Green Chemistry Alliance

*Committed to Product Sustainability in the Global Economy*

January 13, 2012



Ms. Heather Jones
Safer Consumer Products Regulation Coordinator, MS-22A
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

**Re: Safer Consumer Products Draft Regulation**
**(October 31, 2011)**

Dear Ms. Jones:

On behalf of the Green Chemistry Alliance (GCA), we respectfully submit the following comments relative to the Department of Toxics Substances Control's (~~D~~Department") draft Safer Consumer Products Regulation (~~d~~raft regulation") of October 31, 2011.

GCA is a highly diverse coalition comprised of national and state trade associations and numerous large and small companies spanning the consumer market and global supply chain. While GCA and these industries have largely coalesced around major aspects of the process, DTSC must be mindful of the unique issues these industries have identified in complying with the proposed regulatory program. In this regard, GCA urges the Department to examine closely these unique issues and the individual comments submitted by industry.

GCA appreciates the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system and we acknowledge that significant progress has been made on this informal draft as compared to the draft regulations released in 2010. GCA and its coalition members are likewise appreciative of DTSC's willingness to meet with and engage stakeholders in what must seem like an endless round of discussions.

While applauding Director Raphael's commitment to the development of a practical, meaningful, and legally defensible regulation GCA observes nevertheless that the informal draft of said regulation, for numerous reasons identified in the following comments, falls well short of those objectives.

Although conversations with the Director and Department staff leave one with a feeling of confidence that the proposed regulation is sound and workable, a closer review of the actual language reveals serious gaps in the ~~p~~practical, meaningful and legally defensible" manner in which the Department says it intends to implement the program and the latitude which the Department reserves for itself to implement a much less reasonable program with considerably more onerous impacts. It is largely to these excesses of discretion reserved by the Department that the majority

of GCA's comments and those of our coalition members are directed.

We are highly concerned that the current draft proposes to establish an all-encompassing program that appears to exceed the more modest intent of a "practical" approach. Indeed, **virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products**. It is difficult to reconcile the complexity of the draft with the marginal improvement in health and environmental safety it is likely to advance. In addition, full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, GCA and its coalition members strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others.

Many GCA coalition members supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of DTSC scientists. However, the draft regulation fails to be science-based in several important respects: in proposing to identify chemicals of concern only via merging a variety of Lists; in definitions for bioaccumulation, persistence, and reliable information; in proposing a "narrative" not a scientific standard and process for identifying Priority Products; and, in not recognizing the important distinction between "strong" and "suggestive" evidence emphasized by OEHHA in their proposed Hazard Trait Regulation that would address the concept of thresholds for hazard properties as a means to identify a level of concern.

Further, the intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. GCA is concerned, however, that the proposed approach will create an unpredictable framework that will increase uncertainty in the business community. **The proposal as currently drafted threatens vital intellectual property upon which innovation is based.**

The draft gives DTSC full discretionary authority to modify timetables, and to prioritize or reverse decisions on the basis of narrative standards that lack objective criteria. As a result, compliance with the regulation will be a challenge for all entities, particularly those outside California (and those outside the United States). In addition, **it will be nearly impossible for companies to design compliant products or retailers to confidently select inventory since compliance is an ever-shifting target under the current draft.**

GCA agrees with DTSC's practical approach to identify two to five Priority Products as the regulatory program is initiated. This will enable DTSC to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. GCA strongly recommends DTSC consider a more focused program concentrating **on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm.** We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

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 GCA website at www.greenchemistryalliance.org. Thank you!

Sincerely,

John Ulrich
Co-Chair
Chemical Industry Council of California

Dawn Sanders Koepke
Co-Chair
McHugh & Associates

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor
Debbie Raphael, Director, DTSC
Jim Jones, Acting Assistant Administrator, U.S. EPA Office of Chemical Safety and Pollution Prevention
Paul Anastas, Assistant Administrator, U.S. EPA Office of Research and Development
Jared Blumenfeld, Regional Administrator Pacific Southwest, U.S. EPA

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**Green Chemistry Alliance Signatories**

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Cleaning Institute
American Coatings Association
American Forest & Paper Association
Amway
Association of Global Automakers, Inc
Association of Home Appliance Manufacturers
Automotive Aftermarket Industry Assoc (AAIA)
BASF
The Boeing Company
California Aerospace Technology Association
California Automotive Wholesalers' Association (CAWA)
California Chamber Commerce
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
California New Car Dealers Association
California Paint Council
California Restaurant Association
Can Manufacturers Institute
Chemical Industry Council of California
Chevron
Citizens for Fire Safety Institute
Consumer Healthcare Products Association
Consumer Specialty Products Association
Dart Container Corporation
Defoamer Industry Trade Association
Del Monte
DuPont
Ecolab
Ellis Paint
EPS Molders Association
ExxonMobil
Fashion Accessories Shippers Assoc
Florida Chemical Company, Inc
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Independent Lubricant Manufacturers Assoc
Industrial Environmental Association
IFRA North America
Information Technology Industry Council
International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Industries Inc.
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National Assoc of Chemical Distributors (NACD)
National Electrical Manufacturers Association
National Shooting Sports Foundation (NSSF)
Natural Products Association
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Rio Tinto
Rubber Manufacturers Association
SABIC Innovative Plastics
Scott's Miracle-Gro Company
Silicones Environmental Health & Safety Council
Smith & Vandiver
Solar Turbines
Society of Chemical Mfgs & Affiliates (SOCMA)
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
Styrene Information Research Center
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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# EXECUTIVE SUMMARY

## NOTABLE IMPROVEMENTS

The Department has taken a very detailed and deliberate approach to this latest iteration of the Safer Consumer Product regulations. We commend the Department on its hard work and thoroughness. There are several areas of improvement we would like to point out and that we believe should be maintained moving forward:

- The Department proposes three mechanisms for determining Chemicals of Concern (COCs): 1) an initial listing, 2) a Departmental identification process and 3) a public petition process. While GCA has some specific concerns about 1) and 3) detailed later, we believe these three processes are important procedural elements for identifying COCs and should be maintained as part of the final regulations;

- The Department has taken a very pragmatic approach with respect to the collection of data. We believe the Department has chosen the most efficient process, using publicly available data when it can and requiring submissions when needed. The recently announced agreement with US EPA can provide additional help in this regard. We believe this will result in more rapid identification of Chemicals of Concern and Priority Products with alternatives assessments being conducted sooner and avoiding delay in regulatory decisions and making improvement that will benefit public health and the environment;

- The Department's stated approach to focusing initially on two to five chemical-product combinations is a practical approach to begin a program that to GCA's knowledge has yet to be undertaken to this degree anywhere else in the world;

- The Department's attempt to allow some flexibility in the Alternatives Assessment process for manufacturers conducting assessments is a positive step in the right direction. The emphasis on the use of a work plan is also positive and supported in concept by the GCA; and

- The elimination of third-party verification makes the Alternatives Assessment process more efficient without compromising the level of quality of the submissions.

## AREAS OF SIGNIFICANT CONCERN

### REGULATORY DUPLICATION

The statute is clear on the matter of regulatory duplication, stating that it does not authorize the department to supersede the authority of other agencies and directing that the Department shall not duplicate or adopt conflicting regulations for products already regulated or subject to pending regulation. The proposed draft goes beyond the statute to assert Department dominance where it believes it would provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were not listed as a Priority Product. Regulatory duplication for any product should be a straightforward question – is the potential health or environmental impact from the chemical in the product regulated by another agency or not? Where that is the case, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

## CHEMICALS OF CONCERN (CoC) IDENTIFICATION PROCESS

AB 1879 requires the Department ~~to~~ establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern." However, instead of proposing a science-based process for identifying chemicals of concern, the Department simply relies on merging 22 lists compiled by a variety of governmental, intergovernmental, and academic interests. If followed, this approach will result in a chemical of concern list containing well over 4000 chemicals. It is not a process for selecting chemicals of concern (as statutorily prescribed), is not meaningful, and is not legally defensible. A number of the proposed sources for this merged list do not represent the appropriate selection of work from authoritative bodies. The establishment of a non-credible list of more than 4,000 substances will become irrelevant and will do little to motivate broad-based action by manufacturers. It is so overwhelming that it will have the opposite effect—more likely, all product manufacturers and retailers except those involved in selected Priority Product/Chemical of Concern pairs will ignore it. In detailed comments GCA provides specific recommendations for the development of a credible list of Chemicals of Concern.

## CHEMICALS OF CONCERN & CONSUMER PRODUCT PRIOIRITZATION PROCESS

As drafted the regulation identifies a vague process by which the Department will prioritize and establish a list of ~~P~~riority Products." GCA appreciates that the identification of chemical of concern/priority product pairs is intended to be risk-based, as it requires some consideration of exposure and the potential for harm. It is unclear, however, how the Department will objectively utilize the initial criteria and the ~~K~~ey Criteria" to assess and prioritize products based on a list of thousands of potential chemicals of concern. An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which the Department will identify priority products. This process should focus on intentionally-added chemicals in products and reasonable and foreseeable exposure to those chemicals. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint – it will only serve to politicize the process that was originally intended to rely on science-based decision making. In detailed comments, GCA provides specific recommendations for clarifying and improving the proposed process for chemical of concern/priority product identification.

## *DE MINIMIS* EXEMPTION LIMIT

GCA supports a reasonable *de minimis* limit of 0.1% (1,000 ppm) of the identified chemical of concern (CoC) by weight in the final consumer product.

*De minimis* provisions are standard in a variety of chemical and product safety laws. Europe's REACh chemical law applies a 0.1% *de minimis* level as a default in products. REACh's 0.1% *de minimis* applies broadly, even to so-called Substances of Very High Concern that become banned in Europe. Additionally, this is a limit that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS), in the European Cosmetic Directive and in global transport and worker regulations. The basis for these laws is that low, but measurable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low. More importantly, 0.1% is a practical limit that will avoid unnecessary assessments and reformulations based on the mere presence of trace contaminant amounts of a chemical of concern. The Department should limit the application of the regulation to intentionally added chemicals; not contaminants and trace elements.

Additionally, the document fails to recognize the important distinction between ―strong" and ―suggestive" evidence emphasized by OEHHA in their proposed Hazard Trait Regulation. This distinction is important in terms of both indicating defensible classification of a chemical as possessing a particular hazard trait and in providing supplemental information (the ―suggestive" evidence) that may be of informational use but is less credible as a criterion for action. This omission should be corrected and the distinction incorporated into the proposed regulation.

Further, the *de minimis* provision should be self-implementing. As currently drafted the ―*de minimis* exemption" process requires significant effort on the part of both the Department and manufacturers to demonstrate that a chemical is not present. This approach is very resource-intensive and will only serve to distract the Department from the goals of the regulation.

Finally, using the sum of concentrations for the de minimis limit is not consistent with any known regulatory regime, and will create significant compliance issues for both the Department and the regulated community due to uncertainties in testing and inability to use existing chemical data for assessments.

## ALTERNATIVES ASSESSMENTS

While there are notable improvements indicated above, the Alternatives Assessment requirements remain highly onerous and lack clarity in a number of sections. While a large company may be able to adapt to the regulations and its requirements, small and medium sized companies, which are the engines for economic growth, will be crippled by the burdens of conducting alternatives assessments in order to continue selling safe and legal products in the state. The AA requirements should be streamlined as much as possible so companies can complete the reports efficiently and effectively to bring safer products to the market.

In GCA's detailed comments we provide specific recommendations for improving the proposed process for Alternatives Assessments.

## ACCREDITATION BODIES AND CERTIFIED ASSESSORS

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

However, GCA prefers the approach proposed in the current draft regulation, utilizing assessors (including company employees) licensed by accreditation bodies, as opposed to previous proposals that required third-party completion of all alternatives assessments. As demonstrated by industry during the ―Alternatives Analysis III: Industry Practices in Product Research and Development, an Alternative Analysis" symposium, on September 15, 2011, experience in product development should be a significant credential leading to assessor certification. In detailed comments GCA provides specific recommendations for this Article.

## REGULATORY RESPONSES

The imposition of regulatory responses have the potential of making products unacceptable to consumers or imposing such cost that a manufacturer may cease making the product available in California. The consequences of imposing substantial cost or forcing the withdrawal of products for sale in California are so significant that the various regulatory responses should be imposed only under circumstances that are necessary to carry out the purposes of the underlying statute. GCA is highly concerned that a number of the regulatory provisions exceed the scope of the statute and should therefore be removed or modified to be consistent with the law. Furthermore, it is critical that the regulatory response provisions be clear and specific, so that responsible entities may understand how the provisions will affect them and that discrimination during implementation can be avoided.

## TRADE SECRET PROTECTION – State Action & Competition Law

An unintended consequence of the lack of protection of competitively sensitive information in the draft regulation will arguably result in anticompetitive behavior through the exchange of competitively sensitive information between and among competitors. The exchange of such information between and among market competitors as called for in the regulation was not contemplated by AB 1879 or SB 509. The draft regulation requires such activity by posting Preliminary and Final AA submissions (full or redacted) on the Department's website (Section 69501.6(b)(4)&(5)); posting on its website of every replacement product notice (Section 69501.6(b)(1)); and *de minimis* notifications posted on its website (69501.6(a)(5(D)(1)&(10)). Significantly, if the Department does not accept a claim for trade secret protection under Section 69510.1(c) the entire AA may be posted on its website - the AA will include sensitive information about economic viability, the alternative identification and selection process, and ultimate determinations for how the company will address any regulatory responses. Because the authorizing legislation does not clearly articulate a state policy to impede or impair the competitive process in the manufacture, supply or distribution of Priority Products, any conduct proposed by the draft regulation which has the effect of impeding or impairing such competition would expose industry participants to liability under applicable federal antitrust laws. Therefore, for these reasons, the draft regulations should be amended to expressly make clear that any information provided which is designated "Trade Secret" will not be included on the Department's website, and that such information provided will not be accessible under applicable freedom of information requests except as provided in statute.

## PUBLIC PARTICIPATION & TRANSPARENCY

To promote clarity and certainty, GCA urges the Department to ensure that the draft regulation provides opportunities for robust public participation opportunities. The regulation should also allow for petitions to remove chemicals and products from the prioritization and assessment process. It is critical that the Department address all substantive public comments following each opportunity for public review.

# # #

**Guide to GCA Detailed Comments**

**Draft Safer Consumer Products Regulation**
**(October 31, 2011)**

## ARTICLE 1 – GENERAL

Section 69501. Purpose and Applicability
Section 69501.2. Definitions
Section 69501.3. Duty to Comply and Consequences of Non-Compliance
Section 69501.4. Information Submission and Retention Requirements
Section 69501.5. Chemical and Product Information
Section 69501.6. Availability of Information on the Department's Website

## ARTICLE 2 – CHEMICALS OF CONCERN IDENTIFICATION PROCESS

## ARTICLE 3 – CHEMICALS OF CONCERN & CONSUMER PRODUCT PRIOIRITZATION PROCESS

Section 69503.1. Applicability
Section 69503.2. Priority Product Prioritization
Section 69503.4. *De Minimis* Exemption
Section 69503.4. (b)(1) and (b)(2) Cumulative Concentration for *De Minimis*

## ARTICLE 5. ALTERNATIVES ASSESSMENTS

Section 69505. Guidance Materials

- Alternative Assessment (AA) in the Research and Development Paradigm
- Positive Aspects of the Alternatives Assessment Portion of the Draft Regulation
- Challenges and Opportunities for Improvement
- Timeframes
- SCOPE of AA process – Stage 1, Stage 2, and Consortia/Anti-Trust
  Stage 1 AA – Showstoppers
  Stage 2 AA: Focus on Designated Chemical of Concern and Alternatives
  Stage 2 AA: Relevant Factors
  Stage 2 AA: Focus on Designated Chemical of Concern and Alternatives
  Stage 2 AA: Technological & Economic Feasibility of Alternatives
  Stage 2 AA: Externalized Costs
- Consortia/Anti-Trust

Section 69505.5. Alternatives Assessment Reports

- Focus on Designated Chemical of Concern and Alternatives
- Compliance with Law
- Focus on Designated Chemical of Concern and Alternatives
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**ARTICLE 6. REGULATORY RESPONSES**

Section 69506. Applicability
Section 69506.1. AA Report Supplemental Report Requirements
Section 69506.2. No Additional Regulatory Response Required
Section 69506.3. Product Information for Consumers
Section 69506.4. End-of-Life Management Requirements
Section 69506.5. Product Sales Prohibition
Section 69506.6. Other Regulatory Responses
Section 69506.7. Exemption from Regulatory Response Requirements
Section 69506.8. Regulatory Response Determination Process

**ARTICLE 7. DISPUTE RESOLUTION PROCESSES**

**ARTICLE 8. ACCREDITATION BODIES AND CERTIFIED ASSESSORS**

Section 69508. Qualification and Certification of Assessors
Section 69508.1. Qualifications for Accreditation Bodies

**ARTICLE 9. AUDITS**

**ARTICLE 10. TRADE SECRET PROTECTION**

Introduction
Section 69510. Assertion of a Claim of Trade Secret Protection.
Section 69510.1. Department Review of Trade Secrecy Claims.

# # #

## ARTICLE 1 – GENERAL

### Section 69501. Purpose and Applicability

**Regulatory Duplication:** The applicability of the regulations is overly broad. As written, these regulations enable the Department to regulate almost any product for any use. At best, this is potentially redundant with medical device, food and drug, and occupational health and safety rules, but could possibly create conflicts with devices or products that are regulated under other authorities, including the California Air Resources Board (CARB). Under the draft regulation, regulatory duplication provisions of the statute apply and products will be excluded from the program if the Department determines that the product is regulated such that, in combination, the regulation:

- Addresses the **same** adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed; and
- Provides a level of public health and environmental protection that is **equivalent to or greater than** the protection that would potentially be provided if the product were listed as a Priority Product.

GCA supports the first criterion and believes that it should be the sole factor in determining regulatory duplication. The second criterion was not intended by the legislature, it is not authorized by the statute, nor is it necessary. The second criterion is an example of regulatory overreach, suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. The statute under Health & Safety Code §25257.1(b) and (c) is clear on the matter, with two applicable provisions:

- ***This article does not authorize the department to supersede the regulatory authority of any other department or agency.***
- ***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.***

Regulatory duplication for any product should be a straightforward question – is the potential health or environmental impact from the chemical in the product regulated by another agency or not? Where that is the case, by definition inclusion of the product in these regulations by the Department would be regulatory duplication, which is prohibited by the statute. This is not a question of the breadth or sufficiency of regulation, which the second criterion appears to address.

The consideration of duplicating and/or conflicting regulations should be done at the ~~"a~~pplicability" stage of the regulation – not merely in the ~~"r~~egulatory response" section following prioritization, alternatives assessment, and other requirements. Completing the listing, prioritization, analysis and regulatory response of a product and/or chemical that is already regulated is a waste of limited Department resources and fails to meet the practical standard the Department and Director are seeking.

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### Section 69501.2. Definitions

**(a)(9) "Alternative"** GCA agrees with the proposed language in §69501.2(a)(9)(B), (C), and (D), which incorporates redesign of the product and/or manufacturing process to reduce

or eliminate the concentration of CoCs, and/or the potential for adverse public health and/or environmental exposures and impacts as part of the definition of ~~a~~lternative." The underlying statute recognizes that developing safer consumer products includes incremental improvements over time which reflects current product improvement processes utilized by consumer product manufacturers. As such, GCA strongly urges the Department to retain these concepts.

**(a)(12) "Assembled Product"** The proposed definition of ~~a~~ssembled product" requires further clarification. It is unclear, for example, whether ~~h~~eterogeneous product consisting of two or more components" includes packaging, the top of a bottle or the delivery device for a formulated product. The Department should provide clarification for this point.

**(a)(14) "Bioaccumulation** In the spirit of drafting regulation that is practical, meaningful and legally defensible, the Department should make an effort to utilize definitions that are widely accepted at the federal and/or international level and that employ specific criteria. GCA is concerned that the definition for ~~B~~ioaccumulation" is a novel California definition and departs even from the proposed definition in OEHHA s Green Chemistry Hazard Traits. The conflict between OEHHA and the Department must be resolved in the next iteration of the draft regulations. In addition, the definition does not establish thresholds – values for bioaccumulations, which clearly indicate what constitutes a bioaccumulative substance.

Recently, the Society of Environmental Toxicology and Chemistry (SETAC) conducted a Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of bioaccumulation science.[1] [2] Much of this science was discussed at the May 2010 OEHHA workshop in Berkeley, California on *Indicators of Ecotoxicity Hazards and Exposure Potential*. The SETAC workshop developed the following definition for a bioaccumulative substance: ~~A~~ substance is considered bioaccumulative if it biomagnifies in food chains." Standard criteria for reporting the extent to which a chemical may bioaccumulate were noted including trophic magnification factor (TMF), biomagnification factor (BMF, both laboratory and field), bioaccumulation factor (BAF), bioconcentration factor (BCF), octanol-water partition coefficient ($K_{OW}$) and octanol-air partition coefficient ($K_{OA}$). The workgroup concluded that the most relevant bioaccumulation criterion is the trophic magnification factor (TMF; also referred to as a ~~f~~ood-web magnification factor"); in the absence of data on the TMF, the BMF (either derived in the laboratory or based on field data) is a reliable indicator. They also concluded that ~~[t]~~he BCF is no longer recognized to be a good descriptor of the biomagnification capacity of chemical substances" and ~~t~~hat the $K_{OW}$ is a highly useful chemical specific descriptor of the bioaccumulation potential of chemicals in fish and many other water breathing aquatic organisms."

In the spirit of drafting regulation that is practical, meaningful and legally defensible, the Department should make an effort to utilize definitions that are widely accepted at the federal and/or international level and that employ specific criteria. GCA is concerned that the definition for ~~P~~ersistence" and ~~B~~ioaccumulation" are novel California definitions and depart even from the proposed definitions in OEHHA s Green Chemistry Hazard Traits. The conflict

[1] Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management,* 5(4):624-637. (http://onlinelibrary.wiley.com/doi/10.1897/IEAM_2008-089.1/pdf)

[2] http://www.setac.org/sites/default/files/ExecutiveSummary.pdf

between the two departments must be resolved in the next iteration of the draft regulation. All chemicals have some degree of persistence (P) and bioaccumulation (B) potential, but P and B as determined by other global regulatory bodies have thresholds for declaring chemicals as such.

***Recommendation:***
*The SCP regulations should use a similar definition of bioaccumulation and accommodate these five criteria (TMF, BMF, BAF, $K_{OW}$, and $K_{OA}$) as an appropriate means of measuring bioaccumulation potential. In addition, the regulations should establish thresholds for what constitutes a bioaccumulative chemical using each of the criteria consistent with the scientific consensus of the Pellston workshop (TMF > 1, BMF >1, BAF > 5,000, Log $K_{OW}$ > 4, Log $K_{OA}$ > 5) and in a tiered order of preference (TMF > BMF > BAF > $K_{OW}$ or $K_{OA}$).*

**(a)(17) Chemical ingredient** A chemical ingredient is assumed to serve a function in the final product. However, as currently written in the draft regulations, contaminants could be considered as a ~~c~~hemical ingredient".

***Recommendation:***
*"Chemical ingredient" means a chemical* ***that serves an intended function*** *in a consumer product.*

**(a)(28) "Economic Interest"** GCA disagrees with the extremely low threshold set for the definition of ~~e~~conomic interests." The Department should consider the practicality of the proposed low threshold for direct and indirect investments, valued at $2,000 or more. The standard of a $2,000 interest, set forth in §18703.1 of Title 2 of the California Code of Regulations, is intended for application to the interests of government officials, those who have a fiduciary duty to the citizens of the State. The level of sensitivity for government officials is not relevant in this case. The Department only needs to assure that an accrediting body does not have a material economic interest in certifying alternatives assessment assessors.

***Recommendation:*** *Revise §69501.2(a)(28) to read:*
*Economic interest in an entity means that an individual, or that an individual~~'~~s spouse or dependent child:*
*(A) Has a direct or indirect investment or* ***controlling interest*** *worth* ***twenty-five thousand ($25,000)*** *or more in the* ***responsible*** *entity…*[3]

**(a)(38) "Functionally Acceptable"** GCA agrees with the proposed definition of ~~f~~unctionally acceptable." The functionality of an alternative chemical formulation for the Priority Product, or an alternative product, is crucial to finding safer alternatives that have the potential to gain consumer acceptance and thus a sustained presence in the market.

[3] Green Chemistry Alliance, Safer Consumer Product Alternatives Proposed Regulations – Post-Hearing Changes, R-2010-05 November 16, 2010 Comments, December 3, 2010, p.13.

**(a)(40) "Hazard trait"** This definition lacks clarity in that it does not actually define what a hazard trait is, but states in a circular fashion that hazard traits are types of hazards. Hazards are, in the context of chemicals, inherent properties that have the potential to lead to adverse effects in humans or wildlife under particular conditions and levels of exposure. In the context of the present regulation, they are toxicities. The definition should be amended accordingly.

**(a)(40 Bis) "Hazard Trait Evidence"_____**The proposed OEHHA Hazard Trait Regulation draws a very important distinction in the strength of scientific evidence linking particular hazard traits to particular chemicals. Their regulation consistently, for each identified hazard trait, distinguishes between ~~"~~**strong evidence"** linking the trait and the chemical, versus ~~"~~**suggestive evidence"**. For each trait, the specific scientific considerations that would lead to a determination of ~~"~~strong" or ~~"~~suggestive" are articulated in order to allow the Department, industry and the general public to understand the foundation for that determination.

***Recommendation:***
*(40 bis) "Hazard trait evidence" means the strength of evidence (either "strong" or "suggestive") that a chemical in question exhibits a given hazard trait, as defined separately for each hazard trait by the OEHHA, pursuant to Health and Safety Code section 25256.1, and specified in chapter 54.*

**(a)(45) Legal requirements** Legal requirements as defined in the current version of the draft regulations should not be limited to the consumer product but should also encompass chemicals used in those consumer products. For example, some chemicals must meet VOC requirements.

***Recommendation:***
*"Legal requirements" means specifications and/or performance standards that* ***a chemical or*** *a product including its packaging is required to meet by federal or Californi*

**(a)(55) "Persistence"** The definition should not include inorganic elements of substances as they, by their very nature, will not be transformed in the environment. In addition, the definition should include thresholds specific to particular environmental media which clearly indicate what constitutes a persistent substance. Revise the definition to read as follows: ~~"~~means the propensity for an organic chemical substance to exist in an environmental medium (e.g., water, soil, sediment, air) in an unchanged form. The thresholds for a substance should be based on national and internationally agreed levels which are as follows: a half-life of greater than 60 days in water (marine or freshwater), greater than 180 days in soil or sediment, or greater than 2 days in air."

**(a)(66) "Reliable Information"** While there are some helpful improvements to this definition, the fundamental problem has not been addressed or resolved. The revised definition identifies a wide variety of sources of scientific information and makes a *de facto* determination that they are ~~"~~reliable". All of the sources mentioned are certainly appropriate for consideration in making decisions. Some include deliberative scientific

processes that actually review the information in studies and judge weight-of-evidence and other factors, e.g. National Academies and reports from government agencies. Such cases can be considered reliable. However, defining everything from every other source as *de facto* ~~r~~eliable" is scientifically bankrupt and has the potential to drive controversy into a program that is intended to be science-based. In particular, (C) ~~P~~ublished in scientifically peer reviewed reports or other literature" is problematic. First, ~~o~~ther literature" is open-ended and could include all manner of unreliable information. Second, it is well established that individual published peer-reviewed studies can be unreliable.

This problem is carried through to a new definition (67) ~~R~~eliable information demonstrating the occurrence or potential occurrence of exposures to a chemicals", which includes a variety of sources of exposure information, but again includes a *de facto* determination of the sources as reliable, independent of the actual reliability of any specific studies.

What would the Department do in a case where there are four peer-reviewed studies that provide entirely different results, or four studies from a variety of the listed sources that come to different conclusions? By the Department's current definition they are all ~~r~~eliable information".

The need for a mechanism to judge studies for reliability is widely recognized by federal agencies with health and safety responsibility and in international fora. 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 has been used for determining data quality and reliability on tens of thousands of studies for over 2000 chemicals in US and OECD HPV programs. Hundreds of thousands of studies on over 5000 chemicals have been submitted to REACh and were rated according to this approach. The same is to occur for additional thousands of chemicals in future years. The methodology is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies.[4]

GCA urges the Department to provide separate definitions for ~~I~~nformation Sources" to include the diverse sources listed in (66) and (67) and then to determine reliability by subjecting those studies to this definition for ~~R~~eliable Information" based on the OECD Manual:

> ***Recommendation:***
> *"Reliable information" is information 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*

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

*of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies.*[5]

**(a)(68) "Responsible Entity"** Regarding ~~"R~~Responsible Entity," GCA suggests that the Department adopt a definition of ~~"m~~anufacturer" that is consistent with the Federal Fair Packaging and Labeling Act (FPLA; 15 U.S.C. §§1451-1461). For products manufactured in a foreign country and imported into the U.S., FPLA requires that the entity that receives the product shipment in the U.S. must assure that the product carries U.S.-compliant labeling that identifies the entity for which the product is ~~"m~~anufactured for" or ~~"d~~istributed by." It is practical for the Department to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the duty to comply to a foreign manufacturer or retailer.

The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the FPLA recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (CARB, CPSC, etc.). All consumer commodities that are legally distributed in U.S. commerce must comply with the Federal Trade Commission labeling requirements, so identification of the responsible entity is simple. As such, subparagraphs (B) and (C) should be eliminated.

**(a)(70) "Safer Alternative"** GCA generally agrees with the proposed definition of ~~"s~~afer alternative," which requires the comparison of the existing Priority Product to the alternative. Further, we agree with the recognition of a risk-based approach to the definition of ~~"s~~afer alternative." However, GCA believes the definition should be modified slightly as follows:

***Recommendation:***
*"Safer alternative" means an alternative that, in comparison with the existing Priority Product, is determined by the Alternatives Assessment to reduce potential adverse public health and environmental impacts.*

**(a)(72) "Sensitive Subpopulations"** The definition of ~~"s~~ensitive subpopulations" is too broad and may present significant issues of compliance for responsible entities depending on how this term is interpreted. There is likely broad agreement that infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness should be included within the definition. However, the use of the phrase ~~"i~~ncluding, but not limited to…" inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of ~~"s~~ensitive subpopulations" in ways that the regulated community cannot anticipate. Has the Department identified what proportion of the population might be considered sensitive? If the entire population is sensitive, none of it is. The Department should carefully review the draft regulation for such instances of open-ended language in this and other sections, giving careful

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

consideration to the inability of product manufacturers, importers, and retailers to comply with such vague regulatory language that could give rise to shifting interpretation over time.

**(a)(74) "Technologically and economically feasible alternative"** GCA agrees with one of the three proposed criteria for defining a ~~t~~echnologically and economically feasible alternative," i.e., ~~(~~A) The current technological knowledge, equipment, materials and other resources available to the manufacturer are sufficient to develop and implement the alternative. The criterion in §69501.2(a)(74)(B) appears to require the Department to determine (or to judge the appropriateness of the responsible entity's analysis of) the return-on-investment between the Priority Product and the alternative. A manufacturer's ~~r~~easonable rate of return, over a reasonable period of time" is trade secret information, will be impossible to determine objectively, and should not be put at risk of public disclosure by means of submission to the Department. In practical terms, if the manufacturer chooses an alternative it is because it was determined that the return-on-investment is adequate.

Nevertheless, a review of the appropriateness of investment returns is beyond the scope of the statute. It is a concept rooted in rate regulation for monopoly utilities where returns are statutorily guaranteed. As for §69501.2(a)(74)(C), assessment of such external costs is beyond the scope of the statute and is potentially so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Even if such an analysis were countenanced, there is no integrated and widely accepted methodology for producing meaningful results cost-effectively and quickly. This would simply add further cost, opportunity for ambiguity and disagreement and delay to an already complex process. Consequently, both of the foregoing paragraphs should be dropped as criteria. Economic feasibility should be addressed normally, looking at capital and operating costs.

**Section 69501.3. Duty to Comply and Consequences of Non-Compliance**

Section 69501.3 of the draft regulation identifies manufacturers as the primary responsible entity, followed by the importer, if one exists and the manufacturer does not comply, followed by the retailer, if the manufacturer and the importer do not comply. As mentioned previously in the Definitions section, the Department should use the provisions of the federal FPLA, which mandates there be a single responsible entity in lieu of the current ~~r~~esponsible entity" construct in the draft regulation. This would provide uniformity with the application by other regulatory agencies (e.g., Federal Trade Commission, the Food & Drug Administration, the Consumer Product Safety Commission, and the California Air Resources Board). All consumer commodities that are legally distributed in U.S. commerce must comply with FPLA labeling requirements.

GCA agrees with the proposed manufacturer or importer off-ramp, §69501.3(b)(1), which ensures that manufacturers or importers will not be held responsible for compliance if they provide notice to the Department that demonstrates that the product-chemical combination is no longer placed into the stream of commerce in California. However, the Department is proposing

to require that the notice include ~~i~~identification and location of the manufacturer~~s~~ or the importer~~s~~, if applicable, retail sales outlets where the manufacturer or importer sold, supplied or offered for sale the product in California" (§69501.3(b)(1)(C)). The value chain on either end of the product manufacturer may be long and complex. For example, there are many transporters, distributors, and retails outlets between the raw material suppliers and the product manufacturers, as well as between the product manufacturers and the end retailer(s). The Department must grant flexibility in this area to reflect the complex nature of today~~s~~ global marketplace.

It is unclear whether the term ~~r~~eplacement product" found in §69501.3(b)(3), refers to an alternative. If so, it we suggest using the term ~~a~~lternative," rather than ~~r~~eplacement product," which is not defined. The reference to ~~a~~ product that replaces" in §69501.3(b)(2) is not clear in this regard.

**Section 69501.4. Information Submission and Retention Requirements**

GCA is troubled by the proposed requirement to have all information submitted to the Department signed and certified by not only the responsible individual in charge, but also by the owner or an officer of the company, or an authorized representative (§69501.4(a)). GCA agrees that this is likely to draw the attention of upper management, but it is unreasonable and unnecessary, as the Department proposes to review each submission, from *De Minimis* Exemption Notifications to Final Alternatives Assessment (AA) Reports. It seems particularly superfluous in the situation where an AA is conducted by a third party, such that, in theory, the company was not involved in the AA itself, and the executive would be forced to inappropriately certify as to the technical accuracy of the third party's work product.

GCA suggests the Department edit §69501.4(c), striking "person," and replacing it with ~~r~~esponsible entity." The idea that someone beyond the set of responsible entities (and their authorized representatives) would be able to answer on behalf of responsible entities is not acceptable.

**Section 69501.5. Chemical and Product Information**

Section 69501.5 of the draft regulation outlines the ways in which the Department may collect information ~~t~~hat it determines is necessary" on both chemicals and products, and GCA largely agrees with the proposal. The proposal for information collection is outlined in four steps, which GCA believes should be a sequential, tiered process. GCA agrees that the Department should begin its information collection by reviewing information in the public domain that is readily available in a useable format, as laid out in §69501.5(1), followed by reviewing information in the public domain that is available by subscription, and then by requesting data from chemical manufacturers or importers. However, GCA finds use of the term ~~n~~ecessary" in Step Four, as proposed, even as a final tier, particularly troubling.

Step Four should be used as the option of last resort if and only if, information in the public domain is wholly insufficient for making a determination about prioritization or the evaluation of an alternative. Requiring large amounts of new testing has the potential to significantly delay the process, which is contrary to the Department's stated desires, and also puts responsible entities

and their products in a regulatory limbo until the testing is complete. Does "necessary" mean for example, "necessary to conduct an alternatives assessment," or ~~n~~necessary to fill a blank in the Toxics Information Clearinghouse?" The Department should better define the conditions under which information will be deemed necessary, and allow stakeholder input on them.

The last provision of §69501.5(c) describes the process by which the responsible entity, chemical manufacturer or importer may find itself on the Failure to Respond List. The responsible party in this case must demonstrate to the Department's ~~s~~atisfaction that it does not have and is unable to produce the requested information" or, the Department may post the responsible party s identifying information on the web site. However, it is unclear how a responsible entity, chemical manufacturer or importer may demonstrate to the Department s satisfaction that it is not able to produce the requested information. What is the objective standard of proof? The Department should provide further clarity.

**Section 69501.6. Availability of Information on the Department's Website**

It is apparent that the Department is proposing to provide an unprecedented level of information about products, chemicals, and manufacturers' business plans to the public, public interest groups, competitors, and retailers. Overall, GCA is concerned that the Department will not have adequate staff resources to properly process, adjudicate, and manage the volume of information that will be reported under the existing draft. The Department should also be mindful how the various forms of information are communicated to the public, notably GCA recommends that the Department exercise a concerted and purposeful effort not to create undue anxiety regarding the chemicals on the initial list. We also suggest striking §69501.6 (a)(7), as it is redundant with §69501.6(a)(5)(D)2.b.

## ARTICLE 2. CHEMICALS OF CONCERN IDENTIFICATION PROCESS

***Section 69502.1. Applicability.***

The criteria specified by OEHHA as constituting ~~s~~trong evidence" are those that typically provide the most direct indications that a hazard trait (or endpoint) is, indeed, linked to or operative with a specific chemical in a causal way or with a strong preponderance of the weight of the evidence. ~~S~~uggestive evidence", on the other hand, is typically used to describe positive but not definitive evidence of such relationships. Many of the tools or mechanisms listed as ~~s~~uggestive" are screening tools utilized to target follow-up analysis that can establish more definitively whether the specific trait is, in fact, manifest. It is simply not appropriate to trigger such far-reaching consequences on the basis of admittedly less-than-conclusive information. Additionally, OEHHA has devoted a great deal of attention and effort to providing the foundation for these judgments. Failure to recognize the significance of this distinction confounds the notion of OEHHA guidance integrated into AB 1879.

> ***Recommendation:***
> ***§69502.1. Applicability.***
> *This article applies to all chemicals that exhibit strong hazard trait evidence for a hazard trait or an environmental or toxicological endpoint, and that may be present in products placed into the stream of commerce in California.*

**Section 69502.2. Chemicals of Concern Identification**

As currently drafted, the draft regulation proposes to proclaim more than 4,000 substances as chemicals of concern (CoC) at the effective date of the Regulation. The chemicals of concern would be derived from 22 diverse lists. Contrary to the overall direction for developing these regulations, GCA believes this approach is not practical, meaningful or legally defensible. There are several major concerns with this approach:

- The statute requires that the Department establish a process to prioritize chemicals of concern. The proposed approach provides no prioritization process whatsoever, and thus is not legally defensible.
- Lists are developed for varied purposes. Merging them with no prioritization for the Department's specific purpose results in the identification of items that are not meaningful and have no place on a chemical of concern list—oxygen, nitrogen, iron, aluminum, silver, exotic species, contraceptives, marijuana smoke, viruses, salted fish, wood dust, sediment, and others. Each of these items is relevant to the purpose of the contributing list, but irrelevant to the SCP regulation.
- While listing over 4,000 chemicals may give the appearance of providing expansive public protection, in fact it creates a meaningless, untargeted and low-resolution concoction. The merged list would include over 450 pesticides plus scores of pharmaceuticals that are specifically exempted by the statute. More than 50% of the substances are not even on the TSCA inventory making them illegal in U.S. commerce[6]; 80% were not reported as manufactured or imported into the U.S. as part of EPA's most recent update; and 90% are not used in consumer products.
- The establishment of a non-credible list of more than 4,000 substances will become irrelevant and will do little to motivate broad-based action by manufacturers. It is so overwhelming that it will have the opposite effect—more likely, all product manufacturers and retailers except those involved in selected Priority Product/Chemical of Concern pairs will ignore it. The massive haystack created here hides the important needles that should be the real focus of this program.

Actual prioritization of CoCs gives credibility to the process. In the long term it will conserve the Department's and the regulated community's resources; and it is mandated by the statute. The timeframe to undertake such a process could be completed in a timely way (within 90 days of the publication of the regulation) and thus avoid any delay in implementing the regulation.

The Department should:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes with the opportunity for stakeholder input and comment (specific recommendations below);
- Merge those lists to generate a set of ~~c~~andidate chemicals of concern";

[6] Not all chemicals have to be included on the TSCA inventory: chemicals which are used in pesticides and in FDA-regulated products do not have to be registered under TSCA, however most are. This includes some pesticide and cosmetic ingredients, pharmaceuticals, and food ingredients.

- Conduct an actual prioritization/screening to identify real Chemicals of Concern. This would encompass several steps:
    1. Clean up the merged lists—remove pesticides, pharmaceuticals, and other substances that are not chemical compounds to which the regulations apply.
    2. Narrow the result from above to identify chemicals made or imported into the U.S. using EPA, FDA and other exposure information such as biomonitoring data;
    3. Further narrow the result to chemicals used in consumer products in the U.S. using EPA, FDA and other information;
    4. Publish the proposed Chemical of Concern list for comment.
    5. Finalize the list.

Furthermore, this approach has several benefits: it can be done quickly without diverting the Department's other efforts to implement the regulation; it produces a large list of candidate chemicals that can serve as a broader marketplace signal, any one of which can readily be moved to a chemical of concern if it is placed into consumer products; it produces a narrowed and targeted list of chemicals of concern not just to support the Department's further work, but that will be more likely to prompt action in the marketplace beyond just its selected Chemicals of Concern/Priority Products; it will more likely have influence in other states and at the federal level, in contrast to the existing draft approach which will have no impact.

As noted above, a variety of source lists are appropriate and will be useful as a starting point in a true prioritization process. While many of the source lists identified by the Department represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment, a number do not, particularly the two OSPAR lists and Grandjean, which should be dropped. In addition, some lists are selected based on exposure such as the CDC list. GCA believes that lists should be those that are developed to identify chemicals with significant hazards and use the exposure sources in the prioritization process. See Appendix A attached. Ultimately the Department must prioritize the various lists and provide the rationale for the inclusion/exclusion of a chemical.

There are additional sources that the Department has not included that GCA supports.

***Recommendation:***

- ***Use*** *the CDC Biomonitoring list as an exposure source in identifying priority products.*
- ***Use*** *the Stockholm POPs list for PBTs, which has been developed through extensive global discussion and consensus.*[7]
- ***Use*** *the REACh XIV Authorization list representing chemicals selected for risk management under REACh should be considered for inclusion, but not the "candidate" XV list. Although the XIV Authorization list does not represent a "completed" list, since identification is still ongoing, the Department would pick up all chemicals on which decisions had been made at the effective date of the regulation.*[8]
- ***Do not use*** *the Grandjean, OSPAR Possible Concern and OSPAR Priority lists.*

[7] http://chm.pops.int/Convention/ThePOPs/tabid/673/Default.aspx

[8] http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp

If the referencing of lists is maintained, where such designation is to be based upon inclusion of the chemical on a specified ~~li~~list", the Department should make that incorporation as legally defensible as possible take the added step of investigating that specific list and coming to a judgment that the linkage of a specific chemical to a specific hazard trait on that list is, in fact, based upon ~~s~~strong evidence" as defined by OEHHA for that trait.

> ***Recommendation:***
> *(a)(1) The chemical is identified as exhibiting a hazard trait on one or more of the following lists, and such identification is based upon strong hazard trait evidence:*

These criteria should, of course, carry forward to provide a stronger legal foundation in any subsequent determination of additional ~~C~~hemicals of Concern."

> ***Recommendation:***
> *(b)Additions to the Chemicals of Concern List. In addition to the chemicals identified as Chemicals of Concern pursuant to subsection (a), the Department may identify chemicals, that exhibit strong hazard trait evidence of one or more hazard traits or environmental or toxicological endpoints, as Chemicals of Concern by considering the following factors for which information is available:*
> *(c) Where a specific chemical listing per the above is uncertain as to whether such listing was based upon strong hazard trait evidence, the Department shall withhold such listing until it has investigated and made a determination to that effect.*

In §69502.2(b)(4) the Department appears to be attempting to streamline the availability of ~~s~~afer alternative chemical[s]" and product prioritization. First of all, it is not obvious to GCA how the Department will determine that a chemical is a ~~r~~eadily available safer alternative chemical that is functionally acceptable" for any application. Presumably, this refers to some hazard trait the Department deems important. However, the section does not address situations where there are other traits for which the alternatives are no better and possibly worse for potential toxicity or environmental hazards. The central question is evaluation of multivariate data. This seems to be the purpose of the alternatives assessment, which comes later in the process.

Further, the ~~s~~afer alternative" provision does not account for the possibility that an ~~a~~lternative" may include ~~r~~eformulation or redesign of the product and/or manufacturing process to reduce or eliminate the concentration of the Chemical(s) of Concern in the Priority Product…" and/or, ~~r~~edesign of the product and/or manufacturing process, using different materials to reduce the potential for…exposures…" (§69501.2(9)(B) – (C)). In this way the draft is internally inconsistent. Finally, the fact that the Department could adjust prioritization merely by ~~c~~onsidering" is not appropriate. For all of the reasons listed in this paragraph, §69502.2(b)(4) should either be rewritten to be consistent with the definition of ~~s~~afer alternative" or struck.

## ARTICLE 3. CHEMICALS OF CONCERN & CONSUMER PRODUCT PRIORITIZATION PROCESS

Many GCA coalition members supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of Department scientists. However, the proposed scope of the draft regulation fails to provide clarity to industry as to what products the Department intends

to be subject to the regulation and reserves inappropriately broad authority for it to select winners and losers in the market.
In this regard, GCA and its coalition members largely support GMA's recommended prioritization process that would require the Department to make quantitative comparisons of hazard and exposure in setting priorities and to focus on those situations with the greatest potential for harm. The Department must employ a rigorous scientific process for selecting chemical of concern/priority product pairs. Instead, a "Narrative Standard" is envisioned by the Department that would allow for a chemical-product combination du jour to be the focus of the regulation rather than a combination that poses the greatest potential for harm. This is not the intent of the enacting statutes or that of the Legislature in passing the measures.

**Section 69503.1. Applicability**

When determining applicability for products that are already regulated by one or more federal or state agencies, exclusion must be provided when another regulation addresses the same risk of injury or environmental threat that has resulted in the Department prioritizing a chemical or product. In many cases conflicting regulations at the state level will be preempted by federal requirements, and attempting to regulate a product when the same risk of injury or environmental threat already has been addressed is a waste of resources. Similarly, when a CoC is necessary to comply with another regulation or statute, this needs to be exempted from the requirements of the law.

The applicability section should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Per the comments above, reasonable and foreseeable exposure through normal use and abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. The U.S. Consumer Product Safety Commission (CPSC), in August 2009, once again endorsed the reasonable and foreseeable exposure criterion in regulation as it relates to the "Children's Products Containing Lead; Interpretative Regulations on Inaccessible Component Parts" (16 CFR Part 1500).

**Section 69503.2. Priority Products Prioritization**

Additionally, once a priority product has been designated it is essential that the listing of these products be accompanied by a concurrent listing of the CoC that triggered the designation as a priority product. The regulation should be clarified to address this issue more directly.

The factors in (a) are very broad-based and important, however, the focus in the exposure criteria seems to be on "presence', "contact' and "occurrence', which are not the same as reasonable and foreseeable exposure. This suggests an entirely qualitative evaluation, which could result in opinions and emotion driving the process, potentially resulting in arbitrary decisions rather than a deliberative scientific effort to identify high priorities—i.e., real and significant threats to public health and the environment. Qualitative information, while directionally helpful in indicating the existence of occurrence, contact or presence, cannot be used in determining whether a situation presents an exposure with the potential for adverse impacts. Presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern must be a primary driving factor in priority setting decisions. The one provision that mitigates this concern is the criterion: "There is significant potential for public

and environmental exposures to the CoC in the product in quantities that can result in adverse public health or environmental impacts". This is similar to the language in previous iterations of the proposed regulations, and GCA strongly supports maintaining this provision in the Regulation.

(a)(1)(B)4.d. of this article deals with exposure factors for use and end-of-life scenarios. Frequency and duration of exposure are mentioned, but ~~l~~level" of exposure is not. This is an important oversight. Exposure science is clear that all three factors must be considered together in determining the potential for adverse impact. Low frequency and low duration exposures can be dangerous if the level of exposure is sufficiently high. On the other hand, high frequency and high duration exposures can be safe if the level of exposure is sufficiently low.

***Recommendation:***
*GCA strongly encourages inclusion of "level" of exposure in this provision.*

The Department does not have regulatory authority under this statute over workplace exposures to CoCs; especially if those exposures occur beyond California's boundaries. Workplace exposures are the jurisdiction of U.S. OSHA and Cal OSHA. Thus these ~~m~~manufacturing" exposure considerations should be removed from this Section.

GCA supports the Department's approach to identify Key Prioritization Criteria in (b) of this article; however, the criteria are employed as an afterthought in the process, and only ~~r~~eviewed for consistency" in (c).

***Recommendation:***
*The "Key Prioritization Criteria" should be applied as the critical prioritization process step after evaluations in (a) have occurred to determine whether a product/chemical combination is a high priority. If they are not used for the critical prioritization step, then product prioritization becomes an entirely arbitrary process.*

The first three Key Prioritization criteria are well stated and appropriate, addressing whether:

- There is wide distribution of the product in commerce and use by consumers;
- The CoC in the product has significant potential to cause adverse public health and environmental impacts; and
- There is significant potential for exposures to the CoC in product in quantities that can result in adverse public health or environmental impacts.

GCA's concern lies in the fact that the draft provides that the Department ~~…~~.shall give priority to products meeting one or more" of these criteria. No products meeting just one or two of these criteria should be prioritized as high priority. All three criteria should be met to include a product/CoC combination as a high priority. The statute is directed at consumer products and requires the Department to base decisions on both hazard and the potential for exposure. If a product is intended for consumers AND made with a CoC that has significant potential for adverse impact AND has significant potential for exposure in quantities that can result in adverse impacts, it should be considered as a high priority. If it only meets one or two of these Key Factors, it should not be a high priority.

There are two Key Prioritization criteria, (4) and (5) which seem to address exposure pathways and need some restatement to properly fit in this article. For both assembled and formulated

products, given the extensive and diverse universe of consumer products, potential exposure should always start with considering 4 pathways—oral, dermal, inhalation and releases to the environment. On item (4), addressing assembled products, the oral route should be included, for example to address mouthing behavior by small children. In addition, releases to the environment should be stated as an exposure pathway, for example to identify copper releases from brake pad linings. On (5), addressing formulated products, the inclusion of (A), (B), and (C) seems to be product oriented, instead of exposure pathway focused and would appear to artificially limit the types of products that the department can consider—by so doing, it could in essence exempt products from consideration. For example there are a host of consumer products that contain complex mixtures of hydrocarbons and other compounds which are formulated but aren't intended to be applied to the body, dispersed as an aerosol or vapor or applied to hard surfaces and thus would appear to be exempted by this construction. In addition, printing and other chemicals that have the potential to fragment from surfaces and form dust particles would be similarly unintentionally exempted. The Department should refrain from describing product related processes that are unique to the nature of each product and instead generically focus on the four standard exposure pathways. Formulated products can be packaged in a variety of ways and delivered in many forms—gas, liquid, foam, gel, powder, granule and solid.

***Recommendation:***

*(4) and (5) should be combined and re-written to parallel (4) by dropping (A) – (C) and stating: "For assembled and formulated products, the product contains one or more Chemicals of Concern that may present potential exposure(s) through inhalation, oral or dermal contact or released to the environment in quantities that can result in adverse public health or environmental impact."*

Finally, the Draft regulations have abandoned any focus on intentional ingredients, those chemicals purposefully included in a product to perform a function. GCA has maintained that the program will be most successful with such a focus. A focus on chasing unintentional trace levels will significantly diminish the public health and environmental benefits of the program. The Department does make its intent clear in presentations, identifying example priority products with chemicals of concern that are intentionally added to perform a function in the final product. Products that contain CoC should not be designated as Priority Products if such CoC are present because of typical low-level impurities in raw materials that do not present concerns for product safety and that while controlled, are not economically feasible to remove. Further, a focus on chasing unintentional trace levels could create a disincentive to using recycled feedstock in the manufacturing process, will be counter-productive to recycling programs and will hinder California's ability to achieve its ambitious new 75 percent recovery goal. Prioritization should be focused on substituting chemistries that are most likely to have the greatest potential risk to public health and the environment.

***Recommendation:***

*GCA recommends the Department consider only chemicals that have been both intentionally added and are above the de minimis level when making product prioritization decisions.*

**Section 69503.4. *De Minimis* Exemption**

GCA appreciates the Department's inclusion of the concept of *de minimis* in the regulations. However, as written, the *de minimis* exemption process described in the Informal Draft Regulation is not how *de minimis* is implemented by any other regulatory program in existence, and is not a process that is practical or useful for either industry or the Department. The intent of a *de minimis* is not to ~~s~~lide under the radar," but rather a value below which there is typically no evidence of harm.

*De minimis* provisions are standard in a variety of chemical and product safety laws. Europe's REACh chemical law applies a 0.1% *de minimis* level as a default in products. REACh's 0.1% *de minimis* applies broadly, even to so-called Substances of Very High Concern that become banned in Europe. The European cosmetic directive also includes a 0.1% *de minimis* level for over 1300 carcinogens and reproductive toxicants. This same level is also used in worker and transportation regulations in Europe and North America. GCA is adamant that California should be consistent with other national and international laws. The basis for these laws is that low, but measureable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low.

In addition, GCA supports the concept that the Department should be able to adjust the *de minimis* from the default based on sound science and reliable information. Experience in the European Classification system (EC No. 1272/2008) is that for 85% of the over 4000 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. This covers all hazard traits, including those that are applicable in the Department's most stringent provision.

The draft regulation sets a two stage *de minimis*, 0.01% for certain hazard traits and 0.1% for the rest. It also provides the Department with the authority to adjust the level. GCA and its coalition members do not agree with this direction and urge the Department to reconsider establishing the *de minimis* at 0.1% for all hazard traits and limit the application of the regulations to intentionally-added chemicals.

Additionally, as the *de minimis* relates to assembled products, the GCA urges DTSC to consider the manner in which other GCA member organizations recommend consistency with similar programs for assembled products that are in effect in other states.

Requiring manufacturers to apply for a *de minimis* exemption is counter to the spirit and intent of a *de minimis* threshold, and will distract the Department from the central goal of the program. The ~~d~~*de minimis* exemption" process in the current draft requires manufacturers to submit a significant amount of data to demonstrate that certain chemicals are not present in a product, and also requires the Department to commit resources to review this data and file a concurrence for each priority product. Forcing a responsible entity, or persons acting on their behalf, to try to prove the negative that a priority chemical is <u>not</u> present is resource intensive, and does not achieve the objective of prioritizing resources on replacing chemicals of concern with safer alternatives, which is the primary objective of the regulation.

Furthermore, as currently written, every manufacturer of a priority product, whether it uses a chemical of concern or not, will be subject to *de minimis* exemption process. Therefore, products that have been redesigned to use different technologies or materials, but perform the same task, will be subject to submitting a *de minimis* exemption. Given the burden of proof to demonstrate that chemicals are not present, any listed priority product may have to be tested for

any chemical of concern that may be present, even if the product does not use the chemical of concern or has been reformulated or redesigned.

> ***Recommendation:***
> *GCA suggests that much of §69503.4 be deleted, with a process in place for the Department to ensure compliance with the de minimis. This compliance assurance program can include manufacturers keeping records and allowing the Department to request information from the manufacturer.*

**Section 69503.4. (b)(1) and (b)(2) Cumulative Concentration for *De Minimis***

*De minimis* is a term used in many different global chemical regulations to define a cut-off limit below which further investigation or quantification is not warranted. This term is universally applied to an individual chemical not a sum of chemicals. The basis for these laws is that low, but measurable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low.

There are several concerns with the Department's approach to use a cumulative concentration for *de minimis* threshold level determination. The cumulative sum for chemicals that exhibit the same hazard trait or environmental/toxicological end point is very problematic for a *de minimis* threshold, as it is not done anywhere else in the world. Furthermore, some chemicals may have more than one hazard trait or end point so it will be difficult for both industry and Department personnel to know which chemicals need to be summed together for the threshold determination. This lack of clarity for which chemicals need to be summed together will make enforcement extremely difficult for the agency and add ambiguity for industry in determining whether or not they are in compliance. In addition, if a chemical gets reclassified or a new chemical of concern gets added to an existing priority product, then industry and Department personnel will have to re-calculate all the existing *de minimis* level summations as the grouping of chemicals subject to the threshold will change. This will add even more complexity to the agency's ability to enforce this provision of the regulation.

Another key concern to setting the *de minimis* threshold at a cumulative sum and not an individual chemical is that the Department's approach will not be consistent with current global chemical regulation *de minimis* thresholds. Having the *de minimis* threshold set at a summation of chemicals means that companies will not be able to leverage information already collected by industry and governments under current global chemical legislation. This will delay the Department's ability to quickly and efficiently implement the new regulation as both industry and the agency will be required to develop new business processes and/or software tools that are capable of calculating the summation of chemicals versus applying the threshold to a single chemical. This will divert valuable agency resources to focus on documenting that chemicals are not present in products from the primary purpose of the regulation which is to identify safer consumer products.

Finally, it is not always possible to analytically quantify all chemicals in a consumer product, especially for assembled products which may have matrix interferences, or some inorganic compounds with analytical methods only for the elements but not the full chemical compound. Therefore, having the *de minimis* threshold set at a cumulative sum of chemicals and not an individual chemical increases the complexity of quantification to a sum total as more and more chemicals may fall into the category of ~~un~~quantifiable." As the Department adds more chemicals to a priority product, the cumulative sum threshold will become more and more

difficult to quantify as the thresholds get smaller and smaller going below any ability of analytical detection limits. This uncertainty will be exacerbated in more complex assembled products and will only make the compliance demonstration and/or enforcement more difficult.
GCA acknowledges the importance of considering cumulative chemical exposures, however, we believe this should be considered during the risk assessment phase and/or regulatory actions, but it is not appropriate for a *de minimis* threshold determination, especially in the absence of appropriate technical data showing collective or synergistic action.

***Recommendation:***
*Apply de minimis threshold levels to a single chemical as is consistent with current global chemical regulatory programs.*

## ARTICLE 4. PETITION FOR INCLUSION OF A CHEMICAL OR PRODUCT IN THE IDENTIFICATION AND PRIORITIZATION PROCESSES

### § 69504.1. Technical Review of Petitions

In considering petitions for inclusion of chemicals in the prioritization process, the Department should make that incorporation as legally defensible as possible and make an early judgment that the linkage of a specific chemical to a specific hazard trait that is being asserted within the Petition, is in fact, based upon ~~-s~~trong evidence" as defined by OEHHA for that trait.

***Recommendation***
*(b)(3)(A) The chemical exhibits strong hazard trait evidence for one or more hazard traits or environmental or toxicological endpoints; and*

## ARTICLE 5. ALTERNATIVES ASSESSMENTS

### Section 69505. Guidance Materials

It would be helpful to the regulated community for the Department to be more specific on what guidance materials will be forthcoming. Guidance should focus on available methodologies for use as needed, not prescriptive requirements. Guidance materials also should undergo draft release and public comment.

### Alternative Assessment (AA) in the Research and Development Paradigm

GCA is pleased with several aspects of the alternatives assessments in the draft regulation. Foremost, we are pleased that the alternative assessment is limited to the Priority Product that contains the CoC responsible for its listing as a Priority Product. It is also apparent that the Department carefully considered the complex nature of alternatives assessments, incorporated a number of key concepts from leading product manufacturers, and allows for a necessary level of flexibility throughout the process.

The alternatives assessment process is essential for developing safe and innovative consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs, expectations, and preferences, is the ability for manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives assessment.

Alternatives assessments may be undertaken by individual chemical manufacturers and/or formulators, or by consortia (with some limitations) representing an industry segment or an entire industry. Due consideration to safety, complexity (different factors are relevant to a specific chemical/product/use combination, and must be evaluated on a case-by-case basis), effectiveness, lifecycle thinking, **consumer acceptance**, and informed decision-making (weighing trade-offs) will ensure a workable, practical, and meaningful Green Chemistry program in California. The most appropriate alternative for a particular product would be selected by the product manufacturer to ensure that it fits well within their unique business model.

A rational, structured and predictable alternatives assessment process is essential from a business perspective. The Department must not ~~"p~~ick and choose" between AAs and mandate a particular alternative but rather evaluate AAs to see that they meet the statutory requirements. A manufacturer has met their statutory obligation when an adequate AA has been completed. The Department may propose varying regulatory responses for a chemical of concern (CoC)/priority product (PP) pairing. The product improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A sensible regulatory approach for conducting an AA should:

- Ensure consumer acceptance – The alternative must provide the same or better performance and *value* to the consumer.
- Be Flexible - Each business model is different: even for similar chemicals/products, the AA outcome may be different (due to, for example, innovative processes or design features). Each manufacturer must be given the latitude to leverage existing tools and approaches to evaluate alternative ingredients/components of their products as appropriate.
- Be Modular - Although all criteria are considered in a multi-factorial evaluation matrix, the most critical parameters are identified and further evaluated for each case.
- Be Effective - An AA has to be practical and meaningful (not just paperwork) in which the change provides a significant benefit to public health or the environment.
- Incorporate Informed Decision-making – Trade-offs must be understood and considered to avoid unintended consequences.
- Allow for a gradual and measured implementation of appropriate or suitable alternatives - Adequate time is necessary to introduce a new product into the marketplace due to complex and lengthy design considerations, development of supply chains, ensuring regulatory compliance, and ensuring and verifying consumer acceptance.
- Include a feasibility check - Provide the opportunity for the reassessment of the regulatory response prior to the deadline for action, if new data or subsequent assessments uncover previously unforeseen concerns with implementing the required regulatory

compliance options, similar to the approach California's Air Resources Board (CARB) employs.

**Positive Aspects of the Alternatives Assessment Portion of the Draft Regulation**

The following highlight the positive aspects of the draft regulations in regards to Alternatives Assessment (AA) that should be kept as a part of the final regulation:

- The scope of an Alternatives Assessment is focused on a specific Priority Product that contains the Chemical of Concern serving as the basis for listing a product as priority. (§69505.3)
- Alternative Assessment is appropriately defined as ~~[~~A]n evaluation and comparison of a product and alternative products…"
- AA is required for only those priority products containing the CoC above the *de minimis* that continue to be placed into the marketplace after the priority product listing (§ 69505.1. (b)(1)).
- Inclusion of §69501.3.(a)(2) wherein the requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity. (Limitations to the use of this section are noted below. However, this does allow for some creative management of substantial portions of an AA to reduce resource costs that may prove especially beneficial to Subject Matter Experts.)
- Inclusion of the potential for an alternate AA process (69505.2).
- Flexibility allowing the manufacturer to use most appropriate methodologies, models, tools, and decision-making process to assess the CoC/PP pair alongside potential alternatives, and to make a determination of the selected alternative (within the context of the company's product position in the marketplace) and the opportunity to propose the most appropriate regulatory response (§69505.5 (n)).
- Only relevant factors need to be considered further, while allowing the manufacturer to explain why other factors are not relevant to the assessment.
- The Two Stage tiered-process envisioned by the Department is a useful approach. The Preliminary AA report submitted after Stage 1 focuses on the function the CoC serves in the PP and identifies and provides an initial comparison of potential substitutes for relevant impacts. The Final AA report submitted after Stage 2 focuses on a comparative assessment at the product level integrating all relevant factors.
- Qualitative as well as quantitative information can be provided for relevant factors. Data gaps identified in an AA are not required to be filled in submitting the Final AA report.
- Including the opportunity within the implementation plan to identify any steps necessary to ensure compliance with existing laws.
- Eliminating third-party verification requirements from the draft regulations.
- Lead assessors can be in-house company experts.
- Trade secret protections are acknowledged.
- A process to dispute the Department's decisions is described.

While some of the underlying themes within the proposed draft regulations are appropriate and appear to be consistent with the existing product development paradigm, there remain many

challenges and opportunities for improvements to help maintain focus of any required Alternatives Assessment.

**Challenges and Opportunities for Improvement**

Timeframes

The timeframe described for Alternative Assessment is unreasonable and unworkable in many cases—innovation is rarely if ever accomplished in 18 months for a single entity. For all practical purposes, the 6- and 12-month timing eliminates the potential for consortia or public-private partnership approaches to accomplishing AA work. This is unfortunate since there will clearly be cases where industry-wide efforts have been shown to be the best way to address substitution. Despite the limitations discussed below, there are clear advantages in sharing some tasks and in encouraging economic viability of some otherwise questionable substitutions.

In some cases—when alternatives to a CoC are well known and there is already widespread adoption in the priority product (e.g., nonylphenol ethoxylates in detergents)—the Draft's proposed 6- and 12-month timing, each with potential 90-day extensions for Preliminary and Final AA development may be workable for individual entities.

The Responsible Entity has six months to do a desk study for AA Stage 1, yet this entity has ONLY 12 months within AA Stage 2 to innovate one or more technically feasible and economically and functionally viable alternatives, develop a safety profile comparison of the base and alternative together with other information on other relevant factors, do market research for consumer acceptance, write the submission for the Department and get management approval to submit. Such innovation, when an alternative is not well known can require three to five years or more, often with many failed alternatives cast aside at different points in the product development process.[9]

Stage 2 lab work and innovation requires resources (i.e., people, finances, and equipment) and time (anywhere from months to years) depending on the size of the project and the complexity of the product. Once the lab research has been completed and the effect of the substitution on the product determined, the material has to be tested in processing labs to see if the new ingredient or series of ingredients can be processed. There are also requirements for compatibility and stability testing. Then, scaling up is necessary at a manufacturing plant.

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[9] For example, for a —simple" substitution in formulated products, a company at a **MINIMUM** would need two months to get scientists & engineers coordinated and in the lab; one year of research to find a material that meets safety and economic requirements, supply, etc. ; three months of process lab testing; six months for testing at the manufacturing plant (to include scheduling for an experiment since plants typically run at capacity); three months of consumer testing (note that not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). From the time one or a few materials are identified for further assessment, on the optimistic side, **AT LEAST** 26 months is necessary for R&D and this is **ONLY IF** an EPA Pre-Manufacturing Notification (PMN) is NOT required. Realistically, a responsible entity should be given 3 years, with the option to extend for another 2 years, plus an additional 1 year if a PMN is required (as the PMN work can be done with an R&D exemption).

However, in most cases, substitutions will be much more complex, and the product system may be more complex. Many substitutions will likely require multiple materials to be substituted for the one objectionable material. A good example is the replacement of phosphate in auto dishwashing (ADW) products. While some companies continue to optimize the formula on phosphate replacement in ADW over the past 25 years, the initial replacement was accomplished in three years. Phosphate replacement required 4 to 5 different chemicals depending on the formulation, in which one of the materials required a PMN (and a New Substance Notification (NSN) in Canada), and another material an NSN. (Each PMN requires 2-5 years of testing, evaluation, report writing and submission. Examples of other PMNs include: DTDMAC to DEEDMAC in liquid softener replacement, DTDMAMS to ethanol, Quat in dryer sheet softener replacement, anionic surfactant LAS replaced with HSAS in coldwater detergent.)

Meanwhile, market research for consumer acceptance is carried out – an iterative process - with relevant and realistic product/material (generated from a manufacturing plant) until consumer satisfaction is achieved with the final product. Additional special testing for specific claims or consumer tolerance in use may also extend the timeframe needed. Not only is the proposed timeframe inadequate for research and development, it may also be inadequate to effectively get a new chemical TSCA-listed under EPA's Pre-Manufacturing Notification (PMN) program.

Although the alternate AA process gives the responsible entity 30 months to submit a final report, this time is still inadequate for all the reasons mentioned above. Additionally, does the Department anticipate the work plans to cover all of the requirements of the Preliminary AA report or is the expectation to have an outline of the company's plan—the approach they plan to take, identify the major blocks of work, and timeline for submissions to the Department (including both any interim as well as final reports)? If the AA work plan has to essentially demonstrate that the tools, methodologies, etc. the company intends to use will provide similar information as the Department's stages do, the responsible entity should be given six months to submit an AA work plan (NOT 60 days) if an alternate process is chosen. Also, an extended timeframe to complete Stage 2 depending on the complexity of the product and the type of substitution is essential. Responsible entities could still however be held accountable (via a regulatory response) to pursue viable alternatives in further research and development.

Flexibility in report submission is also prudent when the responsible entity is a consortium, trade association, or public-private partnership. Anti-trust requirements in the US demand care in building such relationships making them cumbersome since communication must involve a third party for oversight and blinding of some communication. It could take three to four months to build a consortium, before any assessment is done on a chemical of concern/priority product pairing. And, most likely, the assessment for both Stage 1 and Stage 2 will take more time for a consortium to complete (than for a product manufacturer). Thus, an additional provision should be included in which a consortium is permitted to form within one year of the priority product listing prior to any AA. The oft-repeated experience of the ~~"fl~~ame retardants in circuit boards" which is ongoing after more than six years is instructive. Despite a widespread, committed level of interest and effort by the industry in this public-private partnership, there is not yet an alternative that achieves the goal.

In summary, where an alternative is not readily available, not well known or not already broadly adopted, the 6- and 12-month timings are not workable. These timeframes must be expanded to a minimum of 12 months for a Preliminary Report and 24 months for the final for individual company AA's and 18 months/30 months for consortia. A tiered approach could be utilized considering the simplicity/complexity of the product system and the substitution, the availability of alternatives, the extent of research and development needed to identify and investigate alternatives, and whether a consortium approach is being used. Higher tier approaches could require an upfront work plan and regular reports to provide the Department with updates on progress.

**SCOPE of AA process – Stage 1, Stage 2, and Consortia/Anti-Trust**

<u>Stage 1 AA – Showstoppers</u>

In terms of potential alternatives identified for the comparative assessment, it would not be practical or meaningful to require in depth assessment of the universe of ~~"p~~otential" alternatives at this initial stage. The process leading into the Preliminary Report should include an upfront

narrowing approach to reduce the identified alternatives to those that will likely result in a viable change. A very fast and easy way to winnow down the list of alternatives is to include a provision for identification of ~~s~~howstoppers" for which further evaluation is not necessary, thereby focusing limited resources on truly potential alternatives. Showstoppers would not be viable for a number of reasons, whether the alternatives are eliminated on product safety, technological feasibility, economic feasibility, and other factors (e.g., environmental footprint), etc. GCA recommends that in addition to identifying the function the CoC serves in meeting the PP requirements and how the alternatives compare, an opportunity at this stage should be provided to the manufacturer to eliminate from further consideration any alternatives they deem not workable and that show decrements for those parameters that go beyond the PP requirements specified. In addition, the hazard comparison as suggested in the Preliminary stage should serve primarily as a screening tool, focused on quickly identifying and narrowing the list of potential alternatives to viable ones taking into account other AA factors as well.

> ***Recommendation:*** Addition of the following language:
> (NEW) §69505.3.(b)(3)(C)3. *Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines is not viable based on relevant factors in § 69505.4. (a)(2) as compared to the Chemical(s) of Concern.*

Stage 2 AA: Focus on Designated Chemical of Concern and Alternatives

A single Chemical of Concern (CoC) should serve as the basis for designating a product as priority and for the Alternative Assessment process.

In the draft regulations as currently written, there is no limitation on the number of CoC that can serve as the basis for designating a given product as priority. For example, the Department can identify FIVE CoC as serving as basis to prioritize a given product. The subsequent AA would require a comparative assessment of all potential alternatives for each CoC in the priority product with no *de minimis*. The scope and breadth of the assessment could grow exponentially, ultimately leading to paralysis by analysis. To ensure a workable, pragmatic, and meaningful Green Chemistry program, the assessment should focus only on ONE CoC in the Priority Product. To avoid ~~s~~cope creep", the focus of any assessment should be restricted to the CoC that is the reason for the designation of the priority product.

Stage 2 AA: Relevant Factors

As mentioned, the AA should identify ~~r~~elevant" factors which are critical to achieving a focused and efficient AA process. The issue of relevance is confusing and somewhat arbitrary in § 69505.4 (a)(1). The use of the word ~~d~~emonstrable" inappropriately implies that even the slightest impact or change would be relevant. What would constitute a ~~d~~emonstrable contribution" to increasing or decreasing adverse impact AND a ~~d~~emonstrable difference" between alternatives?

The point of this exercise is to focus on relevant factors and set aside irrelevant ones—those that will have no significant and meaningful impact on the outcome. Thus, GCA recommends that in the same spirit of AB1879 with the goal of significantly reducing adverse impacts, ~~d~~emonstrable" should be replaced with ~~**significant**~~**significant**". Significant is an appropriate term and is used as a standard in other places in the draft regulation including the Priority Product/CoC prioritization process, *de minimis* notification requirements, the AA decision process, the Regulatory Response section, and the Accreditation Body section.

***Recommendation:***

*§69505.4. (a)(1) A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if it would constitute both:*

*(A) A ~~demonstrable~~ **significant** contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration; and*

*(B) A ~~demonstrable~~ **significant** difference between two or more of the alternatives being considered, including the Priority Product.*

Additionally, consumer acceptance is ALWAYS relevant. Although a manufacturer has the opportunity to consider consumer acceptance in the alternate AA process, this factor should be explicit among the factors listed in **§69505.4. (a)(2).**

***Recommendation:***

*(NEW) §69505.4. (a)(2)(D) Consumer Acceptance.*

Stage 2 AA: Focus on Designated Chemical of Concern and Alternatives

The scope of the alternatives assessment is broadened substantially when multimedia life cycle impacts and chemical hazards considerations are being requested not only for the CoC and its potential substitutes but also for ALL chemical ingredients known to be in the Priority Product and the alternatives. (§69505.4.(a)(2)(A))

If the AA takes on this greatly expanded focus it would seem that manufacturers would have to analyze for all 4000 CoC with no *de minimis*. This would result in a completely unnecessary waste of resources, extending the time necessary for AA completion and diverting resources from focusing on the real purpose of the AA.

To ensure that such unauthorized ~~-s~~cope creep" does not occur, it's important to maintain focus of the Alternatives Assessment on the CoC/PP pair and their potential alternatives and evaluating only substantial changes to the alternative formulation in which other CoC may have been added, or for which concentrations were increased. It is unnecessary, burdensome, and inefficient to require reporting on all chemical ingredients within the product (and/or alternative), detracting from the goal of the statute of identifying, prioritizing, and evaluating prioritized CoC that may significantly adversely impact public health/environment.

***Recommendation:***

*§69505.4. (a)(2)(A) Multimedia life cycle impacts and chemical hazards, for the chemical**(s) of concern ~~ingredients~~** known to be in the Priority Product and the alternatives being considered based on available information**…***

Stage 2 AA: Technological & Economic Feasibility of Alternatives

On the determination of the ~~-t~~echnological and economic feasibility of alternatives" (§69505.4.(a)(2)(B)3.), the draft regulations propose that the responsible entity consider only the *availability* of the ~~-f~~unctionally acceptable" alternative, *affordability*, and the *purchase price differential* to the consumer. However, these don't directly address the ~~-t~~echnological feasibility" aspect. It must include knowledge and information about other technical consequences of the use of the alternative in the product design as well as the *sufficiency* of existing technological knowledge, equipment, materials, and other resources available to the manufacturer to develop and implement the alternative.

***Recommendation:***

*§69505.4.(a)(2)(B)3. Technological and economic feasibility of each alternative. As part of a determination of whether a "technologically and economically feasible alternative" exists, the responsible entity shall consider all of the following, to the extent applicable:*

a. *The extent to which a functionally acceptable alternative is currently available in the marketplace;*
b. *The affordability of any currently available functionally acceptable alternative; ~~and~~*
c *The purchase price differential between the Priority Product and the alternative~~;~~ and*
(NEW) d. *The current technological knowledge, equipment, materials, and other resources available to the manufacturer are sufficient to develop and implement the alternative.*

Stage 2 AA: Externalized Costs

Regarding economic impacts (§69505.4.(a)(2)(C)), the implications of ~~e~~externalized" costs to government agencies, businesses, public and consumers are potentially so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Moreover, traditionally, it is the responsibility of the government and not the manufacturer to assess the regulatory and macro/micro economic impact of chemical and product alternative regulations as it is government and not industry that is responsible for making public policy decisions. More clear and concrete criteria need to be established by which the regulated entity understands what is required to satisfy this provision. As of today, there are no well-established methodologies that are able to properly assess these types of costs to enable rigorous and meaningful comparisons across all of the A-M elements. The methods are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well being of Californians or their environment. Moreover, the Department should focus on the policy and avoid interference with the free-market system, an element of which is the business choice as to how costs will be passed along to consumers.

**Consortia/Anti-Trust**

For consortia of companies, public-private partnerships and trade associations, multiple responsible entities must come together. There can be great benefits to such programs to drive innovation on common problems. However, there are potential anti-trust concerns with organizing such a group to accomplish the AA objectives as envisioned by the Department. For example, although EU's REACh allows data sharing within Substance Information Exchange Fora (SIEF), data are limited to ONLY health and environmental toxicity considerations. In contrast, the scope of the AA as described by the Department involves company decisions on alternative selections (i.e., business plans) based on a myriad of factors beyond hazard information. The Department proposes to require a number of elements in the Alternatives Assessment Report that a consortium of companies, a public-private partnership, or a trade association would not be permitted to discuss, evaluate and report on because of Federal antitrust restrictions. Among those restrictions are the communication or exchange of confidential competitive information (§69505.4(a)(2)(B)1. and 2.), discussion of prices of ingredients or products and internalized costs to businesses (§69505.4(a)(2)(B)3. and (C)), and discussion of business plans (§69505.4(c)).

In addition to these specific limiting factors, there are constraints to collaboration that come from the novelty of the suggestion. Since formula variation is the basis of market competition, the members of the consortium would be consistently asking the question, "Is this technological solution an obvious result of the AA process or is it a unique solution that should be retained by a single business entity under appropriate confidential protections?" This is significantly different from the EU SIEF experience in which data sharing may be of expensive test protocols and results but the solutions are expected to be common (non-competitive) among industry partners. At best, this will exacerbate the short time frame problem explained above, and at worst, will fracture the consortium under competitive pressures.

A simple solution to eliminate these antitrust concerns and to allow the regulations to fully benefit from the utilization of consortia and other group efforts in the AA process is to limit group activities to a hazard and exposure comparison of alternatives and eliminate §69505.4(a)(2)(B) and (C), and §69505.4(c). This will still test the more restrictive U.S. anti-trust limitations but may demonstrate a collaborative path forward. In order to fulfill the requirements of the Final AA Report, individual companies would have to meet the remaining requirements of §69505.4(a)(2)(B) and (C), and §69505.4(c). This may complicate the reporting process, but this added flexibility will permit the regulations to fully benefit from the efficiency and collected knowledge of consortia.

> ***Recommendation:***
> (NEW) §69505.4.(d). *If the responsible entity is a consortium, trade association, or public-private partnership as provided in §69501.3.(a)(2), the requirements of sections §69505.4(a)(2)(B) and (C), and §69505.4(c) do not apply. The manufacturer, importer, or retailer of a consumer product would subsequently have to meet the requirements of sections §69505.4(a)(2)(B) and (C), and §69505.4(c) in the Final AA Report as outlined in §69505.5.*

**Section 69505.5. Alternatives Assessment Reports**

GCA cautions the Department against requiring the large quantities of potentially sensitive personal and business information the draft regulations propose for inclusion in the AA Reports. The detailed "Supply Chain Information" requested in §69505.5(d) – (e), is superfluous and should be deleted. Full disclosure of facility description and location is not critical to the goals of the draft regulation (much less the proximity to raw or recycled materials) and may result in individual and businesses becoming targets for undue and potentially harmful antagonistic action. Presumably, much of this information has already been provided when manufacturers report that they have a CoC in a priority product.

Focus on Designated Chemical of Concern and Alternatives

Regarding list of chemical ingredients in PP and potential alternatives, §69505.5.(h)(2)(C) within the "Supporting Information" section AND §69505.5.(l)(4) within the "Selected Alternative" section should be deleted. As described above, a list of other chemical ingredients in products is not necessary for the successful analysis of the Chemical of Concern and its alternatives. To avoid detracting from the intent of the statute, the focus should remain on assessing the identified CoC and its alternatives, NOT all chemicals within a product.

Compliance with Law

Within the Implementation Plan (§69505.5.(m)(2)), the proposed text refers to any steps necessary to ensure compliance with applicable federal, state, or local laws. This provision should be expanded to include **international** laws as well. Since companies operating within the U.S. may make & market products for all of North America, compliance with Canada's requirements is necessary (e.g., a New Substance Notification (NSN)).

Focus on Designated Chemical of Concern and Alternatives

In §69505.5.(n), since the driver of the AA is the CoC identified by the Department as the basis for a product being listed as a priority product, and the focus of the AA was the development of alternatives for that specific CoC/PP pair, the manufacturer's proposed regulatory response should focus on the outcome related to that specific CoC/PP pair. It should not attempt to sweep in other potential CoC that were not the focus of the AA.

> ***Recommendation:***
> *"Proposed Regulatory Responses. The Final AA Report must include the identification of any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by ~~any~~* ***the*** *Chemical of Concern****, that is the basis for designation of a product as a Priority Product,*** *that will be in the selected alternative or that is in the Priority Product* ***above the de minimis*** *if the decision resulting from the AA is to retain the Priority Product.*

Compliance Challenges & Regulatory Treadmil**l**

As currently structured, the Draft Regulation is very broad and could potentially result everything having an LCA impact. Instead of streamlining the Alternative Analysis (~~A~~AA") process, the lack of clarity may serve to expand the AA to a meaningless scope. It will ultimately end up being difficult to do an AA because it is so broad or potentially very easy because anything could work. This will result in a lack of a level playing field for manufacturers and inconsistent AA reports being submitted to the Department. Furthermore, GCA is concerned that the regulations as written can end up regulating the same product incessantly without any significant improvement to public health or the environment.

GCA urges the Department to explicitly incorporate into the regulation a consultation with impacted manufacturers prior to the timeframe starting for the Preliminary AA Report. This initial consultation would bring together manufacturers with the Department to understand why the product was selected. The consultation would provide a clear opportunity for the responsible parties to have a dialogue with the Department to outline and discuss challenges to the AA process. The Phase 1 work plan would include the expected time needed to complete the AA Phase 2 report and ensure a level playing field as expectations of the Department would be clear. GCA believes that this would provide a level of clarity currently lacking in the Draft Regulation needed for both manufacturers and the Department.

Additionally, as currently written, a priority product is identified based on CoC selected by the Department. That CoC/PP pair undergoes alternatives assessment to identify potential alternatives. In the report submission, the responsible entity is required to tell the Department about ALL chemical ingredients in their product and the alternative, identifying additional CoC with no *de minimis*. The product is a Priority Product forever. Having focused on the product

for several years, the Department will be biased to continue focusing on the Alternative Product to prioritize it again as a Priority Product. As we heard at the December 8, 2011 legislative oversight hearing on Green Chemistry, Dr. George Daston (P&G) commented that ~~"d~~definitive results" would be a successful criterion, without the need for further regulation of the alternative.

The lack of clarity and overall regulatory treadmill will kill innovation, diverting company resources to continuously assess a product that is already safe. Companies devote substantial resources to ensure the safety of their products, with intentionally-added chemicals and incidental contaminants well below a safe *de minimis*. We urge the Department to narrow their focus on LCA impacts and CoC/PP use pairs that really contribute to significant adverse impact on public health and the environment, and for which an alternatives assessment would be beneficial improving the safety profile for public health and the environment. When definitive results have been achieved, the Department should declare success and move on.

## ARTICLE 6. REGULATORY RESPONSES

### Section 69506. Applicability.

This section essentially provides that the following provisions apply to any Priority Product that completes an Alternative Assessment. Given its universal application, it is critical that the following provisions be clear, so that responsible entities may understand how the provisions will affect them. Further, provisions in this article set up a hybrid process that is neither quasi-legislative or quasi-judicial for imposing regulatory responses. Also, to prevent discriminatory implementation, it is essential that the circumstances giving rise to the various regulatory responses be described with specificity. The regulatory provisions lack specificity, and; therefore, they lack clarity.

The imposition of regulatory responses have the potential of making products unacceptable to consumers or imposing such cost that a manufacturer may cease making the product available in California. The consequences of imposing substantial cost or forcing the withdrawal of products for sale in California are so significant that the various regulatory responses should be imposed only under circumstances that are necessary to carry out the purposes of the underlying statute. Accordingly, the regulatory provisions that exceed the scope of the statute should be removed or modified to be consistent with the law.

### Section 69506.1. AA Report Supplemental Report Requirements.

This section authorizes the Department, at any time, to require responsible entities to provide any information supplementary to the Final AA Report that the Department concludes is necessary to determine and ensure implementation of one or more regulatory responses imposed pursuant to this Article. This section also authorizes the Department, at any time, to require the responsible entity to obtain or **develop** information to fill one or more of the information gaps indentified in the Final AA Report, pursuant to section 69505.5(h)(2), if the Department determines this information is needed to re-evaluate the initial regulatory response.

The potential demand for information is unlimited under subsection (a). That subsection calls for information relating to any and all possible regulatory responses. That includes, under section 69506.2, having to test for every chemical of concern, estimated to be in excess of 3,000 substances, and to establish the concentration of those substances, including, for example, contaminants in drinking water. The same is true under section 69506.3, subsection (a)(2), that provides that the mandate to provide consumer information does not apply if the selected alternative product does not contain a chemical of concern above the *de minimis* level.

Section 69506.5 could result in the Department demanding information about the specific function, technological feasibility, and cost to produce a product in comparison to an alternative product. Section 69506.6 is so broad that it is virtually impossible to anticipate all the types of information that may be demanded, but it would include everything already described as well as possible engineering measures to control access or limit exposure, as well as information about who uses the product and all of the possible uses of the product.

To fully appreciate the significance of subsection (b), one must first review section 69505.5(h)(2) to determine the nature of the information gaps that might exist in the Final AA Report. That section requires the Final AA Reports to include the identification of unavailable reliable information that, if available, could be used to: (A) validate information used for the purposes of sections 69505.3(b) and 69505.4; (B) address any uncertainties in the analysis conducted pursuant to those sections.

Section 69505.3 pertains to the alternatives assessment: first stage. It focuses significantly on identifying and evaluating alternatives to the use of a chemical of concern in the priority product.

Section 69505.4 pertains to the alternatives assessment: second stage. Significantly, subsection (a)(2)(A) requires a multimedia lifecycle impact analysis and an analysis of the chemical hazards for chemical ingredients known to be in the priority product and the alternatives being considered based on available information. These factors include the following:

(1) Physical chemical hazards;
(2) Adverse public health impacts;
(3) Adverse environmental impacts;
(4) Physiochemical properties;
(5) Environmental fate properties;
(6) Materials and resource consumption impacts; and
(7) Adverse waste and end-of-life impacts.

In addition, the Office of Environmental Health Hazard Assessment has identified 39 hazard traits applicable to this aspect of the alternatives assessment.

Accordingly, under the provisions of this section, the Department could require the responsible entity to develop information on each of the seven multimedia lifecycle factors and each of the 39 hazard traits identified by OEHHA. Whether this is the Department‘s intent is not relevant. The regulations are not ~~“p~~practical,” in that responsible entities have no way of knowing what information or demands may be made on them by the Department. As a consequence, the regulation is not ~~“l~~egally defensible.” It is vulnerable to legal attack on two grounds: first, it lacks clarity; the regulated community will have no way of knowing what information may be required.

Second, while the Department has not prepared an Initial Statement of Reasons, it is unlikely that it can substantiate the necessity for a regulation with virtually an unlimited scope.

**Section 69506.2. No Additional Regulatory Response Required.**

This section provides that the Department may impose no regulatory response if it determines after reviewing the Final AA Report that the selected alternative does not contain a chemical of concern at a concentration exceeding the *de minimis* level **and** the selected alternative does not pose significant potential adverse public health or environmental impacts.

The first question is why are these two standards in the conjunctive. Isn't it enough to impose no additional regulatory response if the selected alternative poses no significant potential adverse public health or environmental impact? After all, the purpose of AB 1879 is ~~to~~ limit exposure or to reduce the level of hazard posed by a chemical of concern." Health and Safety Code section 25253(a). Hence, a regulation that contemplates imposing regulatory responses on an alternative that poses no significant potential adverse public health or environmental impact clearly exceeds the scope of the legislation. As such, the Department is proposing a regulation that is inconsistent with the statute and one for which it lacks authority to adopt.

In addition, it is most unlikely that the Department can develop substantial evidence to demonstrate the necessity for requiring both standards to be met before determining that it should impose no additional regulatory response. This is particularly true since the first standard not only provides that the selected alternative contains no chemical of concern above the *de minimis* level, it also provides that for a product containing multiple chemicals of concern, the total concentration of all of those substances exhibiting the same hazard trait or environmental or toxicological endpoint has to total an amount below the *de minimis* level.

Accordingly, the effect of this section is that the circumstances when the Department would impose no additional regulatory response are likely to be very few. This also raises a legal issue. The legislation clearly contemplates that one of the regulatory responses is to be no response. Health and Safety Code section 25253(b). The effect of this regulation is to eliminate that as a realistic option. Once again, the regulation is inconsistent with the statute and the Department lacks authority to adopt an inconsistent regulation.

**Section 69506.3. Product Information for Consumers.**

Subsection (a)(1) of this section provides that the manufacturer of a selected alternative or a priority product for which no alternative is selected (isn't that every product going through the AA process?) is to provide certain information to consumers. The exception to this requirement is that the selected alternative product contains no chemical of concern above the *de minimis* level. As noted above, the *de minimis* level is so strenuous that, again, it is unlikely many circumstances will exist where the exception applies. Shouldn't this regulatory response also be excepted where the product poses no significant potential adverse public health or environmental impact? Again, as noted above, the purpose of the legislation is ~~to~~ limit exposure or to reduce the level of hazard posed by a chemical of concern." Hence, to impose this regulatory response when a selected alternative poses no significant potential adverse public health or environmental impact is inconsistent with the purpose of the act; the

Department lacks authority to adopt an inconsistent regulation; and, it is very unlikely that the Department can demonstrate necessity with substantial evidence for the provision.

In addition, one of the requirements of this section, paragraph (C), subsection (a)(1), requires the manufacturer to provide a list of all chemicals of concern to be in the product. Nothing in that provision recognizes that the chemical of concern could be a trade secret. The statute recognizes the right of manufacturers to protect trade secrets. This particular provision is inconsistent with the statute, and contrary to California's trade secret law if it does not recognize an exemption from disclosure for ingredients that are trade secrets.

Subdivision (b) of this section requires the consumer information to be made available on both the manufacturer's website and on the product packaging, or at the point of retail display. The amount of information required by subsection (a) of this section makes compliance with the disclosure requirement impractical. The amount of information required is too substantial in many instances to be included on the product label. The option of having a manual that is accessible without breaking the product seal is equally impractical for many products. As a consequence, the information will have to be provided at the point of retail display. It is totally infeasible for a manufacturer to install disclosure placards in every retail outlet. That means manufacturers will have to provide disclosure placards in the goods they ship to distributors and retailers, and the burden will fall on retailers to install the information placards. The decisions on how and whether the information is made available will be made by stocking clerks.

**Section 69506.4. End-of-Life Management Requirements.**

This section requires the development of a comprehensive product stewardship plan for selected alternatives or priority products for which no alternative is selected. Once again, the only exception to this is if the product contains no chemical of concern above the *de minimis* level and poses no significant potential adverse public health or environmental impact. The comments made above regarding conjoining these two standards applies equally here. In effect, the exception stated in this section is illusory, and conjoining those two standards is inconsistent with Health and Safety Code section 25253. The underlying statute does not grant the Department the authority to promulgate regulations in this area without an individualized justification for the Priority Product affected, much less one that is inconsistent with the current Health and Safety Code.
In addition to the section requiring the development of a comprehensive product stewardship plan, subsection (a)(1) requires all of the information to be disclosed to consumers by section 69506.3 to be provided in this situation as well. Accordingly, the comments made with respect to that section apply equally here.

The significant aspect of this section is the requirement that a comprehensive product stewardship plan must be developed for the product. To be comprehensive, nearly all manufacturers involved in the production of the product need to participate. A regulation that results in multiple manufacturers participating in a stewardship plan immediately raises questions of anti-trust. For example, sharing the cost of the program requires disclosure about volumes of sale or dollar amount of sales; arrangements with retailers to serve as a collection point for products produced by other manufacturers requires disclosure about manufacturer-distributor-retailer agreements; establishing methods of disposal or recycling of products may entail disclosure of ingredients that are trade secrets. These are but three examples giving rise to anti-trust concerns. The Legislature, in conferring authority on manufacturers to establish

product stewardship plans, has provided an exemption from California's anti-trust and unfair business practice statutes. Only the Legislature can create those exceptions; the Department cannot create exceptions, even by regulation.

The second issue is that the regulation requires manufacturers to **fund** the comprehensive product stewardship plan. The effect of this regulation is the Department imposing a fee on manufacturers. Significantly, the Department lacks authority to impose fees in this manner. The Department has limited fee authority and what it does have has been expressly granted by the Legislature in statute. Absent such legislation, the Department may not impose a fee in this situation. Moreover, the imposition of a fee on manufacturers raises Proposition 26 issues. Accordingly, substantial questions exist about the legal defensibility of this section.

The section also raises substantial questions about the practical effect. For example, it contains several requirements that have been rejected by the Legislature when it has required the establishment of product stewardship plans for, as an example, paint and carpet. Those features have been rejected because it adversely impacts the practicality of such plans. In particular, paragraph (B), subsection (a)(2), requires the stewardship program to compensate retailers and other persons, that is, existing household hazard waste collection programs, to administer or participate in the collection program. While a sister agency, Cal Recycle, supports such compensation, it has been rejected as impractical by the Legislature. The cost of compensating retailers, who, in many instances are willing to serve as a collection point simply to bring people into their facility, and to existing programs that already collect such waste, increases the cost that ultimately is passed on to the consumer. This is an unnecessary cost and need not be part of any end-of-life management program.

As noted above, the Legislature has, in a few instances, created stewardship programs for particular waste products. The regulation should recognize the existence of those programs and include an exemption for any product that is the subject of a legislatively created program. The burden should not be imposed on the manufacturer to seek an exemption under section 69506.7. The exemption should be made explicit in the regulation.

**Section 69506.5. Product Sales Prohibition.**

This section authorizes the Department to prohibit the sale of products, except those meeting the criteria in section 69506.2, that is, the selected alternative contains no chemical of concern above the *de minimis* level and the selected alternative does not pose significant potential adverse public health or environmental impacts. The comments made with respect to section 69506.2 and other sections in which that standard apply, are equally applicable here.

Further, the recall provisions in this section are impractical and unnecessary. Under the Product Recall Safety and Protection Act (AB 1860, 2008) (~~P~~RSPA"), manufactures (including commercial dealers, importers, distributors, wholesalers, and retailers) are prohibited from manufacturing, remanufacturing, distributing, selling or otherwise placing into the stream of commerce a product that is unsafe, knowing the product is unsafe. California Health and Safety Code, §108044. Under the PRSPA, a product is deemed unsafe if it meets one or both of the following:

1. The product has been recalled because it does not conform to state or federal laws and regulations setting forth standards for the product.

2. The product has been recalled for any safety hazard reason in cooperation with the federal Consumer Product Safety Commission or its staff, or voluntarily recalled for any safety hazard reason by the product's commercial dealer, manufacturer, importer, distributor, or wholesaler, and the recall has not been rescinded.

California Health and Safety Code, §108044(b)(1)&(2). Duplicating existing California and Federal law regulating recalls is unnecessary and prohibited by the underlying statute. Health and Safety Code § 2527.1(c). DTSC should eliminate references to mandatory recall and rely upon the existing California PRSPA to address any products that are considered unsafe. A product recall is a significant response and should be considered only in situations where there is a true safety risk to public health or the environment.

Another issue unrelated to the above which deserves consideration is that of a manufacturer selling a CoC/PP to another company (manufacturer or assembler) whereby the safer alternative, if discovered, would be required to undergo additional lengthy ~~-q~~ualification" testing by the Original Equipment Manufacturer for technical feasibility and then approved by a federal or state agency before any changes could be made.

***Recommendation:***

*New (4) Within 60 days the responsible entity files a petition to demonstrate that*

*a. The product is used to meet a critical need in the supply chain of a strategic industry (defense, aerospace, automotive)*

*b. Alternatives need to be evaluated by an Original Equipment Manufacturer (OEM) of a strategic industry for technical suitability*

**Section 69506.6. Other Regulatory Responses.**

Again, this section authorizes the Department to impose any of the preceding regulatory responses, as well as four additional responses except as provided in section 69506.2. Consequently, the comments made with respect to that section apply equally here. Ironically, this section confers substantial authority on the Department to impose regulatory responses, if it determines that it is ~~-n~~ecessary to limit potential exposures to and reduce the level of potential adverse public health or environmental impacts posed by a selected alternative." Yet, it does not exempt a product that poses no significant potential adverse public health or environmental impacts from the application of this regulation. It exempts only those containing no chemical of concern at or below the *de minimis* level.

This section creates substantial ambiguity and lack of clarity. It, in effect, provides that the Department may impose any regulatory response it chooses when it determines that it is necessary to do so. This section appears to be substantially unnecessary since the preceding sections provide specific circumstances when the various regulatory responses would be imposed. While substantial disagreement exists with respect to the appropriateness of those circumstances, at least, they are relatively specific, certainly in comparison to this section. It is impossible for the regulated community to understand the effect and application of this regulation; thereby, failing the basic definition of clarity.

Section 69506.6 is also inconsistent with the statute that it purports to implement. The authority for this section appears to be provided by paragraph (9), subsection (b), of section 25253 of the

Health and Safety Code. That portion of the statute requires the Department to adopt a regulation that ~~s~~hall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis . . .." That subsection then lists eight specific actions, and in paragraph (9) provides, ~~A~~ny other outcome the Department determines accomplishes the requirements of this article."

Paragraph (9) does not, as the Department assumes in regulatory section 69506.6, confer unfettered discretion to impose any regulatory response under any circumstance that it chooses. The phrase ~~A~~ny other outcome" is ambiguous. An outcome is not the same thing as a regulatory response. Nevertheless, the Department has construed the term ~~o~~utcome" to mean any of the regulatory responses identified in paragraphs (1) through (8), as well as ~~(~~A) requiring engineered safety measures to control access to or limit exposure to the Chemical(s) of Concern in the product; (B) restricting the use of the Chemical(s) of Concern that is/are in the product; (C) requiring the responsible entity to initiate a research and development project, or fund a challenge grant that is pertinent to the Priority Product and that uses green chemistry principles; and (D) requiring a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department in a specific time period."

Further, paragraph (9) limits the Department to accomplishing ~~th~~e requirements of the statute." The statute specifies in section 25253(a) that the purpose is ~~to~~ determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." That articulation is much different from subsection (a) of section 69506.6 of the regulation. There, the Department provides that it may impose one or more of the following regulatory responses ~~th~~at it determines are necessary to limit potential exposures to, and reduce the level of potential adverse public health or environmental impacts posed" by the product. Simply adding the modifier ~~p~~otential" to both exposures and adverse public health and environmental impacts changes the circumstance when various regulatory responses may be imposed. The effect is to expand the scope of the regulation beyond the statute, rendering the regulation inconsistent with the statute. Of course, the Department has no authority to adopt an inconsistent regulation.

The structure of Article 6 is to define fairly narrow circumstances when specific regulatory responses will be imposed and leave to the Department to exercise discretion as to what regulatory response to impose under whatever circumstance it chooses. The lack of clarity in this structure was noted above. The purpose of imposing regulatory responses is not to eliminate all potential, or even all, risk. The purpose is to limit exposure or reduce the level of hazard posed by a chemical of concern. To limit" and ~~to~~ reduce" do not contemplate the elimination of all exposures and risk. The implication of much of Article 6 is that significant regulatory responses will be imposed unless there is virtually no risk from the product at all. Similarly, section 69506.6 authorizes the Department to impose any regulatory response to limit potential exposure and reduce the level of potential adverse effects. Addressing potential exposures and potential risks are different than addressing actual exposures and actual risks.

In addition, such a structure is inconsistent with the implicit intent of the Legislature as set out in Health and Safety Code section 25253(b). That subsection sets out a range of regulatory responses, each is unique and obviously intended for certain circumstances. Further, the range of regulatory responses implies progressive action, tailored to address the risk imposed by the product. No greater regulatory response should be imposed than is necessary to minimize the risk of a product, taking into account the purpose of the product, who uses it, and its end-of-life fate.

The statute specifies the following ranges:

(1) Not requiring any action.

(2) Imposing requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.

(3) Imposing requirements on the labeling or other type of consumer product information.

(4) Imposing a restriction on the use of the chemical of concern in the consumer product.

(5) Prohibiting the use of the chemical of concern in the consumer product.

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

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

(8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.

(9) Any other outcome the Department determines accomplishes the requirements of this article.

To implement the concept of progressive regulatory responses, taking into account the various circumstances when a particular response would be appropriately imposed, the following standards are suggested:

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

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

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

(4) To restrict the use of, control access, or limit exposure to a chemical of concern in the consumer product, the Department shall find that the risk of the use outweighs its benefits under certain circumstances or to certain sensitive subpopulations; that the risk can be mitigated to an acceptable level by the specific restriction; and that none of the actions set out in paragraphs 1 through 3 above is sufficient to mitigate the risk under those circumstances or to those sensitive subpopulations to an acceptable level.

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

(6) To prohibit the use of a chemical of concern in a consumer product, the Department shall find that the use poses a high probability of severe, irreversible risk to public health, safety, or to the environment such that urgent action is required; the risk of the use outweighs its benefits; and, none of the actions set out in paragraphs 1 through 5 above is sufficient to mitigate the risk to an acceptable level.

In imposing a regulatory response, the Department should specify the hazard associated with the chemical or chemicals in the product and the specific use of the product that justifies the imposition of a specific regulatory response. The Department should make findings, supported by substantial evidence to establish the standards described above that give rise to the regulatory response imposed.

**Section 69506.7. Exemption from Regulatory Response Requirements.**

This section provides that a responsible entity shall submit a request for an exemption 60 days after the Department issues a notice of the imposition of the regulatory response. This section spells out what is to be included in the exemption request and sets out the standard for the Department granting such a request.

In addition to the process, the standards specified in this section are of particular concern.

The statute most applicable to section 69506.7 is Health and Safety Code section 25257.1. It is set out below for ease in comparing the regulation with the statute that is purportedly being implemented.

> 25257.1. (a) This article does not limit and shall not be construed to limit the department's or any other department's or agency's existing authority over hazardous materials.
> (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.

The clear thrust of the statute is to limit the Department‘s authority to impose regulatory responses. The clear thrust of the regulation is to shift to the responsible entity the obligation to request an exemption from a regulatory response and to justify its request. The implication of the regulatory section is that if a responsible entity fails to request an exemption, or fails to request an exemption within 60 days, or fails to include all of the required information, that the Department will impose a regulatory response even if doing so would violate Health and Safety Code section 25257.1. Accordingly, the regulation is inconsistent with the restrictions imposed by the statute, and the Department lacks authority to adopt an inconsistent regulation.

The regulatory standards also raise substantial legal concerns when compared with the statute. Those standards are as follows:

(A) The required or proposed regulatory response would conflict with one or more requirements of another California or federal regulatory program or an international trade

agreement ratified by the United States Senate, in such a way that the responsible entity cannot reasonably be expected to comply with both requirements.

(B) The required or proposed regulatory response substantially duplicates one or more requirements of another California or federal regulatory program or an international trade agreement ratified by the United States Senate without conferring additional public health or environmental protection benefits.

First, the statute provides that the Department is not authorized to ―supersede" the regulatory authority of any other department or agency. Nothing in the regulation addresses the prohibition against superseding the authority of another agency. That is a significant omission.

Authority can be superseded without it being in conflict or duplicating another regulatory program. This issue is particularly highlighted by paragraph (6)(B), subsection (a), of section 69506.7. That paragraph provides that a regulatory response does not duplicate other regulations if it confers ―additional public health or environmental protection benefits."

Examples will illustrate the legal problem with this regulation. The California Air Resources Board limits the content of volatile organic compounds in certain consumer products. If the Department were to ban the use of the particular VOC, it could not be said that it does not confer additional public health or environmental protection benefits, but it clearly supersedes ARB's regulatory program. The same is also true for the warnings required under Proposition 65. Again, a product ban would arguably confer additional public health and environmental protection benefits, but it does so by superseding the Proposition 65 regulatory program.

The phrase ―without conferring additional public health or environmental protection benefits" is an expansion of the statute. As noted above, the statute provides that the Department shall not duplicate regulations for product categories already regulated or subject to pending regulations consistent with the purposes of this article. Hence, any regulatory program that is designed to ―limit exposure," or ―to reduce the level of hazard posed by a chemical" is consistent with the purposes of the statute. The Department substantially expands the scope of the statute by providing that a regulatory response that confers additional public health or environmental protection benefits never duplicates an existing regulatory program. That is inconsistent with the explicit language of the statute, and the Department lacks authority to adopt an inconsistent regulation.

The Department has used a very narrow definition of ―conflict" in this section. It appears that it has chosen a definition that is used principally when courts determine whether a state law is preempted under the doctrine of conflict preemption.

A definition of conflict used for federal preemption purposes is not appropriate to implement Health and Safety Code section 25257.1. Conflict preemption is a particularly rigorous concept in recognition of the respective role of states and the federal government. Powers not conferred on the federal government are reserved to the states. It was the states that created and conferred authority on the federal government. Hence, for a court to find that a state law conflicts with a federal law requires a clear showing that a person cannot comply with both; thereby, frustrating the purpose of the federal law.

Section 25257.1 involves a very different situation. It evidences the Legislature's intent to avoid conferring super authority on the Department. It recognized that other agencies implement a multitude of other regulatory programs, and that this law is not to be implemented so as to

intrude into the jurisdiction of those other agencies. It is not simply a matter of avoiding a preemption type conflict; it is to avoid acting inconsistently or differently than the agency with the existing authority has chosen to act. This intent is buttressed by the statutory language prohibiting the Department from imposing regulatory responses that "supersede" and "duplicate," as well as "conflict" with existing regulatory programs.

Again, the Department, in adopting a narrow, rigorous definition of "conflict," would act inconsistently with the statute, and it lacks authority to do so.

**Section 69506.8. Regulatory Response Determination Process.**

The process for the Department to issue its regulatory response determination notices is generally acceptable. As noted with respect to section 69506.6, the regulation, to be consistent with the statute, needs to establish specific circumstances for which specific regulatory responses are imposed. The regulation should provide, as noted with respect to section 69506.6, that the Department shall make findings on each of those circumstances and support those findings with substantial evidence.

## ARTICLE 7. DISPUTE RESOLUTION PROCESSES

The provisions in this article, sections 69507 through 69507.6, are generally acceptable. They provide a clear and logical process for resolving disputes. They follow the form of the adjudicatory portion of the California Administrative Procedure Act in providing for an informal and formal process, depending on the seriousness of the action taken by the Department.

The timelines set out in the process appear to be reasonable. The content of the appeal documents and request for review are also reasonable and logical.

A question was raised during the workshop about the provision in subsection (c), section 69507, that an action imposed by the Department shall be stayed during the pendency of a dispute concerning the action. This is a most appropriate and necessary provision. Appeals are often meaningless if the action is taken while the appeal is pending. The analogy that is appropriate to this situation is that it is impossible to put the toothpaste back into the tube after it has been squeezed out. To provide otherwise raises due process concerns about the adequacy of the appeal process.

## ARTICLE 8. ACCREDITATION BODIES AND CERTIFIED ASSESSORS

**Section 69508. Qualification and Certification of Assessors**

The entirety of Article 8 is unnecessary to the efficient implementation of the statute and should be eliminated. The Department will be working closely with responsible entities preparing Alternatives Assessments, and given the authority of the Department to restrict or prohibit the

use of a chemical of concern in a consumer product, the responsible entities will be highly motivated to comply with the regulations.

However, GCA prefers the approach proposed in the current draft regulation, utilizing assessors licensed by accreditation bodies, as opposed to previous proposals that required third-party completion of all alternatives analyses. As demonstrated by industry during the ―Alternatives Analysis III: Industry Practices in Product Research and Development, an Alternative Analysis" symposium, on September 15, 2011, experience in product development should be a significant credential leading to assessor certification.

In-house company experts with 10 or more years of experience have the necessary knowledge, skill, and expertise for product development and should not have to become certified assessors, or should be certified with minimal requirements based on their experience. An R&D scientist must consider a variety of factors in the selection of chemical ingredients for a consumer product. The safety of an individual chemical and life cycle considerations 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, other environmental criteria, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right combination of chemical ingredients for consumer product formulations. In-house company experts appreciate the intricate R&D science invested in developing consumer product formulations and in-depth understanding necessary of consumer behavior and preferences.

Certification however should be invested in those individuals charged with overseeing the various aspects of the alternatives assessment and with ensuring successful execution in meeting the Department's requirements. As discussed, an in-house certified assessor is well positioned to understand how to apply an AA to a Chemical of Concern/Priority Product pairing, with a variety of available experts utilized to address specific aspects of the AA. Product development experience should play a significant role in the time and effort necessary for certification. This approach would be in keeping with previous California precedent; when ―Quality Engineer" was added to the state's categories of engineering technology for which state licensing is available, already-practicing quality engineers with a minimum level of specified experience and/or education were ―grandfathered" and granted a license without a licensing examination[10]. Assessors should also not be required to be technically expert at all aspects of an AA, but should instead be expected to be capable of managing the AA process to be certain that all applicable parameters are considered. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors' work products) that is being certified. The Department should have the ability to challenge the Accreditation body.

The provision for ―Random auditing by the accreditation body or its consultants to ensure the quality of work and proper application of tools by the assessor" (69508.2 (c)(7)(C)) would satisfy quality assurance concerns that the Department has.

Finally, Department staff members who review alternatives assessments should also be certified assessors.

**Section 69508.1. Qualifications for Accreditation Bodies**

Although it appears that criteria by which a body becomes an accreditation body are not explicit in the draft regulations, qualifications and expertise required as noted in 69508.1 are adequate and necessary to designate an entity as an accreditation body. Due to the complex nature of any Alternatives Assessment, the availability and accessibility to a wide range of expertise in various scientific fields are instrumental to a successful accreditation body. Broad skills and knowledge are required to conduct assessments across the extremely broad spectrum of products, chemicals, evaluation factors and impacts that would need to be assessed in AAs as envisioned by this regulation. One area of practice that seems to have been omitted but should be included in 69508.1(a)(5) is Exposure Assessment. The ability to assess exposure will be critical to fully understanding the numerous exposure-related considerations in the AA process, not the least of which is whether and to what degree an alternative comports with the definition of ~~-s~~afer alternative."

The only overarching concern is that if these entities do not include a wide range of expertise from product and chemical manufacturers, then they may never appreciate the intricacies of product development and R&D and be able to convey the nuances inherent in product development within specific industry sectors to applicants.

Nevertheless, the accreditation body should focus on training would-be assessors as project managers. The certified assessor should only be responsible for ensuring that due process for the AA has indeed been followed. The certified assessor should rely on subject matter experts in the various fields and disciplines to provide the necessary information on relevant factors within an AA.

GCA objects to the requirement that an entity seeking accreditation may not have any economic interest in any responsible entity, manufacturer, etc. Given the widespread use of 401(k) plans, etc. as investment tools for retirement it will be difficult, if not impossible, to identify an entity without any economic interest – particularly at the low threshold the Department has described in §69501.2(a)28). We suggest a more reasonable conflict of interest provision.

Finally, we request further clarity as to how the Department defines an ~~-in~~direct investment" versus a ~~-d~~irect investment" (§69508.1(a)(6)). It is important that no eligible entity is unduly precluded from becoming an accreditation body, if they possess all of the specified criteria. Doing business with a major consumer product manufacturer or chemical company to the extent of $2000 is not an appropriate measure of an organization s independence. In addition, there are potential forms of conflict that do not involve money at all. If the goal is to eliminate conflict, the rules must be substantially rethought.

**Section 69508.2. Accreditation Body Designation Requirements.**

It is unclear if the Department considered limiting the scope of the mandatory authorization required of prospective certified assessors in §69508.2(c)(1)(F) to prevent the release of potentially confidential information to accreditation bodies and their agents. Given the failure to identify the necessity of the certified assessor requirement in general, and limit the scope of the

disclosure of confidential information in particular, we believe that §69508.2(c)(1)(F) must be revised as follows to protect the privacy interests of prospective certified assessors:

***Recommendation:***

(c) Each accreditation body shall include in its program, at a minimum, all of the following:

(1) Admission procedures. A summary of application requirements and admission procedures for certification and certification renewal must be included. Required information includes all of the following:

(F) A signed and dated certification statement that reads: ~~I~~ certify under penalty of perjury that the information I have entered on this application is true and complete to the best of my knowledge. I further understand that any false or incomplete statements may result in my disqualification as a certified alternatives assessor. ~~I authorize the employers and educational institutions identified on this application to release any information they may have concerning my employment or education to the accreditation body with which this application is filed and to the State of California."~~

## ARTICLE 9. AUDITS

GCA agrees that beyond good AA Guidance, Department audits, particularly in the early years of implementation will help to increase credibility of the AA process as well as to improve consistency.

## ARTICLE 10. TRADE SECRET PROTECTION

### Introduction

These comments address first the anticompetitive effect of these regulations. That effect will deter the very innovation that the Green Chemistry law was intended to promote. Further, it may compel conduct that will result in violation of federal anti-trust laws. Second, these comments address the specific provisions of Article 10.

The Department's Regulation and Lack of Strong Trade Secret Protection Inappropriately Encourages Anticompetitive Action

In a number of critical respects the regulations could compel the exchange of competitively sensitive information between and among market competitors in a manner not contemplated by the authorizing legislation. Because the authorizing legislation does not clearly articulate a state policy to impede or impair the competitive process in the manufacture, supply or distribution of Priority Products, any conduct proposed by the regulations which has the effect of impeding or impairing such competition would expose industry participants to liability under applicable federal antitrust laws.

There are a number of distinct requirements in the regulations which would create such an exposure for industry participants. Each of these requirements involves the posting of submitted information to the Department's website, which effectively makes the submitted information available to the public, including current and potential competitors of industry participants. The following are a few examples where the posting of submitted information would lead to anticompetitive results not contemplated by the authorizing legislation and therefore where the mandated activity would be precluded by the federal antitrust laws.

1. The proposed regulations contemplate that full or redacted copies of every submitted Preliminary and Final Alternative Assessment Report shall be posted on the Department's website. See sections 69501.6(b)(4) & (5). The reports are required to contain a vast amount of information which could be accessed by competitors and which could allow those competitors to learn about alternatives considered by other parties and whether those alternatives were accepted or rejected by the other parties, along with explanations for the acceptance or rejection. The explanations explicitly must include both technical and economic feasibility analyses.

   During the December 5, 2011 workshop, the Department heard from several industry representatives that any market advantages resulting from alternative chemical research and development by manufacturers will be lost under the regulation as drafted. If the Department requires an alternative selected by one company to be revealed to that company‘s competitors, those competitors have not put the time, funding and resources into developing the alternative and the support for use of the alternative chemical in their product. Thus, a disincentive to consider or develop other competitive alternatives will be an unintended consequence of this information exchange mandated by the Department. This knowing interference by the Department in the ordinary and customary competitive process is unauthorized and unnecessary. The Department‘s regulations must allow for competition to continue in the ordinary manner because the authorizing legislation does not contemplate that competitors will be granted access to the ongoing research, development and decision-making process of their competitors.

2. The proposed regulations contemplate that information concerning every submitted notice of a replacement product shall be posted on the Department's website. See section 69501.6(b)(1). The notices regarding replacement products are required to contain detailed technical and economic information which could be accessed by competitors and which could allow those competitors to learn about replacement products introduced by other parties and implicitly whether the replacement product is experiencing an increase in sales in the state.

   The Department‘s broad publication of competitively sensitive information is inappropriate. If a manufacturer introduces a product which replaces a Priority Product in terms of use and customer base, the Department must be notified and information regarding that notification will be posted. There is no market advantage to the manufacturer if the Department will then use this information to inform competitors of the alternative found and introduced. It is unclear what the Department intends to do with the posting of this information, but it appears that DTSC would either require competitors to adopt the same substitute, or in other ways diminish the market advantage created by being an early mover in the market.

3. The proposed regulations contemplate that a link to any *De Minimis* Exemption Notifications will be posted on the Department‘s website. See sections

69501.6(a)(5)(D)1 & 10. The exemption notifications are required to contain information specifically establishing the *de minimis* levels as articulated in the regulations. Once again, this information could be accessed by competitors and could allow those competitors to learn that other parties are able to manufacture and distribute the Priority Products at constituent levels which qualify as *de minimis*. The exchange of this information will impede the competition process not only by destroying the competitive advantage of the party operating at *de minimis* levels, but also by reducing the incentives for other parties to develop new or different products, since they will simply seek to copy the notified products.

Finally, although the regulations do contemplate a process for all parties to assert a claim of trade secret protection for information submitted to the Department, there is no provision to ensure that the requested trade secret protection will, in fact, be accepted by the Department. See section 69510.1(c). Given the significance of the information, any potential disclosure could reduce competition and/or chill the incentive to innovate. Therefore, in each of these three examples, the regulations could result in liability to market participants under the federal antitrust laws. Therefore, in these examples, and for any other similar situations, the regulations should be amended to make clear that any information provided which is designated as "Trade Secret" will expressly not be included on the Department's website and that such information provided will also not be accessible under applicable Freedom of Information requests.

**Section 69510. Assertion of a Claim of Trade Secret Protection.**

Subsection (a) of this section requires a person who asserts a claim of trade secret protection to submit ~~a~~ll of the following supporting information." Then the regulation lists 13 specific types of information or form requirements that must be included in support of the trade secret claim.

Ostensibly, this section implements the definition of ~~t~~rade secret" found in Civil Code section 3426.1(d). That definition is as follows:

> **3426**.1. (d) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:
> (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
> (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

To be valid, this regulation must be consistent with the statutory definition of trade secret. At least four of the information requirements set out in the regulation that a person must provide to justify a trade secret claim expand on the scope of the statutory definition of trade secret. These are paragraphs (3), (7), (8), and (9).

Paragraph (3) requires the person making the request to state the period of time for which the trade secret protection is claimed and the justification for the period of time specified. Time limits with respect to trade secret protection are irrelevant. A trade secret claim, unlike patents and copyrights, do not have a limited life. As long as the information has economic value and the owner of the information treats it like a trade secret, it remains a trade secret. Hence, this requirement is inconsistent with the statute; the Department lacks authority to adopt an

inconsistent regulation; and, it is unlikely that the Department can demonstrate necessity for requiring information on the time frame of a trade secret claim.

Paragraph (7) requires information on the estimated value of the information to the person or the person's competitors. The statutory definition of trade secret recognizes that trade secrets are property and to be protected must have actual or potential economic value. It is the existence of economic value that is relevant to a determination of whether secret information should be protected, not the amount of that value. Nothing in the law provides greater or lesser protection for information having greater or lesser economic value. Information concerning the presence of economic value, not the amount of that value, would be appropriate.

Paragraph (8) requires a person asserting a trade secret claim to provide the estimated amount of effort or money expended by the person in developing the information. Again, this factor is not relevant to determining whether information is to be protected as a trade secret. Expending a lot of effort and money to develop the information entitles its owner to no greater protection than had the owner developed the information in an ~~a~~ha" moment. Nothing in the statutory definition of trade secret supports the requirement to estimate the amount of effort or money expended to develop the information. Accordingly, this provision is inconsistent with the statute; the Department lacks authority to adopt an inconsistent regulation; and, it is most unlikely that the Department can demonstrate the necessity for imposing this requirement on a person asserting a claim for trade secret protection.

Paragraph (9) provides that a person asserting a claim for trade secret protection shall estimate the ease or difficulty with which the information can be properly acquired or duplicated by others. This section has no relationship with the statutory definition of a trade secret. The statutory definition refers to the efforts made by the owner of the trade secret to maintain its secrecy. It has nothing to do with the efforts or activities of others who could be trying to acquire or duplicate the information. The Department, in paragraphs (4), (5), and (6), have asked for specific information relating to the efforts that the owner of trade secret information has taken to maintain its secrecy. Those factors are generally relevant to the statutory definition. They are the kinds of ~~e~~efforts that are reasonable under the circumstances to maintain . . . secrecy." That is not the case with respect to the provision in paragraph (9), which relates not to the efforts made by the owner of the trade secret information, but to the activities of others. As such, paragraph (9) expands the scope of the statutory definition and is inconsistent with that definition; the Department lacks authority to adopt an inconsistent regulation; and, it is very unlikely that the Department can demonstrate necessity for imposing this requirement as well.

In fact, paragraphs (7), (8), and (9) harken back to a time when the protection of trade secrets was predicated on tort principles. The law was largely developed by the courts on a case-by-case basis. The courts provided a variety of ways to evaluate the property interest that was being protected.

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

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

The statute, section 25257, provides further support for striking paragraphs (3), (7), (8), and (9). It prohibits the release of information to the public that is a trade secret as defined in Government Code section 6254.7 and Evidence Code section 1060.

Government Code section 6254.7 is particularly informative with respect to the definition of a trade secret and, accordingly, factors that are relevant to determining what information is a trade secret. Subdivision (d) provides that ~~"~~trade secrets are not public records" and defines trade secrets as information ~~"~~which is not patented, which is known only to certain individuals within a commercial concern who are using it to fabricate, produce, or compound an article of trade or a service having commercial value and which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it."

Evidence Code section 1060 provides that the owner of a trade secret has a privilege to refuse to disclose the secret. Evidence Code section 1061(a) incorporates, for purposes of the Evidence Code, the trade secret definition in Civil Code section 3426.1.

As noted above, the section 69510 factors go well beyond the trade secret definitions in both the Government and Evidence Codes. The fact that both are referenced in the statute demonstrates the Legislature's intent to restrict the Department to specific definitions of trade secrets and, thereby, restrict the factors required to justify such a claim.

Paragraph (12) requires a claim for information to be treated as a trade secret to be signed by the person's general counsel or other executive with knowledge of the preparation of the substantiating information, ~~"~~certifying under penalty of perjury" that the substantiating information is true. Nothing in the statute confers authority on the Department to dictate a specific person who may assert a claim for trade secret protection. The statute provides that a person providing information may at the time of submission identify a portion of the information as a trade secret, and upon the written request of the Department, shall provide support for the claim that the information is a trade secret. Hence, a person providing information to the Department is the person to provide support for the trade secret claim.

Further, nothing in the statute requires the signature of an executive certifying under penalty of perjury that the substantiating information is true. Such a requirement results in the potential imposition of a criminal penalty if a question is raised about the accuracy of information contained in the substantiating request. The Department lacks the authority to create circumstances that give rise to a criminal penalty; only the Legislature has that authority.

Subsection (c) of this section requires a person who asserts a claim of trade secret protection to include, along with a complete copy of the information being submitted, a redacted copy of the information, excluding the information for which trade secret protection is claimed. On the surface, this provision would appear to be consistent with the California Public Records Act. Government Code sections 6250 and following. The problem with the provision arises in the circumstance in which a person is obligated to provide hazard trait information with respect to an ingredient that is a trade secret.

The Office of Environmental Health Hazard Assessment has identified 39 hazard traits. Hence, in a Final AA Report, the responsible entity will indentify the alternative to the chemical of concern, and in doing so will reveal the likely function of the alternative ingredient in the priority product. That, in turn, will provide significant information about the chemical makeup of the alternative ingredient. Then, the responsible entity has to indicate which of OEHHA's 39 hazards are potentially associated with the alternative ingredient. Substantial information about the chemical characteristics of the alternative ingredient are revealed by indicating yes to this hazard trait, and no to the following three, etc. The regulation has made no provision for this type of situation. That omission raises substantial questions about the practicality of the requirement to provide a redacted copy of, for example, the Final AA Report. A substantial legal issue, i.e., taking of property without due process, is also raised. That issue will be discussed below.

Subsection (f) of this section provides that trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient. This section is included to implement Health and Safety Code section 25257(f), ~~–~~This section does not apply to hazardous trait submissions for chemicals and chemical ingredients pursuant to this article."

As noted above, having to identify which hazard traits may or may not be exhibited by a particular chemical can have the same effect as disclosing the chemical. Requiring the identification or description of hazard traits associated with potential alternatives takes away the ability of a company to protect innovation. The Department is taking away the trade secret protections for innovations by requiring the public disclosure of such descriptive information. In that circumstance, the concept of providing protection for the trade secret is, at best, illusory. Just as was discussed with respect to subsection (c) of this section, the same is true for subsection (f). A mechanism needs to be included to address the circumstance where identifying the hazard traits that may or may not be exhibited by the chemical results in disclosing that chemical.

Without a mechanism to protect fully trade secrets, the regulation and, therefore, the implementation of the statute raises due process concerns. A state mandate, whether imposed by statute or regulation, that results in the disclosure of a trade secret is unconstitutional. Courts have held that a mandated disclosure is a facially unconstitutional taking and deprives companies of property without procedural due process. See, for example, *Phillip Morris, Inc. v. Reilly*, 312 F.3d 24 (2002).

**Section 69510.1. Department Review of Trade Secrecy Claims.**

The Department, in this section, has failed to track the procedure set out in the statute relating to judicial review, and as a consequence, has failed to provide as much protection when trade secret claims are made as the statute provides. Accordingly, the regulation is inconsistent with the statute, and the Department lacks authority to adopt an inconsistent regulation.
Section 25257 provides that if the Department decides to release information claimed as a trade secret, it shall provide notice to the person who submitted the information 30 days prior to public disclosure ~~–~~unless, prior to the expiration of the 30-day period, the person who submitted the information obtains an action in an appropriate court for a declaratory judgment . . . or for a preliminary injunction . . .."

The plain meaning of the statute is that the Department may not disclose the information if an action is filed before the expiration of the 30-day notice. The filing of the lawsuit stays the disclosure. The statute does not require the court to issue any order, ruling, or judgment during the 30 days to stay disclosure. The Legislature did not require the person submitting the information to secure an order, ruling, or judgment to prevent disclosure. The Legislature recognized that several months would be required for a court to resolve a complaint for declaratory judgment. In fact, the defendant in such an action would have 30 days to answer the complaint, taking the parties well beyond the expiration of the 30-day notice, and no order could be made until a motion, at a minimum, was filed and the court could rule on that.

The Department, however, in both subsections (b) and (c) of section 69510.1, states, "During the 30-day period, and for any longer period ordered by a court of law, the Department shall not publicly release or disclose the claimed trade secret information." This sentence provides that the Department will not release the trade secret information during the 30-day notice period, but it will release the information after the expiration of the 30 days unless the court has ordered it not to do so, and it will release the information absent a court order even when the person submitting the information has filed an action.

The statute prohibits the release of the information after an action is filed, imposing no obligation to obtain an order, ruling, or judgment in that 30-day notice period. The regulation requires an order from the court before the expiration of the 30-day notice period to prevent disclosure. It is this inconsistency that renders the last sentence in both subsections (b) and (c) of this section legally indefensible.

# # # #

## Appendix A. Recommendations on proposed lists

*(a)(1) The chemical is identified as exhibiting a hazard trait on one of more of the following lists:*

| | Proposed Chemical Sources for Initial COC List | Hazard Trait | GMA Recommendation |
|---|---|---|---|
| (a)(1)(A) | California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity | Toxicological Hazard Traits:<br>· Carcinogenicity<br>· Reproductive Toxicity<br>· Developmental Toxicity | **Drop. This is a secondary source, drawing from other authoritative lists, thus does not provide any additional information. Strongly disagree with inclusion of IARC 2B, see below.** |
| (a)(1)(B) | California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) | Toxicological Hazard Traits:<br>· Carcinogenicity<br>· Reproductive Toxicity<br>· Developmental Toxicity | **√ Use. Previously recommended by GMA** |
| (a)(1)(C) | Canadian Environmental Protection Act Environmental Registry's Persistent, Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBiT) | Exposure Potential Hazard Traits:<br>· Bioaccumulation<br>· Persistence | **√ Use. Previously recommended by GMA. In 2009, GMA recommended using the 393 priority PBiT chemicals, identified primarily based on modeling. Canada has now assessed and determined action on these chemicals. GMA recommends DTSC use only chemicals where Canada has taken risk management actions (SNAc and use restrictions).** |
| (a)(1)(D) | Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services, Public Health Service, National Toxicology Program | Toxicological Hazard Trait:<br>· Carcinogenicity | **√ Use. Previously recommended by GMA. Agree with including Category A (Known) and B (Reasonably Expected), but not other Categories.** |
| (a)(1)(E) | Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act | Various Toxicological Hazard Traits: | **√ Use. However, this also leads to listed anomalies that are clearly not chemicals for consideration or chemicals of concern.** |
| (a)(1)(F) | European Chemical Substances Information System Persistent Bioaccumulating Toxins (ESIS PBT) | Exposure Potential Hazard Traits:<br>· Bioaccumulation/Persistence<br>· Various Toxicological Hazard Traits | **√ Use. Previously recommended by GMA. Chemicals included should be PBTs "fulfilling criteria" from EU review process** |
| (a)(1)(G) | European Commission Category 1 and Category 2 endocrine disruptors | Toxicological Hazard Trait:<br>· Endocrine Toxicity | **Not authoritative body; work discredited by EU's highest scientific advisors (NAS equivalent). No deliberative scientific process with stakeholder input. No EU regulatory attention for 5 years.** |
| (a)(1)(H) | European Union Directive on Dangerous Substances (Directive 67/548/EEC), Category 1 carcinogens and Category 1 reproductive toxins | This has been superseded by (a)(1)(I) – see below. | **Drop. As noted, superseded by (a)(1)(I)** |

| | | | |
|---|---|---|---|
| (a)(1)(I) | European Union EC 1272/2008 Annex VI, Category 1A and 1B carcinogens, Category 1A and 1B reproductive toxins, and Category 1A and 1B mutagens | Toxicological Hazard Traits:<br>· Carcinogenicity<br>· Reproductive/Developmental Toxicity<br>· Genotoxicity | **√ Use. Previously recommended by GMA. Agree with including CMR from Category 1A (Known) and 1B (Presumed), but not other categories or endpoints.** |
| (a)(1)(J) | International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens | Toxicological Hazard Trait:<br>· Carcinogenicity | **Groups 1 and 2A previously recommended by GCA. Strongly disagree with inclusion of 2B; evidence level is less than other Carcinogen sources.** |
| (a)(1)(K) | Pollutants listed by California or the US EPA for one or more water bodies in California pursuant to section 303(d) of the federal Clean Water Act | Various:<br>· Toxicological Hazard Traits<br>· Environmental Hazard Traits<br>· Exposure Potential Hazard Traits | **Drop. Using these lists appears on the surface to make sense to identify environmental concerns; however, they lead to many unwanted anomalies—listing oxygen, nitrogen, iron, aluminum, exotic species, viruses, sulfates, coliforms, turbidity, etc—clearly not chemicals for consideration or chemicals of concern in the context of the Regulation. Important CoC picked up in other lists.** |
| (a)(1)(L) | Pollutants requiring monitoring and reporting in waste discharges to land that have Notification Levels (NLs) specified under the Waste Discharge and Water Reuse Requirements (WDRs/WRRs) of the Porter-Cologne Water Quality Control Act | Various Toxicological Hazard Traits | |
| (a)(1)(M) | Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act | Various:<br>· Toxicological Hazard Traits<br>· Environmental Hazard Traits<br>· Exposure Potential Hazard Traits | **Might make sense, however, this also leads to listed anomalies that are clearly not chemicals for consideration or chemicals of concern. Important CoC on this list are picked up in other lists.** |
| (a)(1)(N) | US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals | Exposure Potential Hazard Traits:<br>· Bioaccumulation/Persistence<br>· Various Toxicological Hazard Traits | **√ Use. Previously recommended by GMA. Include all listed PBT chemicals.** |
| (a)(1)(O) | Washington Department of Ecology Persistent, Bioaccumulative, Toxic Chemicals | Exposure Potential Hazard Traits:<br>· Bioaccumulation/Persistence<br>· Various Toxicological Hazard Traits | **Drop. Uncertainties in information developed by modeling and the use of thresholds different from federal and internationally accepted levels.** |

*(a)(2) The chemical is identified by one or more of the following lists based on exposures or environmental or toxicological endpoints:*

| | Proposed Chemical Sources for Initial COC List | Hazard Trait | GMA Recommendation |
|---|---|---|---|
| (a)(2)(A) | National Report on Human Exposure to Environmental Chemicals, Center for Disease Control | Various Toxicological Hazard Traits:<br>· Chemicals that are biomonitored are "reliable information demonstrating" exposure | **Drop. Lists for this purpose should be based on hazard traits. This exposure information could be relevant in prioritization. Any substances can be measured in human tissues with appropriate detection methods. As CDC regularly states—exposure alone is not sufficient to indicate cause for concern.** |
| (a)(2)(B) | OSPAR List of Chemicals for Priority Action | Environmental Hazard Traits | **Drop. Not an authoritative body. No deliberative scientific process with stakeholder input.** |
| (a)(2)(C) | OSPAR List of Substances of Possible Concern | Environmental Hazard Traits | **Drop. Not an authoritative body. No deliberative scientific process with stakeholder input. This is a set of un-prioritized 'possible' substances.** |
| (a)(2)(D) | US EPA National Waste Minimization Program list of Persistent Bioaccumulative and Toxic Priority Chemicals | Exposure Potential Hazard Traits:<br>· Bioaccumulation<br>· Persistence<br>· Various Toxicological Hazard Traits | **√ Use. Previously recommended by GMA. Include all PBT chemicals. This list should be under (a)(1) list group for hazard traits.** |

*(a)(3) The chemical is identified by one or more of the following sources of reliable information:*

| | Proposed Chemical Sources for Initial COC List | Hazard Trait | GMA Recommendation |
|---|---|---|---|
| (a)(3)(A) | Grandjean & Landrigan identification of neurotoxicants | Toxicological Hazard Trait:<br>· Neurotoxicity | **Drop. Not an authoritative body. Privately developed, no deliberative scientific process with stakeholder input.** |
| (a)(3)(B) | National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports | Toxicological Hazard Traits:<br>· Reproductive Toxicity<br>· Developmental Toxicity | **√ Use. Previously recommended by GMA. Chemicals included should be those identified as Serious Concern and Concern. Should be moved under (a)(1) group.** |
| (a)(3)(C) | US EPA Integrated Risk Information System (IRIS) identification of carcinogens | Toxicological Hazard Trait:<br>· Carcinogenicity | **√ Use. Previously recommended by GMA. DTSC should include all A-Known, B1/B2-Probable/Likely; should not include C-Possible. Should be moved under (a)(1) group.** |