevant de minimis amount.

Intermediate Manufacturing Materials & Processes

Section 69301.2(a)(42) provides the following two-part definition of "intermediate manufacturing process".

A. The primary processing of raw materials into industrial materials, and

B. The secondary processing of industrial raw materials including, formulating, casting and molding, forming, separating, conditioning, further refining, assembling and finishing processes to manufacture consumer products.

The terms "raw materials", "industrial materials", and "industrial raw materials" are particularly ambiguous in an integrated manufacturing site where one facility's industrial material is or becomes another facility's raw material or industrial raw material.

Multimedia

Missed in the regulation's development is that which is contained in the "multimedia" section, DTSC must show that their regulations do not cause a "significant adverse impact on the public health or the environment." This provision is intended to insure against regrettable substitution. GCA commented regarding this provision and our comments are incorporated by reference and attached to these comments as Exhibit 6.

The Legislature clearly intended for the regulations to be subject to a multimedia analysis and the exception provided in subsection (f) is extremely narrow. The evidence in the record makes clear that the California Environmental Policy Council's (EPC) "conclusive finding of no significant impact" is not supported (See Exhibit 6, GCA letter to EPC dated October 26, 2010, and incorporated by reference herein). Furthermore, the process that was followed to make that finding is highly suspect, and evidences that the Bagley-Keene Act and legal requirements of fairness and procedural due process were violated. In addition, these regulations constitute a project that is discretionary and has a host of reasonably foreseeable direct and indirect physical changes in the environment that could result in a potential significant impact on the environment. Thus, DTSC had a legal obligation to perform a programmatic EIR to inform itself of these impacts, so as to better craft regulations that avoid, minimize or mitigate them. These issues are addressed in more detail the Alston & Bird LLP letters dated October 26, 2010 and November 1, 2010, and incorporated by reference herein.

Nanomaterials

Despite the ability for a manufacturer to claim a *de minimis* exemption, the inability for a manufacturer to seek such an exemption for nanomaterials is especially problematic. Virtually every granular material in commerce in California will have some portion of particle size that would result in the material being considered "nano" under the definition as currently written. Additionally, the current definition used for nanomaterials ("…*the nanostructure is larger than*

*nanoscale in any spatial dimension, but is **1000 nanometers or less in at least one spatial dimension**…"* [emphasis added]) is out of step with virtually every other recognized definition around the world. This difference introduces considerable, and unnecessary, confusion in interpretation and compliance. We would encourage the DTSC to look for a more harmonized definition that facilitates interstate and international commerce rather than one that drives California towards commercial isolation. Most definitions in place currently are based on the ISO Technical Standard 27687 which defines nanoscale as approximately 1-100 nm and nanomaterials as those with one, two or three dimensions in the nanoscale. The merits and limitations of the ISO definition have been thoroughly vetted in a multi-stakeholder process, which has resulted in the ISO definition serving as the basis for most regulatory definitions currently under consideration.

The California Nano-Industry Network (CalNIN) has been working with DTSC to craft proposed amending language that is both responsive to DTSC concerns and still consistent with emerging international standards. GCA urges serious consideration of the recommendations forthcoming from this Network, which has been the primary industry vehicle for interaction on nano-related matters in California.

Place into the Stream of Commerce

Subdivision (a)(53) Goes Beyond the Department's Authority Under the Green Chemistry Law and Is Inconsistent with the Commerce and Due Process Clauses of the Constitution: Subdivision (a)(53) defines "place into the stream of commerce" to include transferring ownership or control over a consumer product "without maintaining sufficient control . . . to prevent the use of the consumer product by a California consumer." This definition expands the scope of the regulations to include persons and transactions that occur outside of California, notwithstanding that they may not intend for the consumer goods to be sold in California. The department has no authority to impose such responsibility under the green chemistry law, and to do so is inconsistent with the Commerce and Due Process clauses of the Constitution.

For the reasons above, subdivision (a)(53) fails to meet the standards for authority and consistency set out in Government Code § 11349.1.

Product Stewardship

Subdivision (a)(61) Is Unclear: Subdivision (a)(61) defines "product stewardship" and declares the "primary responsibility lies with the product producer, or manufacturer, who makes the product design and marketing decisions." This subdivision is unclear because one cannot determine whether the producer or manufacturer has primary responsibility, nor can one determine what that responsibility entails.

For the reasons above, subdivision (a)(53) fails to meet the standard for clarity set out in Government Code § 11349.1.

Reliable Information

It is critical that scientific information used in making decisions in the Green Chemistry program be of high quality—it must be reliable, relevant and adequate. GCA's comments of July 22,

2010 made clear for example, that information from peer-reviewed studies alone is absolutely not a sufficient criterion for reliability. In the Proposed Regulation, information from any one of a wide variety of sources is defined as *de facto* reliable. While we agree that information from all of those sources may be appropriate to consider using a weight of evidence approach to make priority decisions, an entirely separate process is necessary to ensure that the information used is reliable.

The need for a mechanism to judge the reliability of studies is widely recognized by federal agencies and international bodies responsible for protecting public health and safety. They generally recognize that regulating chemicals and products that contain them must be done from a firm base of evidence. 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 the US and OECD HPV programs and in the REACH regulation for determining data quality and reliability. As mentioned earlier, hundreds of thousands of studies of over 4000 chemicals being submitted to REACH by December 1, 2010 will be rated according to this approach. It is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies.
http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

The Proposed Regulation ignores this internationally accepted system and GCA's comments of July 22, 2010, recommending that California incorporate this approach into the Green Chemistry Initiative. The OECD's guidelines for testing are noted in the proposed regulation, and OECD's guidelines along with other study protocols, are appropriately listed as one of many other information sources. However, the OECD approach for judging information quality and reliability has not been referenced in the DTSC's proposed regulations. We find this exclusion disturbing.

GCA recommends that the department provide separate definitions for (1) "Information Sources" to include all sources listed in the proposed regulation and for (2) "Reliable Information" based on the OECD Manual:

> *"Reliable information" is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ("QSAR") approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies."*
> http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

Subdivision (a)(66) Is Unclear: Subdivision (a)(66) defines "reliable information" as data, studies and other information that have been scientifically peer reviewed, or generated using "established federal guidelines including, but not limited to," a specified list. This definition is unclear because use of the phrase "including, but not limited to" makes it completely open ended by and provides no criteria by which one might understand its limits.

For the reasons above, subdivision (a)(66) fails to meet the standard for clarity set out in Government Code § 11349.1.

Responsible entity

In previous comments (November 9, 2009; May 27, 2010; and July 22, 2010) GCA urged the department to use the provisions of the federal Fair Packaging & Labeling Act (FPLA) that mandates there be a single responsible entity in lieu of the current definition in the proposed regulation. This would provide uniformity in requirements and consistency with the application by other regulatory agencies (*e.g.,* the Federal Trade Commission (FTC), the Food & Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), as well as the California Air Resources Board (ARB)). All consumer commodities that are legally distributed in US commerce must comply with the FPLA labeling requirements or even more stringent requirements under other Federal regulatory schemes (i.e. FSA). These requirements include a statement of identity, net quantity statement and name and place of business of the manufacturer, packer or distributor. All of these items must appear in English on the product label, so if a product is imported from China for example, the entity that is receiving the shipment must assure there is US-compliant labeling which identifies on the label that the product is "manufactured for……." or "distributed by……". Because FPLA focuses on the product, retailers are only responsible for the products they package (e.g. store-made packages, such as at the meat counter) or products specifically manufactured *for* the retailer (i.e. private label). This framework also applies to importers, as long as the product meets the definition of a "consumer commodity" under FPLA – the label must display the name of the manufacturer, distributor or packer. This requirement takes care of imports because the entity packaging the commodity into US-compliant labeling will be identified as "manufactured for…" or "distributed by…."

The problem with the "responsible entity" definition in the Proposed Regulation is that it is unnecessary and needlessly complicates the scope of those entities with a duty to comply and creates an uncertain regulatory environment. By rendering multiple parties along the supply chain as "responsible entities" with a duty to comply, DTSC has created a complicated web of compliance and fertile ground for duplication and litigation. The uncertainty inherent in the proposed "responsible entity" definition could conceivably lead to miscommunication among the expansive set of entities responsible for a priority product, at best slowing the compliance process and worse, potentially resulting in failure to comply.

GCA understands DTSC's need to adequately ensure the capability for enforcement to include the entity responsible for distribution of the *Priority Chemical/Priority Product* in California commerce. We are of the opinion that the FPLA labeling requirements will adequately serve this need. California's Air Resources Board has effectively utilized the entity identified on the product label in accordance with the FPLA requirements in their active enforcement of the Consumer and Commercial Products VOC regulation, thus establishing a successful precedent in California. If a manufacturer or distributor (as identified on the product label) is not willing to assume the duty to comply because the product has been distributed in California without the manufacturer or distributor's knowledge, those parties should have the opportunity to first review the situation and, if needed, demonstrate to DTSC that the product entered California commerce by means outside of their direct control. For example, a manufacture or distributor (as identified on the product label) routinely tracks manufacture and distribution of consumer products by a code that appears on the product. Such a code can often confirm for a manufacturer/distributor if the product entered California through approved distribution channels or if the product entered California by some alternate channel. If the latter, DTSC then has a clear picture which entity is responsible from an enforcement standpoint.

Unreasonable Compliance Options for Non-Manufacturer Responsible Entities: In addition to our concerns articulated above regarding the "responsible entity" definition, are the unworkable

compliance options available to non-manufacturer responsible entities in § 69301.4. Specifically, it appears that a retailer who sells a product facing an alternatives assessment would be forced to pull that product from its shelves in order to avoid being subject to Article 5 requirements. While this is not our understanding of the department's intent, the language must be changed to ensure that that the department's intent is actually provided in the language of the regulations.

For example, in subsection (c)(1), the language provides that a retailer may comply with Article 5 by "ensuring" that its requirements are "fulfilled" for the product "within the required timeline" by another person. How could a retailer reasonably make such a guarantee to the department? Whether or not the complex and resource-intensive requirements of Article 5 are actually met within the required timeline will be largely dependent upon a manufacturer or other responsible entity's ability to do so. This is not something that can be reasonably guaranteed by a retailer who simply sells the product, especially if such assurances must be made prior to an alternative assessment process even beginning. Thus, the means for a non-manufacturer responsible entity to avoid an Article 5 alternatives assessment in subsection (c)(1) is not practical or workable.

Second, the department states in subsection (c)(2) that "a responsible entity will not be held responsible for complying with one or more applicable requirements of Article 5" if the requirement "has been fulfilled to the Department's satisfaction" by another entity. This, however, only provides relief to a retailer after-the-fact; or in other words, once the alternatives assessment process has actually been completed. What, then, is a retailer to do prior to this point if they are not willing to make assurances to the department, pursuant to subsection (c)(1), that cannot be reasonably made to begin with?

Unfortunately, it appears that a non-manufacturer responsibility entity would have to resort to subsection (e)(1) in order to avoid carrying out its own alternatives assessment on a product that it does not manufacture in the first place. The language in this subsection provides that a retailer will "not be held responsible for complying with the requirements" of Article 5 if the retailer has "ceased to place the product into the stream of commerce in California." The net effect of this language would be a de facto sales ban of any consumer product that is subject to an Article 5 alternatives assessment until that assessment is complete, which could take years. We suspect that some retailers will be pressured to take this action for any product containing a *Chemical of Concern*, even before DTSC has made determination that they chemical in any consumer product application is actually a "priority" to be teed up for an alternatives analysis. This situation is completely unacceptable. It would significantly and unnecessarily disrupt commerce in California and does not reflect what we understand to be the intent of the department.

To ensure that the language better reflects the department's intent, it must be redrafted so that a non-manufacturer responsible entity can simply rely on the fact that another entity "will be entering" the Article 5 process. This is a much more practical solution than requiring a retailer to "ensure" that another entity "fulfills" the Article 5 process to the department's satisfaction.

To address both issues, we strongly urge DTSC to prioritize the approach to "responsible entity" and consider the entity identified by FTC requirements on the product label as the initial point of contact. In many situations, this entity owns the brand name or trademark and would want to assume the duty to comply to preserve brand equity and reputation.

Subdivision (a)(67) Goes Beyond the Department's Authority Under the Green Chemistry Law and Is Inconsistent with the Commerce and Due Process Clauses of the Constitution: Subdivision (a)(67)(E) defines "responsible entity" to include a "person who is party to a contractual agreement . . . concerning a consumer product that is placed into the stream of commerce in California, unless that contractual agreement specifically states that the consumer product shall not be placed into the stream of commerce in California." This definition expands the scope of the regulations to include persons and transactions that occur outside of California, notwithstanding that they may not intend for the consumer goods to be sold in California. The department has no authority to impose such responsibility under the green chemistry law, and to do so is inconsistent with the Commerce and Due Process clauses of the Constitution.

For the reasons above, subdivision (a)(67) fails to meet the standards for authority and consistency set out in Government Code § 11349.1.

Safer

Subdivision (a)(69) Is Unclear: Subdivision (a)(69) defines "safer" to mean a "demonstrated net reduction of projected public health and environmental impacts." This definition is unclear because the term "demonstrate" is not defined. Although it is clear there must be something more than just a net reduction of projected impacts, one has no way of knowing from the definition what more is required to be "safer."

For the reasons above, subdivision (a)(66) fails to meet the standard for clarity set out in Government Code § 11349.1.

Sensitive Subpopulations

Subdivision (a)(72) Is Unclear, Inconsistent and Goes Beyond the Authority of the Department: Subdivision (a)(72) defines "sensitive subpopulations" to include "individuals with a history of serious illness." This definition is unclear because it could include anyone who has been sick in the past. Moreover, individuals with a history of serious illness do not have common risk traits as do women and children, the two groups specified in Health and Safety Code § 25252(a)(3). Thus, it is beyond the authority of the department and inconsistent with the green chemistry law to include such individuals as a sensitive subpopulation.

For the reasons above, subdivision (a)(72) fails to meet the standards for authority, clarity and consistency set out in Government Code § 11349.1.

Threat

In the definitions section, "threat" is defined as "the potential to cause an adverse effect". Adverse effect is not defined here, but is most unfortunately defined in OEHHA draft regulations as "a biochemical change, functional impairment, or pathologic lesion that negatively affects the performance of the whole organism, or reduces an organism's ability to respond to an additional environmental challenge."

OEHHA's pre-regulatory draft document defines "adverse effect" in words that are very broad and without context in terms of how to use the definition to characterize chemicals' hazard traits.

The clause *"reducing an organism's ability to respond to an additional environmental challenge"* could extend the scope of effects observed in animals or humans to effects beyond commonly measured toxicity endpoints. What would be encompassed by this part of the definition is unclear. Notwithstanding the first part of the definition, this overly broad phrase could be interpreted such that *any* detected perturbation, even adaptive changes, could be classified as an "adverse effect." Doing so would contradict broadly accepted scientific principles. For example, in its landmark report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*, the National Research Council is clear that a perturbation and an adverse effect are not necessarily the same thing:

> *"The consequences of a biologic perturbation depend on the magnitude of the perturbation, which is related to the dose, the timing and duration of the perturbation, and the susceptibility of the host. Accordingly, at low doses, many biological systems may function normally within their homeostatic limits. At somewhat higher doses, clear biological responses occur. They may be successfully handled with adaptation, although some susceptible people may respond. A more intense or persistent perturbation may overwhelm the capacity of the system to adapt and lead to tissue injury and possibly to adverse health effects."*[2]

An adverse effect is not any known biochemical or chemical change, or even any known or measurable precursor along a biochemical pathway that could lead to some degree of perturbation. In the absence of further clarification of intent and applicability, we recommend striking *"or reduces an organism's ability to respond to an additional environmental challenge"* from the definition.

Trade Secret

Subdivision (a)(81) Is Unnecessarily Duplicative: Subdivision (a)(81) defines "trade secret." Trade secret is already defined by § 3426.1(d) of the Civil Code, thus it is unnecessary and duplicative to set out the same definition of trade secret here.

For the reasons above, subdivision (a)(31) fails to meet the standards for necessity and non-duplication set out in Government Code § 11349.1.

§ 69301.4 Duty to Comply and Consequences of Non-compliance: See also: Unreasonable Compliance Options for Non-Manufacturer Responsible Entities

§ 69301.5 - Information Submission and Retention Requirements

Subdivision (b)(5) Is Unnecessary and Goes Beyond the Authority of the Department: Subdivision (b)(5) requires that various documents required to be submitted to the department under the regulations must be certified under penalty of perjury. A required element of the

[2] National Research Council. 2007. Toxicity Testing in the 21st Century: A Vision and a Strategy. Page 48.

certification is that "life cycle thinking and green chemistry principles were considered" in carrying out the duties imposed by the regulation. However, the ISOR fails to explain what objective is served by requiring such a certification and, further, fails to explain why it is necessary for that objective to be served. Even if the ISOR had specifically addressed this certification requirement as it is required to do, the department has no authority to adopt such principles or require that they be followed, as noted in the comments to § 69301.1, above.

For the reasons above, § 69301.5 fails to meet the standards for necessity and authority set out in Government Code § 11349.1 and 1 CCR §10.

§ 69301.6 – Chemical and Product information

The Department Lacks the Authority to Request Data From Manufacturers: The department lacks the authority to require the data described in § 69301.6(c)(1). The authority provided DTSC under AB 1879 does not include the authority to require the submission of data by manufacturers. See H&S Code §§ 25252, 35253 and 58012. DTSC has been directed to obtain the information necessary for prioritization from existing sources. Although DTSC is not limited to existing sources, nowhere in § 25252 and § 25253 does the statute expressly authorize DTSC to require manufacturers to provide the information. Section 25252(b)(3) provides that although DTSC must make maximum use of information already available from government agencies, they are "not required" to reference and use only that information. However, the type of information the department proposes to request from manufacturers (*i.e.,* a description of sales locations, or targeted customer bases) is unrelated to the prioritization factors specified in § 25252(a)(1-3). Section 25252(a)(1 - 3) instructs DTSC to prioritize chemicals and products based on specific factors, including volume in commerce in the state, potential for exposure to the chemical in a consumer product, and potential effects on sensitive subpopulations.

Section 69301.6(c)(1) also incorporates by reference the data set out in § 69302.3 and § 69303.3. Both of these provisions include, for example, with respect to dispersive volume information, projected annual sales by volume and/or mass, annual regional distributions by volume and/or mass, marketing and customer targeted volumes and/or mass, volume and/or mass of the chemical in current use, annual estimated volume and/or mass of the chemical used in products and components, and controlled distribution systems, if any. This exhaustive list of information requested by DTSC goes well beyond what is required to prioritize chemicals or products based on the volume of the chemical in commerce in the state, exposures to the chemical in a consumer products, and potential effects on sensitive subpopulations. H&S Code § 25252(a)(1-3).

The Legislature implied that some information may be submitted by manufacturers, but did not make this mandatory or the only source. See H&S Code § 25257(a) offering manufacturers CBI protections for information provided to the department. The statute therefore lacks express authority to require manufacturers to provide the detailed data outlined by the department in § 69301.6(c)(1). The Legislature has in the past seen it as necessary to grant that express authority for information gathering from industry, as with DTSC's collection of fate and transport information under AB 289 (H&S Code § 57019). Where there may be overlap between information requested by DTSC under the Green Chemistry regulations and information that may be requested of manufacturers under AB 289, DTSC must comply with the procedures set forth in AB 289. The AB 289 procedures include making reasonable attempts to: 1) electronically post the information, 2) conduct a search for the information from public sources,

3) contact all manufacturers, 4) consult with all manufacturers to determine what, if any, information needs to be developed to evaluate the fate and transport of the chemicals, and (5) make reasonable attempts to consult with all manufacturers to evaluate the technical feasibility of developing the information requested by the agency. H&S Code § 57019(c)(1-5). Moreover, the department's authority to require information from manufacturers is limited to the data (such as fate and transport information) outlined in H&S Code § 57019(d)(3)(A-C), and this data is unrelated to the prioritization factors outlined in H&S Code § 25252(a)(1-3).

§ 69301.6(c)(1) – GCA Asserts Subsection Lacks Clarity

In § 69301.6(c) the department outlines the type of data that DTSC proposes manufacturers be required to provide, but also reserves the ability to request additional undisclosed information by including the phrase "but not limited to." This vague reference to potential additional information that the department may request fails to provide clarity and certainty required by the Administrative Procedures Act (APA). *See also, Tidewater Marine Western, Inc. v. Bradshaw*, 14 Cal. 4th 557, 568-69 (1996). It is impossible to know what data DTSC might request, how to comply and whether that which might be required is reasonable. As a result of this vagueness the regulated community forfeits its ability to participate fully in the regulatory development process. The regulated community is not provided an opportunity to comment on whether the information DTSC is considering is appropriate, or even available.

The Department Has Not Shown Why the Suggested Information is Necessary For Prioritization: In addition to the data requested outlined above, § 69301.6(c)(1)(D) also requires the manufacturer to provide the volume of units sold in California, a description of sales locations, the intended use of the product, targeted customer bases, and a description of end-of-life management program, if any. Again, that information goes well beyond what is needed to establish the volume of the chemical in commerce, the potential for exposure, and the potential effects on sensitive subpopulations. § 25252(a)(1-3). Furthermore, much of the data being requested is trade secret information.

Although DTSC has in conversations with GCA tried to assure our members that the information would be protected from disclosure, the more this type of trade secret information is provided to DTSC, the greater the potential for inadvertent disclosures. The risk of release coupled with the burden of substantiating all of the information and potentially having to defend it first to DTSC, then possibly in court, is an unnecessary and enormous burden. Requesting unnecessary detailed information and the resulting need to protect the confidential business information (CBI) adds to the already massive paperwork burden of this regulation and will potentially cause the process outlined in Article 10 to collapse under its own weight.

In the Initial Statement of Reasons (ISOR), DTSC states that the information requested in § 69301.6 will "enable DTSC to have a sound and robust process for identifying and prioritizing Chemical of Concerns and consumer products that contain Priority Chemicals." The ISOR goes on to say 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 § 25252 are fully informed and based on sound science and other relevant information." Turning to the ISOR for § 69301.6(c)(1), the DTSC states that this information is necessary "to enable DTSC to appropriately identify and prioritize chemicals and consumer products" then goes on to just describe the information categories in the regulatory section. Again, nothing in the ISOR describes why marketing plan information, end-of-life management program information, or sales locations in California are required to prioritize chemicals and products.

In summary, there is no necessity for the detailed information requested by DTSC set forth in § 69301.6. DTSC fails to set out in the Initial Statement of Reasons the necessity for the specific provisions of § 69301.6. The Initial Statement of Reasons contains a very general assertion that the information is necessary to have a robust process, but nothing is mentioned with respect to any of the specified items of information that are required.

§ 69301.6 - GCA Asserts Subsection Lacks Necessity

Further, the items set out in § 69301.6 go into much more detail than [*this clause seems at odds with the prior paragraph "nothing is mentioned…"*] is needed to prioritize chemicals and products on the basis of the volume of the chemical in commerce in this state, the potential exposure to the chemical in the consumer product, and the potential effects on sensitive subpopulations, including infants and children. H&S Code § 25252(a)(1-3). Compounding the concern GCA has with the lack of necessity for the detailed information is the fact that much of the data being requested are classic examples of trade secret information (*i.e.*, sales data, targeted customers, locations of facilities and outlets, etc.). Although DTSC has in conversations with GCA tried to assure our members that the information would be protected from disclosure, the more this type of trade secret information is provided to DTSC, the greater the potential for inadvertent disclosures. The risk of release coupled with the burden of substantiating all of the information and potentially having to defend it first to DTSC, then possibly in court, is an unnecessary and enormous burden. Requesting unnecessary detailed information and the resulting need to protect the confidential business information (CBI) will potentially cause the process outlined in Article 10 to collapse under its own weight.

ARTICLE 2 & 3 - CHEMICAL PRIORITIZATION PROCESS

§ 69302 – Chemical Prioritization Process

In the Proposed Regulation on Chemical Prioritization Process (§ 69302), the original concept—using a stepwise process to identify "*Chemicals Under Consideration*," and after public notice and comment, further focusing that into a set of identified "*Chemicals of Concern"*—has been discarded. Instead, two separate ongoing lists would be developed "*Chemicals Under Consideration*" and "*Priority Chemicals*" and all chemicals on both of these lists would be identified as "*Chemicals of Concern*." This is a perversion of the prioritization process and, together with other provisions and requirements, imposes a massive regulatory burden on every physical item in California commerce.

The statute mandates that DTSC identify and prioritize *Chemicals of Concern* and prioritize the uses of the *Chemicals of Concern* in products that should then become the subject of an Alternatives Assessment. Given the thousands of chemicals in California and the hundreds of thousands of different products and millions of components in products in California, there has been broad agreement since the very first stakeholder workshop that a step-wise approach to this prioritization was the only sensible way to screen and identify those chemical and product combinations that pose the greatest public health and environmental threats as a result of exposure to the chemical at levels that can result in human or environmental harm. In previous submissions incorporated by reference (November 9, 2009; May 27, 2010; and July 22, 2010)

GCA has consistently supported this concept. For instance, we recommended that DTSC should take an initial step in chemical prioritization to identify "*Chemicals under Consideration*" based on information available to the department and publish those with the reasoning that led the department to its conclusions. We also recommended that the department conduct public notice and comment, allowing stakeholders to provide additional information to allow the department to move forward to the next step of Identifying "*Chemicals of Concern"*.

In this concept, the "*Chemicals under Consideration*" list plays several roles. First is the role in a notice and comment context that allows the department to gain valuable information from the public that may not be available to the department and help to better inform its "*Chemical of Concern*" decisions. Second, is its role as a queue for future "*Chemical of Concern*" decisions, allowing the department to propose and finalize "*Chemicals of Concern"* in concert with available resources. Finally, the appearance of a chemical on the "Consideration" list plays the role of sending a signal of regulatory concern to the marketplace. Companies making and using a "*Chemical under Consideration"* will be aware of this status and can consider its implication as they make product design, manufacturing, and formulation decisions in the normal course of business.

The Proposed Regulation, by including "finalized" "*Chemicals under Consideration*" as "*Priority Chemicals*," dramatically shifts some of those roles. This new "*Chemicals under Consideration*" list continues to enable the department to gain additional information for priority setting. However, including finalized "*Chemicals under Consideration"* as "*Chemicals of Concern*" for the purposes of the regulation will dramatically increase the impact of those decisions, placing any products that "contain" the chemical in immediate regulatory jeopardy. A permanent and ever growing "*Chemical under Consideration"* list will emerge that has significant economy wide effects. Any chemicals on that finalized list have major regulatory obligations and burdens throughout the balance of the regulation and will encounter them forever, even though they may never be important enough to be finalized as "*Priority Chemicals*." These burdens are placed on chemicals that the department has not yet established meet the requirements for being "*Priority Chemicals*." This is unnecessary, unauthorized and needlessly burdensome.

GCA objects to this approach in the strongest possible terms and asks the department to return to the original concept—separating "*Chemicals under Consideration"* and "*Chemicals of Concern*." ***"Chemicals under Consideration" should be just that—under consideration***. The *"Priority Chemical"* term should be eliminated and returned to its previous named "*Chemical of Concern."* No regulatory compliance burdens should be imposed on chemicals identified as "*Chemicals under Consideration*.

§ 69302.1 & § 69303.1 – Applicability; Duplication

Additionally, § 25257.1(c) of the statute provides that the department "shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." However, the language in the Applicability sections of the Proposed Regulation does not reflect the direction to DTSC provided for in statute. The purpose of the article is to protect human health and the environment. If a product category is regulated by a federal agency for the same public health or environmental risk as the concern that is being addressed under DTSC's Regulation, the product category should be automatically exempted from regulation. Instead, these sections require every aspect of a life cycle to be addressed even if the hazard trait that has triggered

prioritization of the chemical and use of that chemical in the product does not have an impact at a particular stage of the life cycle.

For instance, if mercury has been prioritized as a *Chemical of Concern* because it is a Persistent, Bioaccumulative and Toxic Chemical (PBT), and therefore may have negative impacts on the environment if not properly disposed of; and electronic devices have been prioritized due to the potential issues of disposal at end-of-life; then the fact that California has a ban on landfill disposal of mercury containing products as well as the electronics recycling law should be sufficient to exempt the subject electronic devices containing mercury from this regulation.

Unfortunately, the Applicability sections of the Regulation fail to provide the clear exemption contemplated by the statute. Where another agency or department has the authority to regulate something (even if they choose to not do so) should be sufficient to justify an exemption. If not granted, and DTSC were to regulate, this would lead to overlapping authorities should the other governmental entity decide to do so at some time in the future. This would cause confusion in the marketplace. This concept should also apply in situations where a regulatory authority has undertaken efforts to address a risk, even if it has not completed regulatory actions. Finally, regulatory duplication should also consider international laws and regulations that may already address the purpose of the Proposed Regulations.

The department has failed to clearly articulate how the approach in the draft regulation provides for a higher degree of protection for health and the environment that would be sufficient to warrant duplicating, conflicting with and superseding the regulatory authority of any other department or agency (i.e. CPSA and EPA).

<u>The Proposed Regulation Attempts to Supersede Other Agency Authorities and/or Duplicate Existing Regulations;</u> AB 1879 requires DTSC in preparing the Safer Consumer Product Alternatives Regulation ("Proposed Regulation") to avoid regulatory duplication and actions that would supersede the authority of other departments or agencies. Section 69302.1(a) provides that this article applies to all chemicals that exhibit a hazard trait and are reasonably expected to be contained in products placed into the stream of commerce in California, unless the department makes a determination pursuant to paragraphs (1) and/or (2). Paragraph (1) is included ostensibly to implement subdivisions (b) and (c) of Health and Safety Code § 25257.1. Those subdivisions provide as follows:

> (b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.
>
> (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

In fact, § 69302.1(a)(1) of the regulations is inconsistent with § 25257.1, a statutory provision expressly listed as one of the statutes being implemented, interpreted, or made specific.

As subdivision (a) of § 69302.1 begins, "chemicals that exhibit a hazard trait and are expected to be contained in products are initially selected for consideration." This is consistent with Health and Safety Code § 25252(a). The thrust of the balance of the green chemistry regulations is to then determine whether a particular chemical, because of its "hazard trait" and presence in a consumer product, should be classified as a chemical of concern (priority

chemical) and whether for any of the products in which the chemical is contained, it is present in high volumes, results in the chemical being exposed to Californians, and in particular to sensitive subpopulations at levels of concern for public health or the environment. All of this hinges on the hazard trait and the potential exposure pathways identified in the department's rationale for including a chemical on either the *Chemical Under Consideration* or *Priority Chemical* Lists.

If the particular chemical is determined to be a *Chemical of Concern* and present in a *Priority Product*, the manufacturer of that product is then obligated to conduct an alternatives assessment. Following that assessment, various regulatory responses may be imposed. Those responses may range from no action, reformulation, additional labeling, restrictions of use, to sale prohibitions. The regulatory responses imposed, again, are imposed because of the hazard trait and exposure pathway.

It is those regulatory responses that the Legislature specifically enjoined the department from superseding, duplicating, or conflicting with regulatory authority set out in other regulatory programs. Accordingly, the regulation, to be consistent with § 25257.1, must exempt chemicals at the outset if the chemical or product is subject to regulation by an international, federal or other California regulatory program because the particular hazard trait poses a risk to public health or the environment by virtue of its presence in the products flowing into the stream of commerce in California. Many products are manufactured for worldwide distribution and therefore must comply with international regulations as well as California specific ones. California's regulations must also recognize these restrictions and not impose inconsistent or duplicative requirements.

Section 69302.1(a)(1) of the regulations unfortunately fails to implement the explicit provisions of § 25257.1 and instead imposes an impossible exemption standard. It provides that, "This exemption shall not apply if, after taking into consideration the combined effect of all applicable federal and/or other California State regulatory programs, the department determines that there are significant gaps for one or more life cycle segments, between the combined public health and environmental threats that are addressed by these programs and the public health and environmental threats addressed by Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code and this chapter." The effect of this language is to implicitly repeal the provisions of § 25257.1, prohibiting the department from superseding, duplicating or conflicting with other regulatory programs.

Moreover, the department appears to misread specific provisions in the green chemistry law. Section 25252 requires the department to establish a process to identify and prioritize chemicals in consumer products that may be considered as *Chemicals of Concern.* The identification and prioritization process is to include "(1) the volume of the chemical in commerce in this state; (2) the potential for exposure to the chemical in the consumer product; and (3) potential effects on sensitive subpopulations, including infants and children." Nowhere does § 25252 require chemicals to be identified and prioritized as *Chemicals of Concern* based on all life cycle segments.

Apparently, the department mistakenly construes § 25252.5 to justify its interpretation. This section, however, relates to a review of the regulations by other boards and departments within the California Environmental Protection Agency, the State Department of Public Health, the State and Consumer Services Agency, the Department of Homeland Security, the Department of Industrial Relations, and other state agencies with responsibility for regulating chemicals and consumer products. Those entities are authorized to undertake a "multi-media life cycle

evaluation" in reviewing the regulations. That section does not authorize the department to expand its reach and regulate every life cycle segment of a chemical or product.

The department's attempt to confer authority upon itself is made all the more apparent by restricting the exemption for regulation by other federal or California state programs if a gap exists for one or more life cycle segments addressed by "this chapter." H&S Code § 25252. By requiring every life cycle segment identified in these regulations as having to be addressed by a federal or other California state program before a chemical is exempt, the department is attempting to bootstrap itself into unlimited authority. Because DTSC begins to regulate during the prioritization process for chemicals and products, not at the end of the alternatives assessment, streamlining to avoid regulatory duplication and superseding authorities must be evaluated and dealt with early on in the process. Nothing in the prioritization process suggests that every life cycle aspect must be reviewed. GCA holds that the question of whether or not there is regulatory duplication should ***only*** focus on those hazard traits and/or exposure pathways that are the basis for prioritization.

For example, the regulation requires a comparison of existing chemicals with alternatives. This comparison, according to the regulations, is to be based on a life cycle evaluation. Hence, this chapter, referring to the regulations in total, includes life cycle segments. By referring in § 69302.1(a)(1) to "this chapter," the department seeks to justify its refusal to grant an exemption unless every life cycle segment contained in "this chapter" is subject to regulation by another federal or California state program.

A regulation that expands the scope of the statute that it implements, interprets, or makes specific is inherently inconsistent with that statute and the department lacks authority to adopt it. Government Code § 11342.1, and § 11342.2. *Western Oil and Gas Assoc. v. Air Resources Board*, 37 Cal.3rd 502, 509 (9184); *Preston v. State Board of Equalization*, 25 Cal.4th 197, 219 (2001); *People, ex rel., Dept. of Alcoholic Beverage Control v. Miller Brewing Co*., 104 Cal.App.4th 1189, 1199 (2002).

Particular Concerns Associated with Intermediate Manufacturing Materials & Processes:

The previous comments regarding the regulatory duplication created by the Applicability sections (§ 69302.1 and § 69303.1) of Articles 2 and 3, apply with special import to intermediate manufacturing materials. Although intermediates were expressly excluded in DTSC's detailed regulatory outline (April 15, 2010), they are again included in the proposed regulations. GCA has argued that this is entirely unnecessary and inappropriate.

Furthermore, DTSC has no authority over the regulation of intermediates outside of California; thereby creating a competitively disproportionate and increasingly onerous regulatory burden on California-based businesses. There is no necessity for this expanded regulatory authority as the mandates of the legislation can be fulfilled without subjecting intermediates to additional regulation.

GCA strongly urges the department make clear in intentions in § 69303.3(c)6 and treturn to the conceptual language which was first presented in the April 2010 detailed outline.

§ 69302.1 and § 69303.1 – Applicability: "Reasonable & Foreseeable" Exposure

As currently drafted, the language in § 69302.1 (a)(2) and § 69303.1 (a)(2) establishing exemptions for products and chemicals for which there are "no exposure pathways" will not provide any relief to any product manufacturer, given the absolute nature of this language. When describing exposure, the absence of the qualifying phrase "reasonable and foreseeable use", leads GCA to conclude that the existence of an improbable scenario or combination of circumstances (which might only theoretically result in exposure) would prohibit the product from being exempted. No one can ever prove a negative, and the lack of qualification puts both DTSC and consumer product manufacturers in an untenable position.

While the GCA appreciates the inclusion of use and abuse testing elements in these sections, this language does not appropriately apply this exemption to real world exposure scenarios. Within the Regulations, there must be a reasonable standard to which a manufacturer can reliably demonstrate mechanisms and formulations that prevent exposure to a "*Chemical of Concern*" and seek exemptions for preventing exposure.

As the GCA stated in our earlier comments on July 22nd, consumer products are regulated under various federal statutes, including: the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), and the comprehensive Consumer Product Safety Improvement Act (CPSIA) signed into law in 2008. These frameworks of regulation rely on the concept of a "reasonable and foreseeable" criterion to evaluate whether or not a product will expose a consumer to a chemical. Specifically, the U.S. Consumer Product Safety Commission (CPSC), in August 2009, once again endorsed the reasonable and foreseeable exposure criterion in regulation through the "Children's Products Containing Lead; Interpretative Regulations on Inaccessible Component Parts" (16 CFR Part 1500). Specifically the Regulations stipulate:

> "Use and abuse tests are appropriate for evaluating whether lead-containing component parts of a product become accessible to a child during **normal and reasonably foreseeable use and abuse** of the product by a child. The purpose of the tests is to simulate use and damage or abuse of a product by children and to expose potential hazards that might result from use and abuse -16 CFR 1500.50 –1500.53." [Emphasis Added]

Specifically, the regulations cited above provide for "normal and reasonably foreseeable use and abuse" testing to determine which products could expose a product element to the user. The GCA appreciates that DTSC has attempted to include this concept of use and abuse testing in subsection (c) as a part of product assessment methodologies for exposure. However, GCA asserts that DTSC must make "reasonable and foreseeable" exposure the key determinant for applicability and exposure testing in subsections (a)(2) and (c).

Recommendations*:* The GCA requests that the department address the issues above by amending the Regulations to reflect the language stipulated below for the sections in question; per our previous comments on the Draft Regulations:

> § ***69302.1(a)(2): There are no reasonably foreseeable exposure pathways by which the chemical might pose a threat to public health or the environment in California.***

§ ***69303.1(a)(2): There are no reasonably foreseeable exposure pathways by which the priority chemical, that is contained in the consumer product might pose a threat to public health or the environment in California.***

§ ***69303.1(c): the evidence must include, to the extent applicable, the results of any normal and reasonably foreseeable use and abuse tests, including …***

§ 69302.1 & § 69303.1 – Applicability: Science Based Decisions

Articles 2 and 3 provide that priority decisions will be based on comparison of quantitative hazard and exposure to identify the most important chemicals of concern and priority products. Specifically, the Guiding Principles and the Chemical and Product Priority articles, state:

> *"Chemical and consumer product prioritization processes should seek to identify and give priority to those chemicals, and the consumer products that contain them, that pose the greatest public health and environmental threats, are most prevalently distributed in commerce and used by consumers, and* ***for which there is the greatest potential for consumers or environmental receptors to be exposed to the chemical in quantities that can result in public health or environmental harm.***"(emphasis added)

The Prioritization sections go on to state that information on "*…the frequency of use, and the concentration of the chemical in those products*" must be used in priority setting decisions.

GCA supports these provisions and their rigorous application in selecting *Chemicals of Concern* and *Priority Products* in which they are used. These current provisions are an improvement from the earlier Draft Regulation, which GCA critiqued (July 22, 2010) as problematic to successful implementation of the law and we appreciate that the department has responded to that concern.

The three factors in the Principle (greatest threats, prevalent distribution and use by consumers, and greatest potential for exposure at levels that can result in harm) are drawn from the mandates of the statute and appropriate boundaries for decision making in this area.

Some provisions in these sections indicate that the department should consider qualitative exposure information (e.g. presence in products, occurrence of public health exposures, and breadth of use). We agree that these are appropriate to consider. However, presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern should be the primary driving factor in priority setting decisions. Product concentration and frequency of use are among the critical factors necessary in quantitatively determining exposure to chemicals in products.

Following these principles will help to assure that the department will quantitatively compare the hazards of chemicals and their exposures through products in setting priorities. Implementation of this law is not about dealing with everything, it's about identifying those situations that will make a real difference in improving public health and the environment. The only way to do that is to make judgments about the greatest threats by looking closely at actual hazard and exposure levels to determine whether or not there is a concern.

GCA supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of DTSC scientists. We believe that the current language provides workable direction for making such decisions in a scientifically credible and defensible manner.

§ 69302.2 & § 69303.2: -Chemicals/Products Lists: Hazard & Exposure Information

The regulation should encourage submission of hazard and exposure information during the Chemical and Product priority setting processes.

As part of responding to Department notices of proposed Chemicals and/or Products Lists, manufacturers or consortia of manufacturers should be encouraged to provide information on a chemical's hazards and its reasonable and foreseeable exposures to humans or to the environment as a result of use and disposal of the product(s) in which it is used. Such information would document the known hazards of the chemical and the anticipated exposures from reasonable and foreseeable uses of the consumer product(s) and would indicate how expected exposures compare to the chemical's health and/or environmental hazard threshold level. This information could also indicate anticipated exposures to sensitive sub-populations, information on expected aggregate exposures to the chemical from multiple products and on available control measures. It would be appropriate for the department to consider such information in finalizing Chemicals and Products Lists.

Recommendation: GCA recommends the following including the following language, which would provide DTSC information on real expected exposures and comparisons to the hazard of Chemicals of Concern to assist in finalizing priorities:

> 69302.2 (Insert new paragraph before (c) at page 30, line 29) In responding to Department notices of proposed Chemical Lists, manufacturers or consortia of manufacturers may provide information on a chemical's hazard and its reasonable and foreseeable exposures to humans or to the environment through the product(s) in which it is used. Such information would document the known hazards of the chemical and the anticipated exposures from reasonable and foreseeable uses of the consumer product(s) and would indicate how expected exposures compare to the chemical's health and/or environmental hazard threshold level. This information may also indicate anticipated exposures to sensitive sub-populations, aggregate exposures to the chemical from multiple products, as well as a description of available control measures. Such information shall be taken into consideration by the department in finalizing the Chemicals Lists.
>
> 69303.2 (Insert new paragraph before (c) at page 38, line 11) In responding to Department notices of proposed Products Lists, manufacturers or consortia of manufacturers may provide information on a chemical's hazard and its reasonable and foreseeable exposures to humans or to the environment through the product(s) in which it is used. Such information would document the known hazards of the chemical and the anticipated exposures from reasonable and foreseeable uses of the consumer product(s) and would indicate how expected exposures compare to the chemical's health and/or environmental hazard threshold level. This information may also indicate anticipated exposures to sensitive sub-populations, aggregate exposures to the chemical from multiple products, as well as a description of available control measures. Such information shall be taken into consideration by the department in finalizing the Products lists.

§ 69302.3 - Chemicals Under Consideration

Subdivisions (a) Through (g), and Many of Their Subparts, Are Unclear and Fail To Meet the Necessity Standard for Proposed Regulations: These subdivisions set out a lengthy list of prioritization factors the department may consider to place chemicals on the list of chemicals under consideration pursuant to § 69303.2. While they include a seemingly exhaustive list of more than one hundred specific factors in various categories, they also liberally incorporate the phrase "including, but not limited to" throughout and, as a result, make unclear what else may be included within their scope. Further, while the ISOR includes a few sentences which generally explain the purpose of establishing prioritization factors, and a few other sentences which explain why the various categories of factors are useful in making such determinations, for the most part it provides only an explanation of the meaning of the factor listed and makes no effort to explain its purpose or necessity to prioritize chemicals of concern.

For the reasons above, § 69302.3(a), and each of its subparts, fails to meet the clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision (b)(25) and (d)(5) are unclear: These subdivisions are part of different sections listing specific adverse public health impacts and specific adverse environmental impacts that may be considered as a prioritization factor. Subdivision (b)(25) specifically includes "hazard traits not listed above that relate to adverse impacts on human health" while subdivision (d)(5) includes "other adverse impacts to the environment, not specifically identified." As explained by the ISOR, one purpose of the language in (b)(25) is to allow consideration of hazard traits that are not currently detectable but which may be detectable through future advancements in science and technology. Similarly, the ISOR explains the purpose of (d)(5) is to allow the department to consider future information on chemicals that is not presently known or researched at this time. Nothing could be less clear than a regulation which allows consideration of future criteria that are not presently known and, by definition, cannot possibly be known. If future advances in science and technology allow determination of additional adverse public health impacts, or adverse environmental impacts, the department should amend its regulations at that time.

For the reasons above, subdivisions (b)(25) and (d)(5) fail to meet the standard for clarity set out in Government Code § 11349.1.

Using Regulatory Duplication as a Priority Factor Is Inappropriate: In § 69302.3(h) and § 69303.3(h), the department incorporates regulatory duplication into the consideration of which chemicals will be prioritized and whether a product will be prioritized. The evaluations contemplated by these sections are inappropriate, inconsistent, and beyond the scope of what was contemplated in H&S Code § 25257.1. It appears that DTSC has attempted to make regulatory duplication a prioritization factor rather than the exemption called for in the underlying statute. H&S Code § 25257.1 requires DTSC to exclude any chemical or product from consideration that is already regulated or the authority to do so has already been delegated to another agency.

The DTSC's evaluation should be focused on which hazard trait caused the listing of the chemical and the potential exposure pathway of concern related to the product. DTSC seems to suggest that regulatory duplication would only eliminate the chemical or product when other regulations "address, for each life cycle, segment, the same public health and environmental

threats addressed by Article 14 of Chapter 6.5 of Division 20 of the Health and Safety Code and this chapter." Section 69303.3(h)(2). As stated above, this is inappropriate, inconsistent, and beyond the scope of authority provided to the department in H&S Code § 25257.1. GCA recommends that regulatory duplication be a clear "in or out" exemption where the chemical is already regulated or the product is already regulated for the same concern that caused DTSC to consider listing the chemical or product.

ARTICLE 3 – PRODUCT PRIORITIZATION PROCESS

§ 69303.1 & § 69303.3(c)(6) – Intermediate Manufacturing Materials & Processes

See comments p.38 above

§ 69303.2 - Product Lists

Subdivision 69303.2(d) Fails To Meet the Necessity Standard for Proposed Regulations: The discussion of subdivision (d) in the ISOR does little more than restate the terms of the proposed regulations. The ISOR makes no effort to describe the purpose of each provision, or to explain why each provision is required to carry out its described purpose.

For the reasons above, subdivision (d) fails to meet the necessity standard set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision 69303.2(d)(3) Goes Beyond the Department's Authority to Implement the Green Chemistry Law: Subdivision 69303.2 sets out the process the department will use to identify products under consideration and priority products. Subdivision (d) describes the requirements for the department to determine when a product may be exempt from listing because it contains only a de minimis level of a priority chemical. Subdivision (d)(3) precludes the department from making such a determination for "chemicals, materials, or substances manufactured or engineered at the nanoscale or which contain nanostructures, or are considered to be nanomaterial." Subdivision (d)(3) goes beyond the departments authority because the green chemistry law provides no basis to regulate nanomaterial other than to the extent such material can be considered a chemical or chemical ingredient. In fact, the term nanomaterial cannot be found in either SB 509 or AB 1879.

For the reasons above, subdivision (d)(3) fails to meet the authority standard set out in Government Code § 11349.1.

Subdivision 69303.2(e) Is Inconsistent with the Green Chemistry Law, Contradicts Other Existing Law and Fails To Meet the Necessity Standard for Proposed Regulations: Subdivision (e) states that a product shall not be considered a Product under Consideration or a Priority Product and, therefore, a Tier II AA shall not be required "if the product does not contain any known or detectable amount" of a priority chemical. Conversely, if a product does contain a known or detectable amount of a priority chemical a product will be listed and a Tier II AA shall be required. However, subdivision (e) is inconsistent with the green chemistry law, specifically Health and Safety Code § 25257.1, which precludes the department from superseding the regulatory authority of any other department or agency, or adopting duplicative or conflicting regulations for already regulated products. In particular, California's Proposition 65 initiative

passed by the voters already regulates the presence of naturally occurring or unintentionally added chemicals or chemical ingredients in consumer products. Subdivision (e) conflicts with Proposition 65 because it would require a Tier II AA whenever a priority chemical is present in a product, whether or not the chemical is naturally occurring or unintentionally added. Moreover, to the extent subdivision (e) regulates chemicals or chemical ingredients that are the subject of Proposition 65 but would require no action under that law, the regulation is inconsistent with Health and Safety Code § 25252(b)(2), which requires the department to minimize costs and maximize benefits for the state's economy when adopting regulations to implement the green chemistry law. Finally, the discussion of subdivision (e) in the ISOR does nothing more than restate the terms of the proposal. The ISOR makes no effort to describe the purpose of the provision, or to explain why each provision is required to carry out its described purpose.

For the reasons above, subdivision (e) fails to meet the authority, consistency and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

§ 69303.3 – Products under Consideration: Exposure

Under § 69303.3(a), the designation of "*Products under Consideration"* appears to rely strongly on sales and volume data to approximate exposure to a *chemical of concern* in a consumer product. While in some cases, this might be the only data available to make such determinations; in other cases there will likely be published data or studies that provide exposure information that are quantitative sentinel exposure scenarios representative for an entire product category. In the cases where this data exist or are being developed for a category, DTSC should first give preference to that relevant quantitative exposure data. Specifically under subsection (e) of this section, DTSC must be able to rely on and give preference to quantitative sentinel exposure scenarios for a product.

In § 69303.3(b) above, the lack of a standard for what is deemed an exposure scenario to determine lack of exposure is a serious flaw in the Proposed Regulation. It is critical that exposure pathways result from "reasonable and foreseeable use" of the product. Otherwise there is no standard by which to determine whether there may be an unforeseeable action that might result in exposure and prohibit the chemical from being exempted from the green chemistry process.

Recommendation: The GCA requests that the department address the issues above by amending the Regulation to reflect the language stipulated below for the sections in question; per our previous comments on the Draft Regulation:

> § ***69303.3(b) reasonable and foreseeable potential for the public or the environment to be exposed to the Chemical of Concern contained in the product, during use and disposal of the product.***[3]

§ 69303.3 - Products Under Consideration

[3] Note: GCA strongly recommends the term "Priority Chemical" be eliminated and restored to its previous identifier, namely, "Chemical of Concern." It is in this context and this context only that the above GCA recommendation references "Chemical of Concern" rather than "Priority Chemical."

§ 69303.3 Fails To Meet the Necessity Standard for Proposed Regulations: This section sets out a lengthy list of prioritization factors the department may consider to place products that contain a priority chemical on the list of Products under Consideration pursuant to § 69303.2. While the ISOR includes a few introductory sentences which generally explain the purpose for establishing prioritization factors, and a few other sentences which explain why the various categories of factors are useful in making such determinations, for the most part it only repeats the individual provisions of the regulation and makes no effort to explain how the specific category of information required will be used to implement the green chemistry law, or why it is required to do so. Despite the lengthy list of required information, **§** 69303.3 also makes liberal use of the phrase "including, but not limited to" and, as a result, it is unclear what else may be included within the scope of information.

For the reasons above, § 69302.3(a), and each of its subparts, fails to meet the clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision (c)(5) Is Inconsistent With, and Exceeds the Department's Authority Under, the Green Chemistry Law: Subdivision (c)(5) includes information regarding exposure to workers in the workplace among the types of information that may be considered when placing a product on the Product of Concern list. However, Health and Safety Code § 25257.1 limits the department's authority by proscribing regulation of product categories that are already regulated, or subject to pending regulation consistent with the purposes of the green chemistry law. Here, the proposed language exceeds the authority given the department because workplace exposures are already regulated by the Department of Occupational Safety and Health. Not only is this duplication prohibited by § 25257.1, it is also inconsistent with § 25252(b)(2), which requires the department to minimize costs and maximize benefits for the state's economy when adopting regulations to implement AB 1789 and SB 509 ("the green chemistry law").

For the reasons above, subdivision (c)(5) fails to meet the authority and consistency standards set out in Government Code § 11349.1.

§ **69303.4 - Priority Products**

§ 69303.4 Fails To Meet the Necessity Standard for Proposed Regulations: Section 69303.4 sets out factors the department may consider to identify and designate Priority Products from the list of Products under Consideration. With respect to this section, the ISOR simply paraphrases the individual provisions of the regulation and makes no effort to describe how each category of information will be used to implement a particular requirement of the green chemistry law, or why it is required to do so.

For the reasons above, § 69302.3(a), and each of its subparts, fails to meet the clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

ARTICLE 4 – PETITION FOR INCLUSION OF A CHEMICAL OR PRODUCT IN THE PRIORITIZATION PROCESS

§ 69304 – Petition Process

While GCA supports the inclusion of a petition process, we are concerned that the provisions not only fail to clearly provide for requests to remove chemicals/products from priority lists, but also that manufacturers of implicated chemicals/consumer products do not have any opportunity to provide necessary input on any chemical/product being petitioned prior to DTSC making a final "denied/approved" determination. The process must work both ways and be fully open to public comment.

ARTICLE 5 – ALTERNATIVES ASSESSMENT

§ 69305 – Alternatives Assessments

GCA does not support the unnecessary, unauthorized, and burdensome requirements of Tier 1 Alternatives Assessments (AA) Notifications/Reporting requirements currently proposed in these regulations. As discussed earlier, this should be amended to a voluntary submission processes, unrelated to the timing of product introductions in to California commerce and the department should provide incentives for participation so that safer products are brought to the market quickly.

First is a concern with the Green Screen being cited as the baseline for use in the "chemical hazard assessment" (GCA would prefer the term to be "comparative hazard assessment"). There are a variety of useful tools available for AA that include sections on comparative hazard assessments—besides the Green Screen there are EPA's Design for the Environment case studies and predecessor Cleaner Technologies Substitutes Assessment, the NSF/GCI Greener Chemical Products and Processes Standard, Tim Malloy's Multi-Criteria Decision Analyses submitted to GRSP, the iSustain Green Chemistry Index, the Lowell Center for Sustainable Production AA Framework, and others. Any of these tools provide examples of the simple framework appropriate for comparative hazard assessment between a Chemical of Concern and possible Alternatives. The Green Screen Tool should not be singled out as a "standard".

GCA is also concerned that because the Green Screen is not publicly vetted by California stakeholders, it is not appropriate to be cited for regulatory compliance purposes. It is not a fixed process, but a tool that has evolved over time and presumably will continue to evolve in the future. It is GCA's understanding that Clean Production Action is not bound by a regulatory process by which the regulated community will have an opportunity to provide input to the criteria and approach should Clean Production Action decide to make changes to the framework and criteria in the Green Screen. As noted above, GCA appreciates and strongly supports the inclusion of language in the rest of the AA that allows responsible entities flexibility in using different tools and methodologies and flexibility in focusing on the pertinent factors/key criteria most relevant to the analysis and recommends that the same flexibility be provided for this portion.

Further, regarding Alternatives Assessments (AA) specifically authorized in statute, the proposed regulation separates the Assessment (Tier II AA) into two distinct parts. The Tier II-A AA consists of a "Chemical Hazard Assessment" and an "Exposure Potential Assessment." The Tier II-B AA is a "Multimedia Life Cycle Evaluation," which, beyond typical life-cycle considerations, includes critical considerations such as product performance, economic considerations, technological feasibility, and potential resource impacts from changes to

manufacturing systems. Both parts of the Tier II AA are to be made public (minus information successfully defended as CBI/trade secret).

Altogether, the conduct of an Alternative Assessment will be a very large, difficult and complex task. Each particular Alternatives Assessment will be a unique situation with a unique *Chemical of Concern* and *Priority Product* paring. GCA appreciates and strongly supports the inclusion of language that allows responsible entities flexibility in using different tools and methodologies and flexibility in focusing on the pertinent factors/key criteria most relevant to the particular *Chemical of Concern/Priority Product* in evaluating the potential alternatives. This flexibility is critical to reducing the burden of what will be a difficult and time-consuming process in any case.

However, GCA has a number of significant problems with the Alternatives Assessment and the Tier II approach. First, the draft regulation, § 69305.5(a)(2)(B), states that the Exposure Potential Assessment "is not required if none of the alternatives being considered contain a chemical that exhibits a hazard trait." However, GCA is deeply concerned as it questions how the regulations will be interpreted and implemented after OEHHA promulgates its list of hazard traits pursuant to SB 509. The OEHHA approach includes an exhaustive list of toxicities, pathological observations, and other characteristics and conditions potentially related to an adverse effect. It is not clear that any substance, even the most benign chemicals, would escape this list, since all chemicals exhibit a hazard trait at some level of exposure. Most notably, the OEHHA approach provides no means for a chemical to be classified as "non-toxic". It does not allow non-toxic to exist in the context of the Green Chemistry Initiative. Unless the OEHHA approach is significantly improved in this regard, the Exposure Potential Assessment exemption is meaningless.

Second, a number of factors (product function and performance which includes function and performance, useful life, functional equivalency, technological and economic feasibility, plus economic impact) are included in what is called Multimedia Life Cycle Evaluation, § 69305.5(d). These factors are not life cycle inputs in the traditional sense and are not included in any LCA methodologies. ***They are separate and extremely important evaluation factors that should be considered separate and apart from life cycle factors.***

Third, there is an inconsistency in the regulation relating to judging product performance. As discussed with regard to the definition of "functionally equivalent," § 69301.2(36) is inconsistent in judging performance. GCA objects to this second definition in the strongest possible terms.

Fourth, it appears that DTSC contemplates the two reports will be submitted separately on different due dates. The word "dates" is used frequently in connection with submission deadlines for the entire Tier II AA report. By separating the reports, information about the hazard and exposure dimensions of an AA could be made public *without* any information about performance, useful life, economic considerations, and resource use consequences that are critical for putting multi-dimensional alternatives choices into proper context. Without the information currently partitioned into the Tier II-B AA, public information will be incomplete. The Tier II AA should be a single document, not artificially split into separate submissions that can be misleading and misused. Real world R&D considers all these factors simultaneously in the product development process, usually by means of a series of screening steps, with each step involving a more detailed level of investigation and analysis of the factors for all alternatives and each step selecting alternatives to go forward and discarding alternatives that do not meet the criteria.

§ 69305.3 – De Minimis Level (0.1%) & Exposure

As stipulated in § 69301.2 a *de minimis* level of 0.1% is appropriate and consistent with REACH (See REACH Legislation, Article 7) and should be applied to all chemicals of concern in a product, by weight. However, as noted above, the inclusion of other regulatory exposure levels; as automatic triggers for a lower *de minimis* level, it is inappropriate. See also, GCA comments on Article 1 Definitions: p. 20.

Additionally, under § 69305.3, conditions are stipulated whereby the department may deny a *de minimis* exemption request § 69305.3(d)(2)(A), stipulate a new *de minimis* level § 69305.3(d)(2)(B)1., or also determine that aggregate exposure across products, below a *de minimis* level, could be harmful § 69305.3(d)(3). Under each of these subsections it must be clearly stipulated that DTSC must have quantifiable exposure information to substantiate the denial of a *de minimis* exemption or the establishment of a new *de minimis* level.

Recommendation: Amend § 69305.3(d) as follows:

> ***(d) When the department has quantifiable and reliable information to support a conclusion, the department may set a lower de minimis level under the following circumstances:***

As outlined in the regulation, the de minimis seems only to apply to Priority Products. While GCA believes it necessary and appropriate that it apply to Priority Products, we believe that any product containing a chemical concern below the de minimis threshold should be exempted from these regulations.

Additionally, in § 69305.3 a notification to the department is required to apply the *de minimis* exemption to a "*Priority Product*." This requirement is unnecessary, unauthorized and bureaucratically burdensome. 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.

Article 5, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations: Article 5 sets out the process and requirements to conduct alternatives assessments for consumer products listed as Priority Products. In its discussion of Article 5, the ISOR states generally that its provisions are necessary to provide consistency in the work products submitted and to allow for comparison of data collected but does not explain why alternatives assessments of specific products need to be consistent and comparable with different assessments of different products. Again without reference to any particular provisions, the ISOR also asserts that elements of Article 5 are crucial to identify data gaps for products that contain Priority Chemicals, but fails to explain why such gaps must be identified. Even where the ISOR references specific provisions of Article 5, the discussion never goes beyond general statements and conclusions, none of which demonstrate the necessity of the regulation. Such general and conclusory statements undermine the purpose of the Administrative Procedure Act to provide interested parties a meaningful opportunity to review and comment on proposed regulations. Such an egregious substantive and procedural defect in the adoption process can only be remedied by elimination of the proposed provisions, or amendment to the ISOR and a further opportunity for public review and comment.

For the reasons above, Article 5, and each of its subparts, fail to meet the necessity standard set out in Government Code § 11349.1 and 1 CCR §10.

§ 69305.1 - Alternatives Assessment Notifications and Tier I AA Reports

§ 69305.1 Is Unnecessary and Inconsistent With the Green Chemistry Law: Section 69305.1 requires responsible entities to provide an AA Notification, including a Tier I AA report, before discontinuing a product containing a Chemical under Consideration or Priority Chemical and replacing it with a reformulated, redesigned or replacement product. The ISOR explains that this section is necessary to allow a responsible entity to reformulate or redesign a product without first performing a Tier II AA. However, the Tier II AA process does not apply at all to products which contain a Chemical under Consideration, and only applies to products which contain a Priority Chemical if the product has been designated a Priority Product. Thus, subdivision (a) is not necessary to accomplish the department's stated purpose. Moreover, requiring a Tier I AA report before a product can be reformulated creates a costly and stigmatic barrier to reformulation and is inconsistent with the purpose of the Green Chemistry Law to promote safer alternatives.

For the reasons above, § 69305.1 fails to meet the clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

§ 69305.2 - Tier II Alternatives Assessments: General Provisions

Subdivision (c)(3)(A) Is Unclear and Inconsistent With the Green Chemistry Law: Subdivision (c)(3)(A) requires a Tier II AA to be reviewed and verified by a second lead assessor. The regulations already require a Tier II AA report to be prepared by a qualified and accredited lead assessor. Imposing a second layer of review on the work product of lead assessors who have already demonstrated to the department that they are qualified and accredited to perform such work will significantly increase the cost of the Tier II AA process for little, if any, benefit. The increased costs of the redundant review will slow the pace of product reformulation and, therefore, is inconsistent with the purpose of the Green Chemistry Law to promote safer alternatives.

Subdivision (c)(3)(A)(5) requires that a verifying lead assessor "[h]ave no economic interest in any entity that manufactures, or places into the stream of commerce in California, any Chemical of Concern, Product under Consideration, or Priority Product." This provision is unclear because "economic interest" is undefined.

For the reasons above, § 69305.1 fails to meet the standard for clarity set out in Government Code § 11349.1 and 1 CCR §10.

§ 69305.6 - Tier II Alternatives Assessments Reports

Subdivision (b)(7)(B) Is Unnecessary and Exceeds the Department's Authority Under the Green Chemistry Law: Subdivision (a)(7)(B) requires a Tier II AA reports to include a copy of the contractual agreement between the preparer of the AA Report and the verifying lead assessor.

The ISOR provides no discussion of the rationale for this provision, nor could it because the department has no authority under the green chemistry law to require such information.

For the reasons above, § 69305.1 fails to meet the standard for necessity and authority set out in Government Code § 11349.1 and 1 CCR §10.

ARTICLE 6 – REGULATORY RESPONSE

§ 69306. - Applicability

No Clarity that Regulatory Responses Must be Proportional to the Degree of Risk: This section lays out regulatory responses that the department may take after the submission of a Tier II AA and after public notice and comment on it's proposed response. The options discussed in the regulation mirror those listed in the statute. GCA is concerned that there is no sense of proportion to suggest why different responses may or may not be selected. GCA holds that it is critically important that the department's response must be proportional to the degree of risk posed by the selected alternative. Where there is not an objective risk, no regulatory response should be required. *End of Life Management* requirements or *Product Sales Prohibitions* or *Other Regulatory Responses* should only be undertaken where there is a demonstrable objective risk that must be managed and can be successfully managed with those options.

§ 69306.2 - No Regulatory Response Required

This section provides a series of unreasonable criteria, all of which must be met, before a finding of no regulatory response is made relating to a selected "alternative consumer product". This section fails to consider many likely factors, including:

- A product could contain a Chemical of Concern above detectable levels, or even above 0.1%, and still not present a significant impact on public health or the environment in the intended uses.
- There is no reason to believe that Alternative Products will have lower impacts than Priority Products for all uses.

§ 69306.3 - Product Information to Consumers

If a manufacturer does not "select an alternative" for a Priority Product, then consumers must be informed regarding the Priority Product and its inclusion of Chemical(s) of Concern. This requirement once again presupposes that all Priority Products for all uses will be found to have significant public health or environmental impacts. The requirement for labeling in subsection (c) is especially unreasonable, and should be entirely eliminated.

§ 69306.4 - End-of-Life Management Requirements

Regarding *End of Life Management,* the proposed regulation as a regulatory response goes beyond the scope of statute and is overly burdensome in that it mandates take back programs. Additional methodologies for addressing end-of-life concerns must be included.

Mandatory take-back programs are not warranted for all products. This should be decided on a case-by-case basis as other alternatives could have lower environmental, health or safety impacts. Furthermore, take-back programs can have unintended consequences resulting from disposal of otherwise useful product.

Based on the current very broad definition of "consumer product," this section should be revised to clearly state exemptions for industrial and commercial products, including chemical intermediates. These products already are already subject to or a part of business-to-business (B2B) hazardous waste/recycling arrangements.

§ 69306.5 - Product Sales Prohibition

This section should provide further information regarding how DTSC would "determine… that a safer alternative exists" and thereby order that the product "shall not be made available for use in California." It is important that such an extreme regulatory measure be implemented only under circumstances where significant impacts to public health or the environment can be minimized without other adverse effects. A proposal for this regulatory action should be subject to full notice and public comment. In addition, as noted earlier, mandatory take-back programs are not warranted for all products. This should be decided on a case-by-case basis. Other regulatory or risk mitigation alternatives could have lower environmental, health or safety impacts.

§ 69306.6 - Other Regulatory Responses

The statements that, "The Department may apply any…regulatory responses to any scenario" provides grossly excessive discretion to the department to apply regulatory measures where they may not be warranted under any reasonable interpretation of good public policy. This section should be revised to allow the department to choose the regulatory option that will eliminate or reduce significant risks or impacts without creating other adverse public health, environmental or economic impacts. In addition, all proposals for this regulatory action under this section should be subject to full notice and public comment.

§ 69306.9 - Regulatory Response Report and Notifications

The requirement that manufacturers subject to *any* regulatory action "notify retailers who sell the product or component in California," is excessive and unwarranted for many if not all regulatory actions. This requirement should be implemented only for specific types of regulatory actions where retailer action is needed.

ARTICLE 6 - REGULATORY RESPONSE

Article 6, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations: Article 6 sets out the range of regulatory responses which the department may impose on a Priority Product after the Tier II AA process is completed. In its discussion of Article 6, the ISOR states generally that its provisions are necessary "to specify the regulatory responses regimen that implement Health and Safety Code § 25253(b), and "to clarify, implement, and make specific the provisions of [that section]." Throughout its discussion of Article 6, the ISOR does little more than simply repeat the requirements of each provision and state that it is necessary to do what it does. Such general and conclusory statements fail to demonstrate the necessity of the provisions of Article 6 and deny interested parties a meaningful opportunity to review and comment on the regulations proposed. Such an egregious substantive and procedural defect in the adoption process can only be remedied by elimination of the proposed provisions, or amendment to the ISOR and a further opportunity for public review and comment.

For the reasons above, Article 6, and each of its subparts, fail to meet the necessity standard set out in Government Code § 11349.1 and 1 CCR §10.

§ 69306.4 - End of Life Management Requirements

Subdivision 69306.4(a)(2)(A)(2)(d) Is Unnecessary, Unclear and Exceeds the Department's Authority Under the Green Chemistry Law: Subdivision 69306.4(a)(2)(A)(2)(d) requires a responsible entity's Product Stewardship Plan to identify the Plan's "fair share" of orphan products, which the ISOR explains are "products whose manufacturers or responsible entities are no longer in existence." To justify this provision, the ISOR asserts that, "[n]ot taking [orphan products] into consideration could compromise the success of a Product Stewardship Plan." Nowhere does the ISOR explain why a responsible entity's Product Stewardship Plan should include products that are not the responsible entity's own products. Moreover, the ISOR could not do so because the department has no authority under the green chemistry law to impose the financial or other burden for orphan products on an entity that is not responsible for the product. Finally, this subdivision is unclear because "fair share" is undefined and, therefore, it is impossible for a responsible entity's to determine what its fair share might be.

For the reasons above, § 69305.1 fails to meet the authority, clarity and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision 69306.4(a)(2)(A)(3)(a) Is Unnecessary and Exceeds the Department's Authority Under the Green Chemistry Law: Subdivision 69306.4(a)(2)(A)(3)(a) requires a manufacturer or responsible entity to pay for implementation of a Product Stewardship Plan as a "general cost of doing business, through cost internalization or by recovering costs through arrangements with their distributors and retailers." In effect, this provision seeks to prohibit a plan that would impose its cost to implement on the consumers who purchase the product subject to the plan. To justify this provision, the ISOR states it is "necessary to assess the planning and assumptions under which the plan is being developed." Nowhere does the ISOR explain why consumers should not bear the burden of a Product Stewardship Plan required by the department for a product they purchase. Moreover, the ISOR could not do so because the

department has no authority under the green chemistry law to preclude such a method of financing.

For the reasons above, subdivision 69306.4(a)(2)(A)(3)(a) fails to meet the authority and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

ARTICLE 7 – DISPUTE RESOLUTION

Dispute resolution should clarify what steps are required to achieve a stay of regulatory requirements while disputes are being addressed administratively. While the dispute resolution process outlined has merit, we recommend that a step to provide an outside review be provided before the manufacturer is forced to seek judicial review.

ARTICLE 8 - ACCREDITATION AND QUALIFICATION REQUIREMENTS FOR PERFORMANCE OF ALTERNATIVES ASSESSMENTS

§ 69308, § 69308.1,& § 69308.2 – Rquirements Third Party and In-Houese Assessors, and designated accrediting bodies

GCA is unequivocally opposed to ***mandatory*** third party verifiers, 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 Lead Assessors of 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 a Tier II Alternative Assessment is “complete.”

Additionally, requiring third party verification for *every* Tier II AA will be costly and hinder timeframes for completion of the AA given our understanding of the finite supply of Lead Assessors/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 quality criteria for the performance of alternatives assessment verification by certified third parties, including grievance and dispute resolution procedures for parties who believe their alternatives assessments have been improperly denied verification.

GCA has argued vigorously that DTSC should require third party verification in limited situations and not for every Tier II AA report, when the report has been prepared by an accredited in-house Lead Assessor. As discussed, accredited in-house Lead Assessors are better positioned to understand the subjective Alternative Assessment applied to a Chemical of Concern/Priority Product.[4]

As it relates to Lead Assessors, under the proposed regulation in § 69305.2(c)(3)(A)5 the verifying lead assessor must, "Have no economic interest in any entity that manufactures, or places into the stream of commerce in California, any CUC, Product under Consideration, or Priority Product." This is an impossibly low threshold in this era of mutual funds and other broad and sophisticated economic investments wherein a verifying lead assessor may not easily or readily determine if s/he has any economic interest in any particular entity. At the very least, this threshold must be raised to some reasonable limit above zero. Furthermore, it should apply only to those specific entities for which that verifying lead assessor is performing assessments, not to "any entity." The requirement to demonstrate *"independence and lack of affiliation with any responsible entity, manufacturer, consortium of manufacturers, or trade association"* inappropriately excludes those individuals who have the potential to bring the most valuable expertise to the task.

Article 8, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations: Article 8 sets out 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. In its discussion of Article 8, the ISOR states generally that its provisions are necessary to ensure the reliability and integrity of assessments required to be performed by the regulation. However, the ISOR utterly fails to describe the problem, administrative requirement, or other condition or circumstance which each provision is intended to address, much less why it is required to do so. The ISOR's failure to demonstrate the necessity of any provision of Article 8, as with the other provisions where the ISOR is similarly defective, undermines the purpose of the Administrative Procedure Act to provide interested parties a meaningful opportunity to review and comment on proposed regulations. Such an egregious substantive and procedural defect in the adoption process can only be remedied by elimination of the proposed provisions, or amendment to the ISOR and a further opportunity for public review and comment.

For the reasons above, Article 8, and each of its subparts, fail to meet the necessity standard set out in Government Code § 11349.1 and 1 CCR §10.

Subdivision (a)(4)(A) Exceeds the Department's Authority, Conflicts With Other Law and Is Unclear: Subdivision (a)(4)(A) requires that an applicant for certification as a Qualified Third Party Assessment Entity must submit information to demonstrate "[i]ndependence and lack of affiliation with any responsible entity, manufacturer, consortium of manufacturers, or trade association." This provision exceeds the department's authority because there is no basis to use trade association membership as the basis for precluding participation in process established by the department to implement the green chemistry law. Moreover, such an overbroad restriction violates the First Amendment right of such participants to freely associate. Finally, this provision is unclear because neither "independence" nor "lack of affiliation" are

[4] Note: GCA strongly recommends the term "Priority Chemical" be eliminated and restored to its previous identifier, namely, "Chemical of Concern." It is in this context and this context only that the above GCA recommendation references "Chemical of Concern" rather than "Priority Chemical."

defined and, as a result, potential participants have no way to know to determine what is required in order to participate, or to determine whether issuance or denial of an application is justified.

For the reasons above, subdivision (a)(4)(A) fails to meet the authority, consistency and necessity standards set out in Government Code § 11349.1 and 1 CCR §10.

§ 69308.2 - Requirements for Designated Accrediting Bodies

Subdivision (g)(2) Conflicts With Substantive and Procedural Due Process Protections and Is Unclear: Subdivision (g)(2) provides for the department to revoke a designation as an accrediting body if "a substantial number" of individuals accredited by the body as lead assessors are found to be in violation of the green chemistry regulations. The term "substantial number" is not defined by the regulations and, as a result, the proposed standard is unclear. For example, if 10 individuals accredited by a body are found to be in violation of the regulations, but the body has accredited more than 1000 individuals, the number found in violation probably should not be considered substantial. However, if 2 individuals accredited by a body are found in violation and they are the only ones accredited by that body, that may be a substantial number. Moreover, a standard that considers only the number of individuals found in violation, and not their proportion to the total number certified or the reason for the violation, fails to satisfy substantive and procedural due process requirements guaranteed by the state and federal Constitutions before a license, privilege or permit may be revoked.

For the reasons above, subdivision (g(2) fails to meet the standards for clarity and consistency set out in Government Code § 11349.1.

§ 69308.3 - Lead Assessor Accreditation Requirements for Qualified Third-Party Assessment Entities

It is not clear why the department seeks separate accreditation of Lead Assessors, which appears to be required prior to seeking Assessment Entity status. Furthermore, it is difficult to imagine any person, or even small group of persons, who would have the broad skills and knowledge required to conduct assessments across the extremely broad spectrum of products, chemicals and impacts that would need to be assessed in AAs as envisioned by this regulation.

Article 10 - - CONFIDENTIALITY OF INFORMATION

Introduction

The following comments, submitted in response to the proposed regulations relating to the protection of trade secrets, should be viewed in the context of the value and critical importance that businesses properly place on trade secret information. Trade secrets are among a business' most valuable assets; as valuable (or in some cases more valuable) than hard assets such as manufacturing equipment and facilities.

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

For the expectations of the Green Chemistry Initiative to be met, innovation has to be incentivized, research and development has to be rewarded in the marketplace. That can occur only if manufacturers' trade secrets are protected.

Accordingly, the regulations in Article 10 are viewed with a critical eye, and any diminution of trade secret protection is condemned. The survivability of manufacturers doing business in California and the success of green chemistry depends on protecting trade secrets to the full extent of the law.

GCA Asserts Article 10 Is Not Necessary and Should be Struck In Its Entirety

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

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

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

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

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

§ 69310 - Confidential Business Information

Section 69310 solely provides that DTSC shall comply with the existing laws pertaining to nondisclosure of confidential information, and that it will use existing laws to determine what is confidential information. DTSC is obligated to follow existing law; it has no authority to ignore that law. While it is reassuring to know that DTSC will follow existing law, it is not necessary to state it.

§ 69310.1 - Assertion of A Claim of Confidential Business information

The Duplicative Portions of This Section Are Unnecessary: In § 69310.1, DTSC begins by following the dictates of existing law, requiring a person who wishes to claim information as confidential information to identify the portion of the information that is subject to the trade secret claim. That is set out explicitly in Health and Safety Code § 25257. Accordingly, that portion of this section is unnecessary.

Portions of This Section Are Inconsistent and Expand the Scope of the Underlying Law: Section 69310.1 goes beyond requiring the submitter to identify the portion of the information that is a trade secret and requires it to specify the statutory authority constituting the basis for the trade secret claim, to provide a claims index as required in § 69310.2, and to provide supporting information required by § 69310.4. The latter section sets out 12 specific requirements for supporting a claim that certain information is a trade secret.

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

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

§ 69310.2 Marking and Indexing of Documents

The Duplicative Portion of This Section Is Unnecessary: Subdivision (a) of § 69310.2 again requires a person who submits information, claiming that some portion of the information is trade secret, shall asset that claim at the time of submission. As noted above, this is already required by Health and Safety Code § 25257; it simply duplicates it, and as such, it is unnecessary.

The Portion of This Section Is Inconsistent and Expands the Scope of the Underlying Law: Subdivision (b) of § 69310.2 requires that a person who asserts a claim of confidential information shall provide at the time of submission a separate claims index summarizing the kind of confidential information for which the claim is made, the factual or legal basis for the claim, and the place in the submitted document where the confidential information was originally located. This subdivision of § 69310.2 also provides that the claims index shall be made available in full to the public.

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

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

Despite the explicit provisions of Government Code § 6253, requiring segregation to assure full protection of the trade secret information, § 69310.2 undermines the purpose and specific language of the Public Records Act. It does so by requiring the person submitting the information to describe the type of information that has been excluded and to indicate the specific location in the document where the information was originally located.

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

§ 69310.4 - Support of a Claim of Trade Secrets Protection

Section 69310.4 requires a person who asserts a trade secret claim to support that claim within ten days of a request for support and to meet 12 requirements to support the claim. A portion of this section is ambiguous, lacking clarity; a portion is unrealistic and contrary to specific provisions in Health and Safety Code § 25257, and significant portions are unnecessary and inconsistent with the statutory definition of a trade secret.

A Portion of § 69310.4 Lacks Clarity: Subdivision (a) provides that a person asserting a trade secret claim "and receives a request from the department to support trade secret claims shall, at the time of submission, or within ten (10) days of receipt of a request for support, provide substantiating information." The lack of clarity arises from the inclusion of the phrase "at the time of submission." The introductory part of the section refers to the receipt of a request from the department to support the trade secret claim. Hence, the two choices of providing information at the time of submission or within ten days of receipt of a request create uncertainty as to what is intended. It would appear that it is impossible to submit the substantiating information at the time of submission of the trade secret information if the person asserting the trade secret claim has already received a request from the department. This needs to be rewritten to make clear what the department has in mind.

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

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

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

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

Significant Portions of § 69310.4, Requiring Substantiating Information, Are Unnecessary and Inconsistent with the Statutory Definition of a Trade Secret: The first two paragraphs under subdivision (a) requiring the identity of a person making a claim in a description of the information for which a trade secret protection is claimed are basic to any response for supporting information. As such, it is unnecessary to provide that.

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

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

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

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

Also, as noted above, this provision has no relationship to the definition of a trade secret. In fact, the implementation of this provision could be inconsistent with the definition of a trade secret. For example, the definition of a trade secret states that the information derives independent economic value from not being **generally** known to the public. Information can still be a trade secret even if it has been acquired or duplicated by limited other entities. The test is whether it still derives economic value and not whether it is known by anyone else.

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

Moreover, the implication of paragraph 9 raises confusion and, as such, lacks clarity. The implication of this requirement is that DTSC, in making a decision whether to substantiate a trade secret claim, may exercise discretion and deny a claim if in its judgment someone, such

as a competitor, might be able to acquire or duplicate the information. That introduces substantial uncertainty into the decision process.

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

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

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

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

Again, the department creates ambiguity and uncertainty by including this as a required component of substantiating information. Resulting harm from unlawful misappropriation is not an element of the statutory definition of a trade secret. Yet, requiring this information implies that the department would consider that in making its decision to support a trade secret claim or not. Although the department has not explained how it would use this information, the implication is that it is a relevant factor. If harm is great, is the information more likely to be a trade secret than if the harm is relatively slight? The ambiguity and uncertainty renders this provision invalid for lacking clarity.

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

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

§ 69310.5 Departmental Review of Trade Secret Claims

Section 69310.5 describes the process that DTSC intends to follow in determining whether a trade secret claim is substantiated or not in two different circumstances. The first circumstance is prior to any request for the release of the information having been made and the department initiates on its own such a determination. The second circumstance is following a request for release of the information and the process that DTSC will follow in making a determination in response to that request.

Subdivision (a) of § 69310.5 Is Inconsistent With Underlying Law: Subdivision (a) of § 69310.5 essentially provides that DTSC, after asking a person to support a trade secret claim, will determine whether that claim is substantiated or not. If not, it will provide notice to the person submitting the information and will not release the information to the public for 30 days or for any time extended by order of a court. Subdivision (a) is inconsistent with Health and Safety Code § 25257. The statute provides that information shall be released to the public only in accordance with subdivision (d) of that section. Subdivision (d) sets out the process that the department is to follow after receiving a request for the release of information. In other words, no information claimed as a trade secret is to be made public until first there is a request for the release of that information. Hence, DTSC cannot, as it proposes to do in subdivision (a), release information claimed as a trade secret solely because it decides that the claim has not be adequately substantiated.

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

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

Subdivision (b) of § 69310.5 Duplicates § 25257 and Is Unnecessary: As noted above, the second part of § 69310.5, set out in subdivision (b), deals with the circumstance when the department receives a Public Records Act request for the release of trade secret information. The provisions set out in subdivision (b) simply reiterate the process set out in Health and Safety Code § 25257 and the Public Records Act. It adds nothing toward implementing, interpreting, or making specific either of those existing statutory provisions. As such, subdivision (b) of this section is unnecessary and should be stricken.

§ 69310.6 - Hazard and Trait Submission

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

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

In subdivision (b) of § 69310.6, DTSC provides that "hazard trait submission" means information submitted to the department pertaining to a hazard trait of any chemical or chemical ingredient. While not a precise verbatim iteration of subdivision (f) of § 25257, its meaning is identical. No purpose is served by reiterating the statutory language. It does not further the implementation or interpretation of the statute. As such, it is unnecessary and should be stricken from the regulations.

The Balance of § 69310.6 Is Inconsistent With the Underlying Law: Subdivision (b) of § 69310.6, after stating that a hazard trait submission is information on hazard traits submitted to the department, an obvious tautology, the regulation provides that the term hazard trait submission also includes the identification of the manufacturer of a product containing a *Chemical of Concern* or a chosen alternative. That term also includes information that a particular *Chemical of Concern* or an alternative is present in a product.

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

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

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

Summary of Comments on Article 10

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

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

ARTICLE 11 - SMALL BUSINESSES

Article 11, and Each of Its Subparts, Fail To Meet the Necessity Standard for Proposed Regulations: Article 11 provides the department flexibility to apply less stringent timelines and offer additional assistance to manufacturers or responsible entities that qualify as small businesses, and sets out the process and requirements to qualify as such. While special accommodation of small businesses is a laudable objective, the ISOR fails to describe the problem, administrative requirement, or other condition or circumstance which each provision is intended to address, much less why it is required to do so. In particular, the ISOR fails to demonstrate the basis for the criteria proposed by the regulation in order to qualify as a small business, or the basis for the regulatory relief offered to such businesses.

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 as Exhibit 1 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 has 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

CONCLUSION:

The Green Chemistry Alliance has appreciated the opportunity we have had to constructively work with DTSC and the other stakeholders over the past two years in an attempt to craft a set of workable regulations. We are therefore perplexed and greatly disappointed that at this late date in the process DTSC would choose to veer so dramatically from the path they had been following. These regulations as proposed have entirely lost focus and will not work. The proposed rules lack clarity and authority and seek to impose unnecessary regulatory burdens on all of California's business and industry. Until such time as major issues identified above are addressed, the Green Chemistry Alliance can no longer support the adoption of these regulations. GCA recommends DTSC to withdraw the regulations and develop a more workable program for carrying out the Green Chemistry law. We urge DTSC so seek out the advice of the Green Ribbon Science Panel and other stakeholders who are interested in refocusing the regulations on addressing the areas of greatest risk reduction in a scientifically sound are efficient manner. The Green Chemistry Alliance stands ready to constructively participate in such an effort.

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