Personal Care Products Council

Committed to Safety, Quality & Innovation

(IC)41- Personal Care Products Council

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By Electronic Mail

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
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RE: Safer Consumer Products Draft Regulations

Dear Ms. Jones:

The Personal Care Products Council (Council)[1] is pleased to submit the following comments on California's Safer Consumer Products draft regulations that were developed by the Department of Toxic Substances Control (DTSC) and publicly released on October 31, 2011. Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in California and throughout the United States, and therefore have a strong interest in the scope and applicability of these regulations.

INTRODUCTION

Since the inception of California's Green Chemistry Initiative in May 2007, the Council and its members have engaged with California legislators, regulators, non-governmental organizations, and the business and scientific community to provide thoughtful insight, ideas, and comments in an effort to develop a practical and effective regulatory framework that would promote sustainable innovation while making meaningful improvements to the protection of human health and the environment.

While the Council objected to many of the provisions in the originally proposed (2010) regulations, it is evident from the recently released draft that DTSC heard some of our concerns and made important

[1] Based in Washington, D.C., the Council is the leading national trade association representing the $250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. The Council was previously known as the Cosmetic, Toiletry, and Fragrance Association (CTFA).

modifications. Despite positive changes, however, there remains additional work to be done to make the current draft regulations more effective and less burdensome for the regulated community. Therefore, in this spirit of cooperation, the Council respectfully submits the following comments, both general and specific, in the hopes that DTSC will consider them and make our suggested changes to the regulations before issuing the formal proposal.

KEY POINTS

Below are the primary points that the Council raises in these comments:

1. **Initial List of Chemicals of Concern.** The chemical identification process proposed by DTSC is inherently flawed and scientifically indefensible.

2. **Priority Products.** Product prioritization needs to have *objective measures and procedures* in place so that public health and environmental impacts can be assessed by industry. Without definitive criteria in place, DTSC can make priority product determinations at will and industry has no basis on which to judge or challenge those determinations.

3. **Timelines**. The timelines are completely unrealistic and unworkable, particularly with regard to the alternatives assessment (AA) process.

4. **Alternatives Assessment**. It is critical that innovation, flexibility, and consumer acceptance be incorporated into the alternatives assessment process, along with a gradual and measured implementation period.

5. **Regulatory Duplication.** DTSC must clarify precisely when a regulated product is exempt and when it is not. Otherwise this exemption will have no utility.

GENERAL COMMENTS

As a preliminary matter, the Council would like to offer the following observations and general comments about the draft regulations.

SMALL BUSINESS IMPACT

Small businesses in the United States represent an astounding *99.7* % of all employer companies.[2] They employ about half of all private sector employees, pay 43% of total U.S. private payroll, and have

[2] "Small business" is defined by the U.S. Small Business Administration as 500 employees or less.

generated 65% of net new jobs over the past 17 years.[3] Clearly, small businesses are a critical part of each state's economy – and this is particularly true in California where small businesses make up *99.2%* of firms. In fact, California routinely has more small businesses, more minority-owned business, and more women-owned businesses that any other state in the Union.[4]

This is why it is important that DTSC consider small business impacts when drafting its Safer Consumer Products regulations. At the federal level, agencies are required under the *Regulatory Flexibility Act of 1980* to assess small business impacts that could result from regulation and consider measures to "level the playing field" between large and small business. Many states, through statute or executive order, have adopted similar protections for small businesses, recognizing the strategic importance of small businesses in ensuring economic prosperity. Yet DTSC has not provided any relief or consideration for small business in its draft regulations. The requirements for conducting an AA, for example, are so potentially costly and time and resource-intensive that most small and mid-sized businesses will be unable to comply.

There is a provision in the draft regulations allowing companies to use existing AAs that are "substantially equivalent" to the Final AA report requirements (§69505.1e), and the Council applauds DTSC for including this provision. But in cases where an existing AA is not available to utilize, the burden will remain on small businesses. As such, the Council strongly urges DTSC to develop provisions providing flexibility for small and mid-sized businesses – perhaps coordinating with the state's Small Business Advocate or the SBA Office of Advocacy's Regional Office – as a way to sustain and protect the viability of this important segment of California's economy.

TIMELINES

One overarching concern that the Council has with the draft regulations has to do with the timeframes imposed on businesses. While abbreviated timeframes throughout the draft are a concern generally, they become exceedingly problematic in the context of AAs.

Specifically, the draft regulations set a 6 month and 12 month submission deadline for Preliminary and Final AA reports, respectively. While such short timelines may be workable where alternatives to a Chemical of Concern are well-known, where AA leverages data from international agencies/standards,

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[3] U.S. Small Business Administration, Office of Advocacy: http://www.sba.gov/sites/default/files/sbfaq.pdf.

[4] U.S. Small Business Administration, Office of Advocacy, *The Small Business Advocate* "Small Business Profiles by State", March 2011: http://www.sba.gov/sites/default/files/Small%20Business%20Advocate%20March%2011.pdf

and there is already widespread adoption in the priority product (e.g., nonylphenol ethoxylates in detergents), they would be very challenging in cases where data for alternatives must be created or in instances where the alternatives must first undergo testing in product formulations to ensure that it provides similar or better performance and value to the consumer.

Consider that a responsible entity has 6 months to do a desk study for the Preliminary AA, yet only 12 months for the Final AA to innovate one or more technically feasible and economically and functionally viable alternatives, develop a safety profile comparison of the chemical 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, could easily take *several years*, often with many failed alternatives cast aside at different points in the product development process. Innovation is rarely, if ever, accomplished within such a short timeframe. Such innovation, when an alternative is not well known can require 3-5 years or more, often with many failed alternatives cast aside at different points in the product development process. As such, the Council recommends including a 3-5 year timeframe to provide sufficient time for industry to identify a viable alternative.

It is equally important to note that the 6- and 12-month timing, for all practical purposes, eliminates the potential for consortia or public-private partnership approaches to accomplishing AA work. Consider that it could take months just to build a consortium, and that the assessment for both Stage 1 and Stage 2 will take far more time for a consortium to complete (than for a product manufacturer) given the level of coordination necessary.[5] The Council recommends that DTSC provide additional time/timeframes for consortia to develop and submit alternatives assessment work.

ALTERNATIVE ASSESSMENTS

The Council strongly advocates for a sensible regulatory approach for conducting an AA and encourages DTSC to consider the excellent presentations made by industry at the September 15, 2011 AA Symposium in Sacramento. At the symposium, industry identified several important factors that should be incorporated into an AA process, including:

[5] Consider the public-private partnership that was developed to address flame retardants in circuit boards: the work to identify a viable alternative is *still ongoing after more than 5 years* despite a widespread, committed level of interest and effort by industry.

- Consumer acceptance: the alternative must provide the same or better performance and *value* to the consumer;
- Flexibility: each business model is different, and even for similar chemicals/products, the AA outcome may be different (due to, for example, innovative processes or design features). DTSC should ensure that each manufacturer is given the latitude to leverage existing tools and approaches to evaluate alternative ingredients/components of their products.
- Effectiveness: 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. Likewise, DTSC should issue guidance for conducting and preparing an AA, in order to have more consistent submissions that result in more efficient reviews and that will provide small businesses with a template for preparing such assessments.
- Informed Decision-making: trade-offs must be understood and considered to avoid unintended consequences.
- Gradual and measured implementation: 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.

In addition, DTSC should include some sort of "feasibility check" on a particular regulatory response 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.

REGULATORY DUPLICATION

The Council applauds DTSC for including an exemption in the draft regulations for chemicals and products that are already regulated by one or more federal or state government entities.[6] Under this exemption, if a chemical or product is regulated by another state or federal agency for the same public health concern or environmental impact that is the basis for its listing by DTSC, then it would be exempt.

Under the Food, Drug and Cosmetic Act of 1938, personal care products are comprehensively assessed for human health concerns and regulated by the U.S. Food and Drug Administration (FDA). Consequently, if a chemical-product combination is identified by DTSC *solely* because of questions on human health, and the product is a personal care product, there would be "regulatory duplication" with FDA and that product therefore would be exempt from these regulations. In order to accomplish the purpose of this exemption, DTSC will need to provide its rationale for why a particular chemical-product

[6] §69501(4)

combination was selected (e.g. life cycle segment of concern, route of exposure concern, etc.) so that companies can determine whether the exemption will apply. The Council recommends DTSC include language to this effect in the regulations.

Moreover, in order for this exemption to have any utility, it must be very clear how it will operate. DTSC must provide clear guidance in the regulations, preferably using examples of products that would be exempt under this provision, in order to make it effective. As currently drafted, the exemption is too vague and offers no real insight into how it will apply.

Finally, the Council would also recommend amending the draft regulations to state that, where a federal or state agency has the *authority to regulate* (even if it chooses not to), this should be sufficient to justify an exemption. If an exemption is provided for in these cases, and DTSC decides to regulate, it could potentially lead to overlapping regulations by different authorities, particularly if the other agency decides to regulate at some time in the future. This will result in confusion and uncertainty for the regulated community.

ANTITRUST

The Council strongly supports the provision allowing a consortium of companies, private-public partnership or trade association to fulfill, in lieu of the responsible entity, the requirements set forth in these draft regulations.[7] There can be great benefits to such efforts to drive innovation on common problems. Nevertheless, DTSC must recognize and address the potential antitrust concerns with such a provision.

Consider that to form a consortium of companies, public-private partnerships and trade associations, multiple responsible entities are brought together. If these entities were to collaborate on developing an AA, for example, they would need to share and discuss confidential competitive information,[8] prices of ingredients or products, and internalized costs to businesses,[9] and business plans.[10] The sharing of such information is markedly different from the EU's REACh program, which allows data sharing within its Substance Information Exchange Fora (SIEF), because the REACh data are limited to only health and environmental toxicity considerations.

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[7] §69501.3(a)(2)

[8] §69505.4(a)(2)(B)(1) and (2)

[9] §69505.4(a)(2)(B)(3) and (C)

[10] §69505.4(c)

Moreover, since formula variation is often the very basis of market competition, the members of the consortium would be consistently be faced with 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.

The Council strongly recommends that DTSC continue to include the "consortia" provision, but further consider what action will be necessary to mitigate the antitrust concerns discuss above.

SPECIFIC COMMENTS

The Council also offers these specific comments to the individual provisions of the draft regulations:

ARTICLE 1: GENERAL

§69501: Purpose and Applicability
Subparagraph (b)(4)(a) - PAGE 4

As mentioned above, the Council supports the inclusion of the "regulatory duplication" provision that exempts consumer products already regulated by one or more federal or State of California regulatory programs, or international trade agreements, providing equivalent or greater protection of public health or the environment.

While the Council continues to maintain that under this provision personal care products are exempt, or at a minimum, that chemical-product combinations of a cosmetic selected for human health reasons are exempt, we also suggest the following additional change. Given that DTSC is referencing examples of U.S. safety authorities in their hazard determination, it should also include internationally recognized regulatory programs, such as the European Commission's Scientific Committee on Consumer Safety (SCCS), or at a minimum give manufacturers the option to follow international guidance that already considers environmental impacts.

To that end, the Council recommends modifying Subparagraph (b)(4)(a) to read as follows:

> *"This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s),* ***and/or***

internationally recognized regulatory programs, *and/or applicable international trade agreements ratified by the United States Senate, that, in combination...."*

§69501.2: Definitions
Subparagraph (9)(A): Alternative – PAGE 7

The definition of "alternative" should not require the removal of product functions. Less performance is ultimately less competitive and less sustainable in the market.

As such, Subparagraph (9)(A), which defines the removal of a chemical of concern as an "alternative", should be stricken in its entirety.

Subparagraph (25): *De minimis* – PAGE 9

The Council suggests DTSC set a uniform *de minimis* amount for all chemicals at 0.1%. This would make the draft regulations consistent with a majority of state, federal and international regulations, including the European Union's R.E.A.C.H. framework, which employs a 0.1% by weight *de minimis* threshold for reporting. Both Washington and Maine, as part of their green chemistry regulations, have articulated a 0.1% *de minimis* threshold as well.

In addition, the definitions of the hazard characteristics cited in DTSC's draft regulations, derived from title 22, California Code of Regulations, division 4.5, chapter 54, are extremely broad and bear no relationship to consumer product exposures. For example, data suggesting that a chemical is an oral carcinogen or neurotoxicant would categorize that chemical as a carcinogen with a lower *de minimis* level despite the fact that it is unlikely to be ingested in consumer products.

To avoid these issues, the Council recommends adjust the *de minimis* definition as follows:

(25) "De minimis level" means 0.1% by weight.

Subparagraph (70): Safer Alternative – PAGE 15

With regard to the definition of a "safer alternative", the Council recommends the following change to better reflect the purpose of the alternatives assessment process in draft regulations:

(70) "Safer alternative" means an alternative that, in comparison with the existing Priority Product, reduces or avoids, potential exposures to, one or more Chemical(s) of Concern, <u>is determined by the alternative assessment</u> so as to reduce potential adverse public health and environmental impacts.

If the presence of a chemical in a consumer product does not lead to significant exposure to that chemical, eliminating its use would be of no public health benefit. In that case, the choice of an alternative that eliminates use of a Chemical of Concern would be of no use.

Subparagraph (74): Technologically and Economically Feasible Alternative – PAGE 16

Companies can only control the costs of what they purchase, manufacture and commercially sell. Traditionally, it is the responsibility of the government and not the manufacture 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.

Manufacturers would not have the visibility on all externalized costs. Until validated methods and systems are in place to accomplish this aggregation, the Council recommends the following change:

> *(74) "Technologically and economically feasible alternative" means an alternative product or chemical for which:*
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> > ~~***(C) The alternative does not increase aggregate externalized costs to consumers, public health, and the environment.***~~

§69501.3: Duty to Comply and Consequences for Non-Compliance
Subparagraph (a)(2): Duty to Comply – PAGE 17
The Council applauds DTSC for allowing trade associations to fulfill the requirements of this chapter on behalf of the responsible entity; nevertheless, as stated above, DSTC needs to assess and consider the antitrust ramifications of this provision, and what needs to be done to address them.

§69501.5: Chemical and Product Information
Subparagraph (a)(4): Generating New Data – PAGE 20

Under this provision, DTSC can request manufacturers generate new data if it determines it is necessary to implement the regulations. This potentially onerous requirement eliminates the competitive/economic incentive for developing data if other manufacturers can use it without compensation.

ARTICLE 2: CHEMICALS OF CONCERN IDENTIFICATION PROCESS

§69502.2: Chemicals of Concern Identification
Subparagraph (a)(1): Initial List of Chemicals of Concern

The entire chemical identification process proposed by DTSC is inherently flawed. According to the draft regulations, the Initial List of Chemicals of Concern is comprised of chemicals that exhibit a hazard trait or an environmental or toxicological endpoint, defined as being listed on any of a number of different "authoritative" lists, regardless of the relevance of the specific list to consumer product exposures. There are several reasons this approach is flawed, including:

1. **DTSC Fails to Account for OEHHA Hazard Trait Regulation**

AB 1879 directs DTSC to work with OEHHA in developing criteria to evaluate chemicals and their alternatives. The criteria would include hazard traits and environmental and toxicological endpoints identified by OEHHA, pursuant to SB 509. Yet, in its draft regulations, DTSC fails to incorporate the fundamental concept set forth by OEHHA in its proposed Hazard Trait Regulation regarding the strength of evidence linking hazard traits to particular chemicals.

The proposed OEHHA Hazard Trait Regulation draws a very important distinction in the strength of scientific evidence linking particular hazard traits to particular chemicals. For each identified hazard trait OEHHA's proposed regulation distinguishes between "*strong evidence*" linking the trait and the chemical, and "*suggestive evidence*". In fact, for each hazard trait, the specific scientific considerations that would lead to a determination of "strong" or "suggestive" are articulated in order to allow DTSC, industry and the general public to understand the basis for that determination.

In other words, a chemical would be a Chemical of Concern only where the hazard trait(s) responsible for that determination is linked specifically to that chemical by *strong evidence* as determined for that specific hazard trait under the draft OEHHA Hazard Trait Regulation ("Class One" hazard traits). Thus, only chemicals exhibiting Class One hazard traits would be listed as Chemicals of Concern. OEHHA staff would then be responsible for classifying hazard traits of each CoC through a process similar to Proposition 65, including public notice of proposed chemical listings, identifying the classification criteria considered before final listing, scientific rationale, and public notice and comment, and/or hearings.

The criteria specified by OEHHA as constituting *strong 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.

"Suggestive evidence" would have informational value in linking the chemical to a specific trait ("Class Two" hazard traits) and would be considered in evaluating alternatives. *Suggestive evidence* is typically used to describe positive, but not definitive, evidence of a causal link between a chemical and a hazard trait or endpoint. Many of the tools or mechanisms listed as "suggestive" by OEHHA are screening tools utilized to target follow-up analysis that can establish more definitively whether the specific trait is, in

fact, manifest. *Suggestive evidence* would not be sufficient in isolation, however, to determine a "Chemical of Concern" in the first place. The criteria for triggering the regulatory scrutiny in the first place (the determination of a Chemical of Concern) should be reserved for the most robust scientific judgments – i.e., those founded on *strong* evidence.

Given the vast scope and application of DTSC's draft regulations, it is critical that the links between a hazard trait and a chemical are direct, clear and scientifically justified. It is simply not appropriate to trigger such far-reaching consequences on the basis of less-than-conclusive information.

Moreover, relying on OEHHA's guidance regarding the strength of evidence required to link a chemical to a hazard trait only serves to strengthen the scientific rigor of judgments made by DTSC in identifying "Chemicals of Concern" without requiring any further testing or analysis. OEHHA has devoted a great deal of attention and effort to assessing the strength of evidence required for making a chemical of concern determination and providing the foundation for these judgments. Failure to recognize the significance of the distinction between *strong* and *suggestive evidence* only serves to frustrate the mandate to include OEHHA guidance as set forth in AB 1879.

2. DTSC Fails to Consider Exposure

The list of lists approach fails to account for exposure pathways relevant to specific consumer products. When identifying Chemicals of Concern, each chemical should be evaluated individually with the relationship between the safety data and consumer product-related exposures clearly delineated. A hodge-podge of different lists, with different criteria and no discussion of relevant exposures, is not scientifically defensible. That is, simply because a chemical is on a list somewhere doesn't mean it's relevant to the exposures DTSC is trying to regulate.

3. Sources Are Not Scientifically Defensible

The "list of lists" concept is flawed because none of the lists identified by DTSC in the draft regulations were intended to serve as an authoritative source for this type of legislation, and each one has vastly different criteria for listing a chemical. For example, the IARC list was designed to rank chemicals as to their carcinogenic potency using epidemiological, animal or *in vitro* models. Other environmental laws, such as the Safe Drinking Water Act, use that information to quantitatively estimate the cancer risk from specific exposures, and compare that estimate to a predetermined benchmark to determine the regulatory response. Similarly, the Canadian Environmental Protection Act Environmental Registry Persistent Bioaccumulative and Inherently Toxic list uses environmental effect data to quantitatively estimate the environmental effects of discharges into the environment, again comparing the estimate with a predetermined benchmark. This approach allows for scientific discourse and consensus-building

around the connection between the data and impact of interest. No other major chemical regulation takes the "binary" approach of AB 1879 that the presence of a chemical on the list is a trigger to regulation without further assessment of exposure potential. Combining this "binary" approach across a multitude of lists examining different types of exposures and effects multiplies the scientific errors and creates a hodgepodge of chemicals with no common characteristics indicative of the need for regulation.

Other notable problems with the "authoritative" sources cited by DTSC include, for example, the following:

a) California's Safe Cosmetic Program. The reference to this program is wholly inappropriate and should be eliminated. The Safe Cosmetics Act is a reporting statute, not a regulatory one, and it is rife with mistakes. According to officials charged with managing the Safe Cosmetic Act list, it contains a variety of "chemicals" – including calcium carbonate, aloe vera gel, Vitamin E, Vitamin A, etc. – that should not be listed. More importantly, there are no *de minimis* or safe harbor levels associated with the listed chemicals (i.e., assumes listed chemical is unsafe at *any* concentration), nor routes of exposure considerations. Due to these issues and other significant problems with its implementation, the Safe Cosmetic Program list has not even been made publicly available; consequently, it should not be considered an authoritative source for these regulations.

b) The Washington Department of Ecology Persistent Bioaccumulative Toxin (PBT) List. Washington's PBT list uses criteria that are inconsistent with the U.S. Environmental Protection Agency PBT list, which is also referenced. This highlights that DTSC has merely attempted an overly expansive "data grab" rather than set out scientifically valid criteria for identifying chemicals.

c) IARC 2B chemicals. As noted above, it is critical that DTSC rely only on *strong evidence* of the link between a chemical and a hazard trait or endpoint. For this reason, referencing the IARC 2B list is particularly offensive since it is comprised of chemicals that are only *possibly* hazardous, rather than *known* to be hazardous. There is no suitable justification for including IARC 2B chemicals, and thus this is another example of the problems with using a "list of lists" approach.

d) OSPAR List of Chemicals for Priority Action and OSPAR List of Substances of Possible Concern. Neither are authoritative lists, and the initial compilation of these lists did not include a deliberative scientific process or allow for stakeholder input.

e) Grandjean & Landrigan Neurotoxicants. This list is a privately developed paper, the development of which did not include a deliberative scientific review process or have opportunity for stakeholder input.

f) European Commission Category 1 and Category 2 Endocrine Disruptors. It is well known that endocrine disruption is a nascent science without strong scientific consensus. Consider that there is no universal definition of "endocrine disrupter." Moreover, endocrine disruption is essentially a mode of action; that is, endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a chemical's ability to interact with components of the endocrine system. And evidence of interaction with endocrine processes does not necessarily give rise to adverse effects.

Moreover, the list of lists approach offers no mechanism for challenging a listing. By making the list immediately public in conjunction with the publication of the final regulations, the potential harm to companies will likewise be immediate. DTSC's rationale that it intends to "send a signal to the marketplace" in publishing the initial list ignores the financial ramifications that could result from such a listing, and is very likely a "regulatory taking" under the law.

At the very least, DTSC needs to articulate the types of chemical exposures and associated safety risks they intend to reduce or eliminate with this regulation. The process of listing a specific chemical on the CoC list needs to be clearly connected with this goal and the data used to support this connection needs to be transparent and open to scrutiny by experts and members of the public. Other regulations cited as a source for AB 1879, including the Safe Drinking Water Act, the Clean Air Act, and even California Proposition 65, incorporate transparent, scientifically defensible methods for regulating specific chemicals and should be used as a model for the chemical selection process in the current regulation. Without such transparency, regulated industries have no basis upon which to challenge DTSC's determinations, further supporting the concept of "regulatory taking."

Based on the foregoing, the Council strongly recommends eliminating the "list of lists" approach for a more scientifically valid and defensible approach to chemical identification.

ARTICLE 3: CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS

§69503.2: Priority Product Prioritization

Subparagraph (a)(1): Potential Adverse Impacts and Exposures – PAGE 27

DTSC should clearly specify how public health and environmental impacts will be measured; it can't just be open-ended. Consider, for example, the Safe Drinking Water Act has specific exposure-impact

models (the "No Observed Adverse Effect Level" concept, reference doses, cancer potency factors, etc.,) which can be objectively measured, and chemicals that don't meet the criteria are subsequently regulated. DTSC's draft regulations, in contrast, have no such objective criteria; DTSC can measure and make determinations at will, making it impossible for industry to understand a chemical listing. In addition, with the lack of objective criteria to measure against, the process of alternatives assessment becomes very difficult or impossible.

Overall, this entire section is inadequate and ill defined. It must be far more transparent and objective – with objective measures and procedures established for product prioritization so that all stakeholders can be assured the process is open, fair, and objective. Further, the definition of consumer product needs to be clarified so a product named as a priority product is not overly broad and not overly narrow. Specifically, the definition of product needs to take into account, product form, production function, and product use.

Subparagraph (a)(1)(B)(4)(b)(iii): Worker Exposure – PAGE 28

Worker exposure is within the jurisdictional purview of California OSHA, which occupies the field in ensuring and addressing exposures in the workplace. This subparagraph should be deleted in its entirety, or, at a minimum, modified to read as follows:

> ***~~Workers, c~~Customers****, clients and members of the general public who use, or otherwise come into contact with, the product or releases from the product in the home, ~~workplace~~ or other location,* ***not including places of work.***

Subparagraph (a)(3): Other Regulatory Programs – PAGE 29

As stated above, the Council supports the inclusion of the "regulatory duplication" provision that exempts consumer products already regulated by one or more federal or State of California regulatory programs, or international trade agreements, providing equivalent or greater protection of public health or the environment.

Given that DTSC is referencing examples of U.S. safety authorities in their hazard determination, however, it should also include in its priority product assessment internationally recognized regulatory programs, such as the European Commission's Scientific Committee on Consumer Safety (SCCS), or at a minimum give manufacturers the option to follow international guidance that already considers environmental impacts.

To that end, the Council recommends modifying Subparagraph (a)(3) to read as follows:

> *Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs,* ***and/or internationally recognized regulatory programs****, and any applicable international trade agreements ratified by the United States Senate, under which the product or the Chemical(s) of Concern are regulated…*

Subparagraph (b)(4) and (5): Key Prioritization Criteria – PAGE 29

The references to "assembled products" and "formulated products" are totally unnecessary since part of the "Key Prioritization Criteria" that DTSC will consider already includes potential public and environmental exposures, product distribution in commerce, and exposure pathways. There is no need to single out these product classifications and therefore the Council recommends deleting them.

Subparagraph (c)(4): Saver (sic) Alternative – PAGE 29-30

As noted in the definition of "safer alternative", the Council recommends the following change to better reflect the purpose of the alternatives assessment process in draft regulations:

> ***~~Saver~~ Safer*** *Alternative. The Department may, at its discretion, consider whether there is a* ***~~readily available~~ safer alternative from an approved AA~~, that is functionally acceptable and technologically and economically viable,~~*** *to further adjust the prioritization prior to listing a product as a Priority Product.*

A "safer product" conclusion must be supported with credible evidence, and whether a product is technologically and economically viable should be irrelevant in determining product safety.

§69503.4: *De minimis* Exemption
Subparagraph (b)(1): Formulated Products – PAGE 31

This subparagraph of the draft regulation references *§69505.2(a)(25),* which does not exist. Please include the correct reference.

Subparagraph (c)(3)(A)(1a): Naturally Occurring Contaminant – PAGE 32

The reference to raw materials in this subparagraph should be clarified. As written, the phrase "that are common and are frequently used to produce the product" seems to be referring to naturally occurring contaminants instead of raw materials.

§69503.5: *De minimis* Exemption Notifications

This provision seems to require everyone to submit a *de minimis* exemption, even if the product could not possibly contain a chemical of concern. As written, manufacturers would be required to unnecessarily issue requests for *de minimis* exemption on literally thousands of formulated products that don't include the chemical of concern. The *de minimis* exemption should focus only on known detectable levels that are also below threshold values.

ARTICLE 4: PETITION PROCESS OF A CHEMICAL OR PRODUCT

Given the proposed size of the Chemical of Concern list, and the potential universe of priority products, it seems unnecessary to allow/consider petitions to add to either list. At a minimum, DTSC should disallow any entity or member of the public to request additions to the list *until such time* as each of the initial chemicals of concern and priority products has been addressed. Then DTSC could allow requests to add to the lists, and subsequently allow for petitions to evaluate such requests.

ARTICLE 5: ALTERNATIVES ASSESSMENTS

§69505: Guidance Materials
Subparagraph (b): Posting AAs on Web Site – PAGE 35

> *The Department shall also post on its website AAs that the Department is aware of, and* ***that meet all the requirements of Safer Consumer Products AAs*** *and are available in the public domain, at no cost, and are supported by reliable information. The posting shall indicate, for each AA, the name of the person that prepared the AA.*

Manufacturers are likely to use the posted AA as starting templates. Therefore any examples should fully meet DTSC requirements.

§69505.1: Alternative Assessments: General Provisions
Subparagraph (e): "Substantially Equivalent" AAs – PAGE 37

The Council supports the inclusion of the "*substantially equivalent*" language that allows a responsible entity to use an alternate AA process to meet its regulatory obligations.

Subparagraph (g): Failure to Respond – PAGE 37

This subparagraph states that any failure by DTSC to respond to a compliance determination or appeal within the specified timeframe does not automatically mean, for example, that an AA is compliant. The

Council would recommend adding language that DTSC's failure to respond also does not mean, for example, that an AA is *not* in compliance either. To that end, we suggest the following modification:

> *Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination within sixty (60) days from receipt of the Preliminary or Final AA Report, or failure of the Director to respond to an appeal submitted under section 69507.2 within sixty (60) days, shall not cause a Preliminary or Final AA Report to be deemed compliant* ***or non-compliant.***

§69505.2: Assessment of Priority Products and Alternatives
Subparagraph (b): Substantially Similar AAs – PAGE 38

The Council supports the inclusion of the "substantially similar" language that allows a responsible entity to use an alternate AA process to meet its regulatory obligations.

§69505.3: Alternative Assessments: First Stage
Subparagraph (b)(3)(C): Step 3, Initial Screening of Alternative Chemicals – PAGE 39

This subparagraph reads as follows:

1. *Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines may pose greater adverse public health and/or environmental impacts than the Chemical(s) of Concern.*
2. *Subparagraph 1. does not apply to a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern. However, a responsible entity is not required to retain, for further consideration in the AA, a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern.*

First, this section appears to switch from *potential adverse* impact to *adverse* impact, which is not defined in the draft regulations. Also if the interpretation is still on potential adverse impact, then the rule allows one to eliminate virtually all alternative candidates, as ingredient choices are just trade-offs.

Second, (C)2 is also very confusing. Does the phrase *"lesser or greater individual adverse"* mean that a scale or ranking of certain chemicals is or will be available for a manufacturer to use regarding the individual adverse impact (e.g., Is reproductive toxicity is greater than immunotoxicity? Or is carcinogenicity greater than bioaccumulative?) The Council would ask DTSC to clarify this subsection, or if it intends to prioritize hazard rankings, to share such prioritization.

Third, 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 "potential" alternatives at this initial stage. There should be an upfront narrowing approach to reduce the identified alternatives to only those that will likely result in a viable change. A quick and easy way to winnow down the list of alternatives is to include a provision for identification of "showstoppers" 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, on technological feasibility, economic feasibility, or other factors (e.g., environmental footprint), etc.

The Council recommends that in addition to identifying the function the CoC serves in meeting the Priority Product requirements and how the alternatives compare, manufacturers should be allowed to eliminate from further consideration any alternatives they deem not workable. As such, we recommend adding the flowing subparagraph:

> ***§ 69505.3.(b)(3)(C)3. Screen out 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.***

§69505.4: Alternative Assessments: Second Stage
Subparagraph (a)(1): Second Stage – PAGE 40

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 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. Likewise, the focus of any assessment should be restricted to the CoC that is the reason for the designation of the priority product.

The draft regulations do not touch exposure pathway and life cycle segment until second AA. This should be introduced much earlier in the definition of "product of concern" or through a *de minimis* like exemption. Ideally these concepts should be used in defining Products of Concern.

Further, the AA should identify "relevant" factors that 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 "demonstrable" inappropriately implies that even the slightest impact or change would be relevant. What would constitute a "demonstrable contribution" to increasing or decreasing adverse impact *and* a "demonstrable 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, "*demonstrable*" should be replaced with "*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.

As such, the Council suggests the flowing modification to this subparagraph:

> *(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.*
>
> *(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.*

§69505.4: Alternative Assessments: Second Stage
Subparagraph (A)(3): Externalized Costs – PAGE 41

Regarding economic impacts (§ 69505.4.(a)(2)(C)), the implications of "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 manufacture or industry 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. The Council recommends deleting references to such externalized costs.

Subparagraph (h)(c) and (l)(4): Supporting Information and Selected Alternative – PAGE 43-44

Regarding the list of chemical ingredients in PP and potential alternatives, §69505.5.(h)(C) within the "Supporting Information" section AND §69505.5.(l)(4) within the "Selected Alternative" section should be deleted. 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.

Subparagraph (m): Implementation Plans – PAGE 45

Within the Implementation Plan, 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)).

Subparagraph (n): Focus on Designated Chemical of Concern and Alternatives - PAGE 45

The word "any" should be removed or replaced with "chemical(s) of concern that are bases for listing of Priority Product" for products being retain or not changed and still part of the California stream of commerce. The "any" seems to go beyond the COCs used to deemed the product a Priority Product.

Since the driver of the AA is the CoC identified by DTSC 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 chemical-product combination, the manufacturer's proposed regulatory response should focus on the outcome related to that specific combination. It should not attempt to sweep in other potential CoC that were not the focus of the AA. As such, the Council proposes that the language be revised:

> *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.*

ARTICLE 6: REGULATORY RESPONSES

§69506.3: Product Information for Consumers

Subparagraph (a)(1): Selected Alternative Product – PAGE 48

Reformulation without a conclusive result in the Alternative Assessment will not lead to safer products in California. AAs that are inconclusive should be exempted. As such, this subparagraph should be deleted:

> ~~***(a)(1) Except as provided in paragraph (2), during the time that a selected alternative product, or a Priority Product for which an alternative is not selected, is offered for sale in California, the responsible entity shall ensure that all of the following information is made available to the consumer prior to any exposure to the Chemical(s) of Concern:***~~

ARTICLE 7: DISPUTE RESOLUTION PROCESSES

The Council applauds the inclusion of a dispute resolution provision in these regulations.

ARTICLE 8: ACCREDITATION BODIES AND CERTIFIED ASSESSORS

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 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.

Certified Assessors

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, 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 DTSC'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, product safety and regulatory experience should play a significant role in the time and effort necessary for certification. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors' work products) that are being certified. DTSC 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.

ARTICLE 10: TRADE SECRET PROTECTION

§69510.1: Department Review of Trade Secrecy Claims

Subparagraph (c): Judicial Review

The Council supports the inclusion of protections for confidential business information and trade secret, as these issues are critically important for businesses. Nevertheless, when a dispute arises between a company and the Department regarding the status of a trade secret claim, the filing of a claim for judicial review by a company should indefinitely toll the release of protected information until the court has resolved the dispute.

As such, subparagraph should be amended as follows:

*If the submitter fails to cure the deficiency within the timeframe specified, the Department shall notify the submitter by certified mail that the claimant is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief. ~~During this 30-day period, and for any longer period ordered by a court of law, t~~**Upon such filing for judicial relief, T**he Department shall not publicly release or disclose the claimed trade secret information **until a final decision has been made by a court of law as to its protected status.***

CONCLUSION

The Council would like to thank DTSC for its efforts in crafting regulations to reduce or eliminate hazardous chemicals from consumer products. The Council greatly appreciates DTSC's ongoing effort to engage the businesses and promote transparency in the process, as well as the extensive time and effort expended by its staff in making the revisions.

Regardless of these procedural questions, the Council still hopes to use this as an opportunity to work collaboratively with DTSC during the implementation phase of the green chemistry regulations. Given that our member companies' products are among the primary focus of the revised regulations, the Council would like to be in a position to positively influence the method and manner that the green chemistry regulations are ultimately implemented.

The Council appreciates the intent of California lawmakers to reduce the hazards associated with exposure to toxic chemicals in consumer products and ultimately their environment. Our industry is also committed to that goal and has created internal structures and processes, based on scientific principles and described in presentations to DTSC in June 2011, to insure the health and environmental safety of our consumers while providing the product performance, stability and other attributes they expect. This regulation, with its overly broad and opaque standards for categorizing chemicals and extremely restrictive processes for evaluating alternatives, will effectively reverse our own attempts at creating safer products by creating a confusing, contradictory set of goals and mandates. Our creativity and innovation will suffer as we divert our resources to complying with this regulation. We appreciate that DTSC faces a statutory deadline for issuing these regulations, but we believe that it is critical that DTSC construct a program that is workable from the onset, with a narrowly drawn scope, requirements that are not cost-prohibitive, and flexibility in its approach to innovation.

To that end, the Council urges you to consider our comments, and those of the Green Chemistry Alliance of which the Council is a member, to avoid creating barriers to innovation, detrimentally impacting the

California and U.S. economy, and ultimately failing to improve protection of public health and the environment.

Sincerely,

Thomas F. Myers
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December 30, 2011

(IC)42- Boots Retail USA

California Department of Toxic Substances Control
1001 "I" Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Comments on Informal Draft Regulations for Safer Consumer Products R-2011-02

Boots Retail USA wishes to draw attention to the following comments concerning the Informal Draft Regulations:

Section 69502.2 - Chemicals of Concern Identification.

Notice and opportunity for public comment

Prior to finalizing the initial Chemicals of Concern List, public notice of the initial List should be provided with an opportunity for public comment, as is currently the case in the Informal Draft for the initial Priority Products List[1].

Retain the Safe Harbor/Exceptions in source list for a Chemical of Concern

A chemical that is included in the initial and subsequent Chemicals of Concern List should retain the same exemption that the source list for the chemical provided. For example, California's Proposition 65 provides a safe harbour level for Retinol and Retinol Esters in daily dosages of less than 10,000 IU, or 3,000 retinol equivalents. Also Carbon Black and Titanium Dioxide are not covered, if they are not airborne, unbound particles of respirable size or if they remain bound in a product matrix.

Section 69503.4 - De Minimis Exemption

Provide opportunity for notice and public comment

Public notice and the opportunity for comment should be provided when the Department of Toxic Substances Control (DTSC) moves to establish a lower or higher De Minimis exemption level than previously specified for a Priority Product, if it meets certain

[1] Sec. 69503.3(b)

criteria[2]. This should be done prior to the change being finalized, as is provided for the initial Priority Products List. Notice and the opportunity to comment is especially important in the case where a change would trigger the 180 day deadline for submission to the DTSC of a Preliminary Alternatives Assessment (AA) Report.

Section 69504 and 69504.1 - Applicability and Petition Contents, and Technical Review of Petitions

Define "Reliable information"[3]

The DTSC should provide guidance as to what constitutes the "reliable information" that must be submitted in support of a petition to the DTSC to include a chemical in the Chemicals of Concern List or a product in the Priority Products List. Such information should be based on scientific fact, in the context of relevant peer-reviewed scientific reports and studies confirmed by a recognized and established relevant scientific body.

Section 69506.1(b) - AA Report Supplemental Information Requirements

The guidance[4] that the DTSC will prepare to assist in "performing AAs" should include a clarification as to what is meant by the term "unavailable reliable information that, if available, could be used,"[5] otherwise known as an "information gap." Clarification as to what is meant by the term is critical given that the DTSC can "at any time require the responsible entity to obtain or develop information to fill one or more of the information gaps identified in the final AA report."

Article 8 - Accreditation Bodies and Certified Assessors

In the final regulation, the DTSC should clarify whether entities and individuals located outside of the United States are eligible to be designated as Accreditation Bodies[6] and as Certified Assessors[7].

Sincerely,

Ansis M. Helmanis

cc: Steve Lloyd, CEO, Boots Retail USA

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[2] Sec.69503.4(c)(1) and (2)
[3] Sec.69504(a)(5)
[4] Sec.69505
[5] Sec.69505.5(h)(2)
[6] Sec.69508.2
[7] Sec.69508

(IC)43- The American Industrial Hygiene Association

December 29, 2011

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

RE: Draft Regulations for Safer Consumer Products, Chapter 55, Division 4.5, 22CCR

Submission via electronic means – GCRegs@dtsc.ca.gov

Dear Ms. Jones:

The American Industrial Hygiene Association (AIHA) expresses its appreciation to the California Department of Toxic Substances Control (DTSC) for the opportunity to comment on the draft regulations for Safer Consumer Products, Chapter 55, Division 4.5, Title 22 California Code of Regulations.

AIHA, and its 10,000+ members, is the premier association serving the needs of professionals involved in occupational and environmental health and safety practicing industrial hygiene in industry, government, labor, academic institutions, and independent organizations. The AIHA mission is to promote healthy and safe working environments by advancing the science, principles, practice, and value of industrial hygiene. A healthy workforce is essential to the success of American industry, our economic recovery, and our future position in the global economy.

These comments are in addition to the comments submitted by the California Industrial Hygiene Council and are the board approved comments of the national AIHA. Comments on this draft were developed by the AIHA Stewardship and Sustainability Committee.

AIHA offers the following comments on this Draft:

Comments for the Proposed
DTSC Safer Consumer Products Regulation

This proposed regulation has been reviewed by members of the AIHA Stewardship and Sustainability Committee and comments are based from the perspective of the AIHA position paper "Integrating Stewardship and Sustainability Considerations in Chemical Management Reform and Innovation". AIHA promotes the development of science-based public policy to better inform the potential risks and benefits of chemicals. Effective Chemical policy reform

should drive effective prioritization of chemical risks based not exclusively on their intrinsic hazards, but also on the potential for occupational exposures in the workplace, during consumer use, and through “end-of-life” management or disposal. While AIHA supports the movement toward safer chemicals that this regulation attempts to promote, the committee has several concerns with the framework and implementation of this proposed rule which are detailed below:

Priority Products Prioritization (Section 69503.3)
This proposed rule wrongly presumes that the presence of chemical in a product which makes the chemicals of concern (COC) list, and is above an arbitrary de minimus levels at the component level, should be evaluated for substitution. The criteria to determine whether a chemical moves onto a list of “chemicals of concern” must be scientifically and technologically sound. This determination should not be based solely on the intrinsic hazard of a chemical without consideration of the product life cycle, exposure potential, and application (intended use). This approach also fails to consider the societal value of a material. In addition, the inclusion of a chemical to the list of “priority products” based on broad de minimus level is of concern. There are maximum concentration levels (MCLs) for many materials that would not fit any of the criteria for concern. These include disinfectants, copper, and nitrate to mention a few. For instance, if a consumer product contains copper over the de minimus level, would it need to be removed?

Chemicals of Concern Identification (Section 69502.2) The list that identifies a chemical of concern under section 69502.2 is too broad and not well prioritized. For example, the inclusion of the following lists pose problems: bodies of water in California, pollutants requiring monitoring (L) and all of the (2) lists. Some of these lists like the Oslo/Paris convention for the protection of the marine environment of the northeast Atlantic (OSPAR) List of Substances of Possible Concern may include chemicals for which there is no actual reason for their presence on this list other than a structural similarity to a chemical of concern. The “authoritative” bodies are far too wide and includes very questionable lists (i.e., Center for Evaluation of Risks to Human Reproduction (CERHR) no longer exists).

Alternatives Assessment (AA) (69505.1, 69505.2)
The methods/models used and qualifications needed to conduct a sound alternatives assessment are not clear in these sections and are subject to abuse. Established Life Cycle Assessment methods should be used to evaluate potential environmental and health impacts in order to make informed risk based decisions through comparative analysis of chemicals and substitutes. This responsible and robust evaluation is necessary to assure that burdens are not simply shifted or result in unintended consequences. It is unclear how the AA process addresses how one would weigh categories if alternatives proved beneficial in one endpoint category but worse in another category when compared to the priority list chemical. It is critical the use/application of the chemicals and alternatives must be carefully considered in such evaluations. For example, the precautionary purchasing efforts in San Francisco used a robust AA process to determine that the selection of a less toxic pressure treated wood could be used in playgrounds (replacing the carcinogenic chromated copper arsenate with a less toxic copper compound). However, this copper alternative would be detrimental for marine species and thus not used in aquatic environments. Thus, the AA did not lead to an automatic ban of the chemical of concern. How would this rule assure that all AA processes follow a robust evaluation as to avoid making potentially devastating decisions on chemical use? How is this managed?

Alternative Assessor Certification
This requirement is severely flawed. How can anyone have four years of professional experience performing an assessment that this regulation invented? How would competency be measured? What experience and knowledge is needed? It is vital that this assessment be conducted by a qualified person who understands life cycle assessment (LCA) modeling and the complexities of such studies (i.e., data quality, uncertainty in end point analysis, interpretation of results, potential rebound effects, etc.). The qualifications for accreditation bodies are also of concern. For instance, the ability to teach maternal and child health would qualify you to be an accrediting body?

General Comments of the Overall Framework

- The regulation needs to shift the burden of the identification and reporting of consumer product risks from the regulating bodies to the manufacturer/producer of the product. This was the major paradigm shift caused by the EU's Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) directives. This proposed regulation by the California Department of Toxic Substances Control keeps this burden at the regulatory level. This has been one of the major criticisms of the Toxic Substance Control Act (TSCA) and a key reason why TSCA has been such a regulatory failure.

- The proposed regulation is flawed in that DTSC is proposing to take on the role of other agencies. For example: Section 69502.3 Chemicals of Concern list – The chemicals of concern identification (section 690502.20) includes lists from international, State and Federal environmental and health agencies. This is a very comprehensive list which includes a wide range of chemicals of concern. This raises the question as to why DTSC needs to take on the role of the identification of additional chemicals of concern. At the State level this role is already played by the Office of Environmental Health Hazard Assessment (OEHHA). OEHHA has this role for the Prop 65 list which is one of the referenced lists in the proposal. Why create another regulatory body when there are more than a sufficient number of listed chemicals where more chemicals continue to be added.

- Priority Product Prioritization – Once again the DTSC is taking on the role that should be that of the manufacturer/producer of the product. Rather than taking on this role DTSC should look to existing LCA schemes for this evaluation and require the manufacturer/producer to follow these schemes.

- Insufficient staff and budget to effectively enact this proposed regulation – The current proposed regulation would require the addition of significant staff and budget. The current financial budget crisis creates insurmountable hurdles to the enactment and implementation of this proposed regulation as it is currently written.

As DTSC moves forward, AIHA offers its breadth of experience as a resource to assist the DTSC with this initiative. Providing sound science to the policymaking process remains a goal of AIHA and our members. AIHA appreciates the opportunity to work with DTSC to help

achieve the mutual goal of protecting American workers and we look forward to further opportunities to work with the DTSC on this and similar issues and regulatory priorities.

If AIHA can be of any further assistance, please contact me. Thank you.

Sincerely,

Aaron K Trippler
(signature)

Aaron K Trippler
Director, Government Affairs
AIHA

cc: Chair, AIHA Stewardship and Sustainability Committee
California Industrial Hygiene Council - Officers

Association Connecting Electronics Industries

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December 28, 2011

Via Electronic Submission

California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
1001 I Street
Sacramento, CA 95814-2828

RE: Informal Draft Safer Consumer Products Regulation

IPC – Association Connecting Electronics Industries® appreciates the opportunity to comment on the Department of Toxic Substances Control's (DTSC) informal draft regulation for Safer Consumer Products (hereafter referred to as proposed regulation). IPC is a strong advocate of environmental regulations that provide an environmental and economic benefit and protect human health. IPC is seriously concerned that the proposed regulation will fail to improve the health and safety of California's citizens because the proposed scope is unwieldy and un-implementable. IPC believes a targeted, prioritized approach will allow industry and DTSC to effectively use available resources. Should DTSC wish to expand the scope of covered products and chemicals, a phased-in approach would ensure that all products and chemicals of concern are eventually covered in the regulation. IPC is also concerned that the proposed time frame for alternatives assessments is impractical for companies to comply with and DTSC to enforce. The citizens of California, DTSC and industry would all be better served by a more manageable approach to a green chemistry regulation.

I. About the IPC

IPC, a U.S. headquartered global trade association, represents all facets of the electronic interconnection industry, including design, printed board manufacturing and electronics assembly. Printed boards and electronic assemblies are used in a variety of electronic devices that include computers, cell phones, pacemakers, and sophisticated missile defense systems. IPC has over 3,100 member companies, including over 250 member companies located in California. As a member-driven organization and leading source for industry standards, training, market research and public policy advocacy, IPC supports programs to meet the needs of an estimated $1.7 trillion global electronics industry.

IPC is committed to a number of voluntary environmental initiatives including several of EPA's Design for the Environment partnership projects, the development of the Electronic Product

Environmental Assessment Tool (EPEAT) standard[1], and the green chemistry standard through the American Chemical Society and National Standards Foundation.

II. DTSC Should Adhere to the Original Plan for a Green Chemistry Regulation

IPC strongly encourages DTSC to adhere to its original science-based, lifecycle approach to evaluating chemicals under a green chemistry regulation. The California legislature initially envisioned a regulation that would move California toward a cradle-to-cradle economy, which focuses on a product's lifecycle and attempts to ensure minimal waste or pollutants are produced at any stage of a product's life. DTSC's proposed regulation directly undermines this goal by proposing to publically list chemicals of concern and priority products prior to conducting an alternatives assessment. Listing chemicals of concern and priority products for unknown reasons and/or undefined impacts prior to fully evaluating the environmental, social and economic impacts of potential alternatives will create de facto black lists and could have detrimental unintended environmental consequences. Electronics manufacturers use certain chemicals of concern because of their unique energy efficiency, safety or performance characteristics when no viable or environmentally-preferable substitutes exist. For example, review of the U.S. Environmental Protection Agency (EPA) Lead Free Solder project[2] illuminates the environmental trade-offs inherent in chemical substitutions. The study evaluated the environmental impacts of tin-lead solder versus lead free alternative solders. According to the study, the increased energy use associated with the higher operating temperatures required for manufacturing lead free soldered electronics was projected to cause higher air pollution, acid rain, stream eutrophication, and global warming impacts than tin-lead soldered electronics. In addition, adverse impacts to waste water were caused by nickel compounds and cyanides in lead free solders that are not contained in tin-lead solders. Listing chemicals and products to be banned without conducting thorough, comprehensive alternatives assessments will inevitably lead to inadvertent negative environmental impacts.

III. DTSC Will be Challenged in Attempting to Implement and Enforce Such a Far-Reaching Regulation

The proposed regulation places a great deal of responsibility on the state of California. Given California's limited resources, IPC is concerned that complete, appropriate enforcement and implementation of this proposed regulation may be beyond the current capacities of the state. In order to ensure an effective regulation, DTSC will need to hire a number of additional technical staff to evaluate the voluminous amount of information that will be received. Under the proposed regulation, DTSC staff must:

- Prioritize Chemicals of Concern (COCs) and Priority Products.
- Evaluate and approve alternative assessment work plans and reports received from hundreds of manufacturers in a timely manner.
- Carry out enforcement action against manufacturers who do not obey any part of the regulation once implemented.

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[1] http://www.epeat.net/

[2] U.S. Environmental Protection Agency. August 2007. *Solders in Electronics: A Life Cycle Assessment.* Available at http://epa.gov/dfe/pubs/solder/lca/index.htm.

IPC encourages DTSC to implement the changes suggested in these comments to ensure the draft regulation is implementable and enforceable.

IV. The Proposed Regulation Subject to Review Under Other State Legislation

As currently written, the proposed regulation would be subject to review under S.B. 517. S.B 517 requires all major regulations to undergo a rigorous economic analysis before they can be adopted. The proposed regulation qualifies as a major regulation because it would cost industry over $50 million. IPC commends Governor Brown for signing an important piece of legislation that, if implemented and enforced, would reduce regulatory burdens on California's businesses.

V. Prioritizing Chemicals of Concern is Essential for an Effective Regulation

IPC believes that DTSC has taken on an enormous, unmanageable task by proposing to initially list thousands of COCs. DTSC needs to prioritize COCs in order to have a manageable, effective regulation. If DTSC attempts to regulate thousands of chemicals all at once, the agency will not be able to enforce the regulation. DTSC will be inundated by the thousands of alternatives assessments for each use of each of the thousands of regulated chemicals. By addressing thousands of COCs at once, the extremely hazardous chemicals will be lost in the shuffle and may not be adequately addressed. Using a prioritized list of COCs based on actual risks will allow DTSC to phase-in additional chemicals at an orderly, manageable pace, resulting in an efficient and effective green chemistry regulation.

Listing COCs prior to thoroughly evaluating their potential risk to human health and the environment will create a de-facto black list of chemicals. Prior to listing a COC, DTSC should ensure that each COC listed in a final regulation has been thoroughly evaluated to ensure they pose a substantial risk to human health and the environment. Failing to do so will create a black list of chemicals and could cause regrettable substitutions. A list of COCs will force companies to quickly replace those chemicals without first conducing comprehensive alternatives assessments to ensure the replacement chemical is better for human health, the environment, and product functionality. DTSC should implement a phase-in approach for identifying COCs rather than initially listing thousands of chemicals in order to avoid regrettable substitutions.

While IPC believes COCs should be listed individually rather than referencing lists, the lists of chemicals cited in the proposed regulation that would be considered COCs should be reevaluated. The lists referenced in a final regulation should be authoritative lists from public regulatory bodies. However, all of the lists referenced in the proposed regulation are not from authoritative bodies. For example, Proposition 65 contains several chemicals because they were included on other lists. COCs identified in a final regulation, whether it is individually or on a list, should have strong scientific evidence to support that they are harmful to human health and the environment. COCs from sources without any supporting scientific basis should be ignored. DTSC should review the lists of chemicals included in the proposed regulation to ensure they are lists from authoritative bodies.

VI. The Criteria for Prioritizing Priority Products Should Include Risk

The criteria for prioritizing Priority Products should include risk. In order to include risk in and streamline the prioritization process, DTSC should use the following criterion for prioritizing Priority Products: Significant potential for public and environmental exposures to the COC(s) in quantities that can result in adverse public health or environmental impacts. This criterion incorporates the other proposed criteria and takes both hazard and risk into consideration. Furthermore, DTSC should not determine that a product is a Priority Product solely based on its wide distribution in commerce and use by consumers. There is no correlation between the quantity of a product in commerce and its toxicity or potential to cause adverse health and environmental impacts. DTSC should use the criterion proposed above in order to efficiently identify products that pose the greatest risk to human health and the environment.

VII. The Contents of a Petition to Include Additional Chemicals/Products Must Be Robust In Order to Ensure Efficiency

The supporting information for a petition to add additional COCs and/or Priority Products must contain strong scientific evidence. DTSC should set a high level of completeness and quality for all petitions received. DTSC should require the same quality of information as an EU REACH dossier. This level of completeness and quality would help DTSC ensure they are receiving quality information and that their resources are efficiently used. Requiring quality information would help DTSC focus on important chemicals and products not already included. DTSC should set rigorous qualifications for the information contained in all petitions submitted for review.

VIII. A De Minimis Threshold Should Be Included in a Final Regulation

IPC commends DTSC for establishing a de minimis threshold. A de minimis threshold will help ensure that the significant uses of COCs are addressed. COCs used in trace amounts typically do not cause significant adverse impacts to human health and the environment. IPC supports establishing a de minimis threshold in a final regulation.

IX. The Process for Performing an Alternatives Assessment is Complex and Burdensome

IPC believes that DTSC has grossly underestimated the amount of resources needed to conduct an alternatives assessment and substitution, if necessary. Finding viable alternatives that provide the same level of functionality and reliability takes a great deal of time (years) and effort. For example, the EPA's Design for the Environment (DfE) Flame Retardant in Printed Circuit Boards Partnership[3] has been working for five years to evaluate alternatives for certain flame retardants found in printed circuit boards. When evaluating alternatives, it often requires consideration of the entire product, a process that often takes several years, because drop-in replacements are rare. Manufacturers must conduct an analysis of each potential alternative to determine whether it is better for human health and the environment than the substance being removed. If the determination is made that the alternative is better, the manufacturer must produce a small number of products that contain the alternative chemical and those products must go through several rounds of requalification testing to ensure the product is reliable,

[3] http://www.epa.gov/dfe/pubs/projects/pcb/index.htm

functions properly and meets the same product specifications. If the newly formulated product does not meet the performance specifications then the manufacturer must repeat the entire process.

We urge DTSC to outline an implementation timeline of no less than four years for manufactures to complete an alternatives assessment of chemicals or products that pose an actual risk. This time frame is similar to the time frame set forth in the European Union Restriction of Hazardous Substances (RoHS) Directive, which allows manufactures enough time to ensure that their product can function properly and reliably without the restricted substance. IPC members are still dealing with issues with lead-free electronics resulting from the RoHS ban on lead in electronics since that directive became effective on July 1, 2006. Giving manufacturers at least four years to conduct an alternatives assessment will ensure that consumer products manufactured and sold in California will function properly and reliably.

DTSC should allow manufacturers to continue using a COC in a Priority Product if the alternative provides the same level of human health and environmental protection. COCs in a Priority Product should only be replaced if the alternative provides an increased human health and environmental impact. Replacing a COC with an alternative that does not provide an increased human health and environmental benefit would waste resources without providing a commensurate benefit.

IPC commends DTSC for proposing partnerships to aid in compliance. Partnerships have the ability to bring the best resources and expertise together so that the alternatives assessment will provide valuable information that industry and DTSC can use. Partnerships will significantly reduce the amount of resources expended by both industry and DTSC because duplicative alternatives assessments will be eliminated. DTSC should include the establishment of partnerships in in a final regulation.

X. Completed Alternatives Assessments Should Not Be Posted on DTSC's Website

DTSC should not post completed alternatives assessments (AA) on their website. Based on the proposed scope of an AA, manufacturers will spend a significant amount of resources to complete an AA and posting the final AA for some else to use, free of charge, puts the manufacturer that conducted the AA at a competitive disadvantage. DTSC should consider an alternative approach to making a final AA publicly available. DTSC could implement a provision that would require a manufacturer to release an AA upon request from an interested stakeholder. DTSC could also consider requiring manufacturers to register with the agency in order to have access to final AAs. IPC strongly urges DTSC to consider an alternative approach to making final AAs publicly available in order to avoid putting manufacturers at competitive disadvantages.

XI. The Proposed Regulation Appears to Violate Existing State Legislation

The proposed regulation fails to comply with AB 1879 because the proposed regulation does not establish simple, readily available tools to assist with compliance. In particular 25253 (c) states:

> The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

In the proposed regulation, DTSC has not ensured that tools are available, simple, and accessible to aid manufacturers in decision-making and compliance. While the proposed regulation states that guidance materials will be made available, IPC believes these guidance materials should be available now, so that manufacturers can review them to determine how they will meet the requirements. DTSC must ensure that simple, accessible tools for compliance to the proposed regulation are available to the regulated community prior to finalizing the regulation in order to ensure compliance with AB 1879.

XII. Conclusion

IPC is a strong advocate for scientifically-based environmental regulations that improve environmental conditions, protect human health, and stimulate the economy. It is essential for DTSC to scale down the scope of the proposed regulation in order to implement a feasible regulation. If DTSC attempts to take on too much at one time, the entire program may fail. DTSC, industry and citizens of California would be better served by an incremental program that implements a phased-in approach to chemicals regulations. Finding viable alternatives takes a great deal of resources to ensure that the alternatives are better for human health and the environment and provide the same level of functionality and reliability. IPC urges DTSC to allow ample time for manufacturers to complete alternatives assessments. Simplifying the draft regulation will enable DTSC to more easily implement and enforce the regulation.

IPC appreciates the opportunity to comment and encourages the agency to take our suggestions into strong consideration.

Sincerely,

Stephanie Castorina
Manager, Environmental Programs

San Francisco Water Power Sewer
Services of the San Francisco Public Utilities Commission

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(IC)45- San Francisco Water Power Sewer

December 27, 2011

Via email: drafael@dtsc.ca.gov & gcregs@dtsc.ca.gov

Debbie Rafael
Director
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulations, R-2011-02 October 2011 Post-Hearing Changes

Dear Ms. Rafael,

I am writing to express my support for recent changes by the Department of Toxic Substances Control (DTSC) to the proposed Safer Consumer Products Regulations and to communicate a few outstanding concerns.

The San Francisco Public Utilities Commission (SFPUC) treats millions of gallons of wastewater and stormwater each day to remove harmful pollutants before the water is discharged into the San Francisco Bay and the Pacific Ocean. That effort is made more difficult by toxic, bioaccumulative chemicals found in a wide variety of consumer products.

DTSC's latest draft of the Safer Consumer Products Regulations is a bold step in the right direction for California and I commend your agency's efforts. Specifically, the new draft regulations have improved the process by which products are placed on the list of Priority Products, changed the prioritization criteria to include considerations such as worker safety and potential adverse public health and environmental impacts, and expanded the scope of entities that may be responsible for compliance with the regulations.

I support the recent changes lowering the levels of chemicals considered to be de minimus. However, I urge DTSC to exercise its authority to specify even lower de minimus levels when toxic chemicals have hazard traits with serious potential impacts at trace amounts such as endocrine disrupters. I am also

Edwin M. Lee
Mayor

Anson Moran
President

Art Torres
Vice President

Ann Moller Caen
Commissioner

Francesca Vietor
Commissioner

Vince Courtney
Commissioner

Ed Harrington
General Manager

concerned by the absence of mandatory third party review of each Alternatives Assessment. Given the ability of companies to claim trade secrets while having their own certified scientists doing alternatives assessments, it is crucial that there be meaningful third party review to protect public confidence in the process.

Missing from the proposed regulations is language expressly stating that nanomaterials are chemicals that may be subject to the regulations. While nanotechnology has a bright future, it is important we proceed with a careful eye toward public health and environmental impacts. I also urge DTSC to include language stating that when the Safe Consumer Products Regulations are in conflict with other state or federal regulations that the strictest regulation in regard to toxicity shall prevail.

California is about to embark on a ground breaking new approach to chemicals regulation; and the recent changes to the Safer Consumer Products Regulations give me new hope that our efforts will be successful in protecting public health and the environment. Thank you for your consideration of my concerns.

Sincerely,

Francesca Vietor
Commissioner
San Francisco Public Utilities Commission

cc: Regulations Coordinator, Department of Toxic Substances Control (gcregs@dtsc.ca.gov)

December 27, 2011 (IC)46- Bay Area Clean Water Agencies

***Sent via email to:* gcregs@dtsc.ca.gov**

Department of Toxic Substances Control (DTSC)
P.O. Box 806
Sacramento, CA 95812-0806

Re: Comments on Informal Draft Regulations for Safer Consumer Products: R-2011-02

Dear DTSC Staff:

The Bay Area Clean Water Agencies (BACWA) appreciates the opportunity to comment on the Informal Draft Regulations for Safer Consumer Products. BACWA is a joint powers agency, formed under California Government Code section 6500 *et seq.*; our members own and operate publicly-owned treatment works (POTWs) and sanitary sewer systems that provide sanitary services to over 6.5 million people in the nine-county San Francisco Bay Area. BACWA members are public agencies, governed by elected officials and managed by professionals charged with protecting the environment and public health.

BACWA applauds DTSC staff for their work on the draft regulations for Safer Consumer Products. BACWA hopes that these regulations will provide a mechanism for preventing harm to public and environmental health from consumer products. POTWs are very effective at removing many kinds of biological and chemical pollutants from municipal wastewater before it is discharged to our lakes, rivers estuaries and oceans. However, it is impossible for POTWs to treat or control (through pretreatment or pollution prevention outreach) the vast array of organic and inorganic compounds that are in commercial use today. Some of these chemicals will pass through the treatment plant unchanged where they may harm aquatic life and/or indirectly enter into the drinking water supply. Other chemicals may be degraded or transformed through the natural treatment process into new compounds with environmental implications. Chemicals removed from wastewater may partition into our biosolids (sewage sludge), which could limit options for beneficial reuse of these rich organic materials. Finally, some compounds may harm the biological treatment processes themselves, thereby interfering with a POTW's ability to comply with regulations designed to protect water quality.

In the past, POTW's ability to take action on a specific compound was limited largely to the legislative arena. For example, municipal wastewater agencies have appealed to the legislature for assistance controlling the following products:

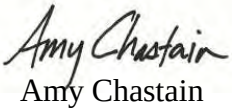
- Mercury in thermometers, thermostats, lighting and switches;
- Copper in brake pads;
- Paradichlorobenzene in urinal deodorizers; and
- Lindane in head lice and scabies treatments (non-pesticide products).

While successful, these efforts took many years and many resources to accomplish and highlighted the need for a more comprehensive and coordinated approach. Wastewater agencies are encouraged that DTSC's regulations may address many pollutants of concern to the wastewater community. We have attached detailed comments to ensure that the regulations are sufficiently robust to address products that threaten harm to the water environment and our public infrastructure.

One way to ensure that wastewater treatment and water quality priorities are addressed is by seeking technical guidance on which chemicals to evaluate from the State Water Quality Control Board and Department of Fish and Game. However, we are concerned that DTSC does not have adequate resources to review the many products on the market today. If DTSC does not receive sufficient funding for this effort, POTWs will likely continue to seek help from the legislature on products that are a priority for water quality.

Thank you for the opportunity to provide our comments. If you have any questions, please contact Melody LaBella, with the Central Contra Costa Sanitary District, at (925) 229-7370 or mlabella@centralsan.org or Karin North, with the City of Palo Alto, at (650) 329-2104 or Karin.North@cityofpaloalto.org.

Sincerely,



Amy Chastain
Executive Director

Attachment – Detailed Comments

Definitions (Article 1)

Definition of Adverse ecological impacts (3). Section (G) of this definition is exceptionally important because is the only portion of the entire definition of "adverse environmental impacts" that addresses the most common water pollution and POTW operational problems.

Definition of Adverse environmental impacts (4). Add "Adverse waste and end-of-life impacts" §69501.2 (7). If this addition is not made, DTSC would miss POTW operational impacts. An alternative would be to add "adverse waste and end of life impacts" whenever "adverse environmental impacts" is used throughout the regulation.

Recommend adding "Non-compliance with local, state, or Federal environmental laws and regulations" to this definition for clarification purposes. Analyzing for and demonstrating non-compliance is often simpler than determining the environmental impacts associated with the non-compliance.

Definition of Adverse waste and end-of-life impacts (7). Modify (C) to read: "*Discharge or* disposal of the priority product *or waste streams containing the chemical from the priority product*…." This will allow DTSC to address products like molybdenum in cooling water additives, which is discharged to sewer systems together with cooling water system discharges.

Delete the final phrase in Subsection (C) ("and that may result in the release of Chemicals of Concern to the environment."). Operational interference at a POTW may cause the discharge of partially treated wastewater that does not necessarily include the chemical of concern.

Definition of Adverse water quality impacts (8). This definition is incomplete. The definitions of "adverse ecological impacts" and "adverse public health impacts" capture most relevant environmental endpoints through reference to Chapter 54. A better definition would be "cause or contribute to violations of water quality standards, adverse effects to aquatic ecosystems, or degradation of any waters, including surface or ground waters."

Definition of Chemical (16). The definition should include degradates, metabolites, and reaction products in the environment. If this change is not made here, changes will be necessary throughout the regulation to ensure that DTSC adequately captures chemicals for which the environmental problem is a degradate, reaction product, or metabolite. The definition should also clarify that when an element is listed (e.g., copper) that organic and inorganic chemical compounds containing that element are also included (e.g., copper oxides, copper sulfate, brass and other copper-containing alloys, copper naphthenate).

Definition of Economic impacts (27). This definition should be revised to include externalized costs, including but not limited to government costs (e.g., POTW-related costs).

Definition of Environment (31). This definition should be revised to include wastewater collection, wastewater treatment, and biosolids management systems.

Definition of Environmental Fate Properties (32). Should include identification of degradates, metabolites, and reaction products that will be formed in the environment, and municipal wastewater treatment fate data requirements. The U.S. EPA Office of Pesticide Programs uses the following municipal wastewater treatment environmental fate data requirements: activated sludge sorption isotherm, ready biodegradability, modified activated sludge respiration inhibition test, and porous pot study (see http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series835.htm).

Definition of Lifecycle (46). This definition should specifically include reasonably anticipated misuse, activities associated with use (e.g., cleaning after use), and common accidents involving products.

Definition of "Reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical" (67). This definition should be removed because it severely, and unnecessarily, limits the types of scientific information that DTSC may consider when identifying a chemical of concern or a priority product.

Should DTSC feel that it is essential to define this phrase in a manner that specifies (and therefore limits) the types of scientific information that would be allowable for DTSC to use, it should consult with the Green Ribbon Science Panel to create a definition that includes the full range of scientifically sound methods for development of reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical.

In Subsection (H) 4., when a chemical interferes with a waste treatment process, the end result may not necessarily be that the same chemical is discharged to the environment. Other chemicals may be discharged at higher concentrations (e.g., bacteria or excess nutrients might occur in wastewater effluent) or a composting facility might not be able to create usable compost (which of course is not "discharged").

Chemicals of Concern Identification Process (Article 2)

While we support DTSC's approach to developing the initial list of Chemicals of Concern, the proposed set of lists needs expansion to better reflect current and emerging water pollutants. We recommend that DTSC consult with the Water Boards to identify a more comprehensive set of lists of water pollutants. For example, any toxic pollutant for which a California Water Board has established a water quality objective should be a chemical of concern.

Without modifying the definition of "chemical" it would be challenging to create a listing that captures chemicals where degradates, metabolites, or reaction products cause environmental harm. Similarly, the definition of chemical would be a simpler place to address the need to capture families of related chemicals (e.g., all copper compounds and alloys), because it would be untenable to list every single one.

Chemicals of Concern and Consumer Product Prioritization Process (Article 3)

Product Prioritization Criteria. This section needs revision to ensure the ability to prioritize products that harm the environment. The Priority Products Prioritization, Potential Exposures Section 69503.2 (a) (1) (B), could effectively de-prioritize products that impact POTWs and, therefore, our aquatic environment. We do not believe that this is DTSC's intent. We urge DTSC to reconsider listing of a limited set of "considerations" in the regulations, i.e., to delete everything in Section 69503.2 (a) (1) (B) starting with "considering:" and the entire remainder of the section.

Should DTSC feel that inclusion of specific use patterns or exposure pathways in this section of the regulations is essential, it should consult with the Green Ribbon Science Panel to create a scientifically-based selection of priority use patterns and/or exposure pathways.

If DTSC elects to revise, instead of removing, the existing text we suggest the following revisions:

> Cumulative exposures (a) (1) (B) 3. The criteria for cumulative exposures should include water pollution. Please delete the word "household."

Accumulation and persistence are not appropriate limitations in (a) (1) (B) 4. e. Both of these words should be deleted. Water quality problems are no longer exclusively associated with persistent, bioaccumulative toxins. All that is necessary is that the pollutant be present and the concentration of the pollutant be sufficient to harm aquatic life or ecosystems.

Wastewater consideration. Recommend adding a new consideration:

> "5. Used or discharged in any manner that creates a pathway for the chemical of concern or its degradates, metabolites, or reaction products to reach a sewer drain."

Other regulatory programs (a) (3). AB 1879's provisions to avoid regulatory duplication do not provide that requirements related to a chemical be a consideration in prioritization. Since DTSC seeks to avoid regulatory overlap related to products—and does not seek to preclude prioritization of products that create pollution that must currently be managed through costly pollutant abatement programs like POTW treatment processes, it should modify this subsection to delete mention of the regulation of chemical of concern.

Additional Prioritization Criteria. Two key criteria are missing from this section:

- Externalized costs (e.g., costs for water pollution control), particularly costs to local government agencies.
- Products associated with violations of environmental laws (e.g., Clean Water Act, California's Porter Cologne Act)

Subsection (b), Key Prioritization Criteria should be modified to avoid de-prioritization of water pollutants discharged to POTWs. Options include deleting subsections (4) and (5) (preferred) or including an additional criterion that would capture POTW discharges, e.g., "Used or discharged in any manner that creates a pathway for the chemical of concern or its degradates, metabolites, or reaction products to reach a sewer drain." Since POTW discharges may be associated with both assembled and formulated products, this criterion should apply to all products.

Process for Consideration of the Prioritization Factors. DTSC should consult with the Water Boards during this process.

Opportunities for POTW Input Prior Earlier in the Alternatives Assessment (AA) Process

Based on our experience with U.S. EPA pesticide Registration Review, we strongly recommend that DTSC incorporate an opportunity for input early in the AA process, before the scope of the AA is finalized. We have found that POTW discharge pathways have often been missed in pesticide risk assessments work plans. Because of our comments identifying these pathways, U.S. EPA has been able to modify its work plans such that it can complete a POTW discharge assessment along with its assessments of other environmental exposure pathways. Before EPA provided this early public comment opportunity, POTWs could not know that this pathway was missed until EPA proposed its regulatory decision. At this point, it was inconvenient and time-consuming for EPA to revisit its environmental risk assessments.

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hill@khlaw.com

December 30, 2011

Via Electronic Mail and Regular Mail

Ms. Heather Jones
Safer Consumer Product Regulations, MS-22A
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806

Re: Comments on the Informal Draft Regulations for Safer Consumer Products

Dear Ms. Jones:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the informal draft regulations for Safer Consumer Products (SCP) issued on October 31, 2011, to implement Article 14 of chapter 6.5 of division 20 of the California Health and Safety Code (hereinafter, "the Green Chemistry Initiative" or "GCI"). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry. Members of this Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, transporting and serving food products. The comments provided herein reiterate the Coalition's position that food contact materials and substances used as components of food contact materials should be excluded from the scope of GCI regulations. We hereby incorporate by reference comments from the Coalition's submissions dated November 1, 2010, and December 3, 2010, on the draft *Safer Consumer Product Alternatives* regulation, copies of which are enclosed.

The Food Packaging Coalition (hereinafter, "the Coalition") appreciates your efforts to continue the open stakeholder process that DTSC has conducted relative to the development of the Green Chemistry Initiative (GCI), a process in which the Coalition has participated since 2009. The Coalition commends DTSC's responsiveness to concerns raised by Coalition partners with previous iterations of the GCI regulations. In particular, the Coalition appreciates that DTSC has incorporated more flexibility into the Alternatives Assessment (AA) process and has included provisions in the SCP informal draft regulations whereby a responsible entity may rely on an alternate process to prepare an AA Report, provided that the alternate process substantially meets the requirements of section 69505.5 and uses the same factors, associated exposure pathways, and life cycle segments as those specified in sections 69505.3 and 69505.4 of the SCP informal draft regulations. This allows companies to rely on and enhance existing approaches to

product development and improvement without costly implementation of a new and rigid evaluation approach that would yield no further improvement in the safety of product alternatives identified through the process. The Coalition also supports DTSC's plan to issue an initial list of two to five Priority Products to facilitate a learning process.

The Coalition remains concerned, however, with the absence of clear exemption language in the SCP informal draft regulations for food contact materials that are clearly regulated at the federal and state level. In the Coalition's November 1, 2010 and December 3, 2010 submissions, we provided support for the fact that food contact materials are already fully and effectively regulated throughout their life cycle by the U.S. Food and Drug Administration (FDA) and California governmental agencies for the protection of public health and the environment. Our analysis demonstrates that further regulation of these materials by DTSC under the GCI would be duplicative and in conflict with the existing federal regulatory scheme.[1] Furthermore, this duplicative regulation would divert DTSC's finite resources from those substances that present a real risk to public health and environment.

Food packaging and other food contact materials are essential to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf life of products, preventing food waste. The inclusion of food contact materials within the scope of California's GCI will not further the goals of the green chemistry statutes and may actually impede our industry's development of new food packaging materials that can improve the safety and environmental profile of these materials, as well as the safety, quality, and availability of the food supply while reducing food waste due to spoilage.

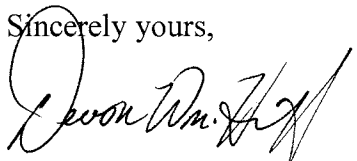
For the reasons set forth above and in comments previously submitted by the Coalition, we respectfully request that DTSC exclude food contact materials and substances used as components of food contact materials from the scope of any regulations promulgated to implement the GCI.

* * *

[1] GCI Section 25257.1(c) states, "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."

We thank you for your efforts and consideration of our views, and we look forward to further collaboration as this process moves forward. If we can provide you with additional information or clarification, please contact Devon Hill at (202) 434 4279 or hill@khlaw.com.

Sincerely yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

Enclosures

Members of The Food Packaging Coalition

American Chemistry Council - Plastics Foodservice Packaging Group
American Forest & Paper Association
Can Manufacturers Institute
Flexible Packaging Association
Foodservice Packaging Institute
Grocery Manufacturers Association
North American Metal Packaging Alliance, Inc.
Paperboard Packaging Council
Recycled Paperboard Technical Association
Retail Industry Leaders Association
SPI – The Plastics Industry Trade Association

cc: The Honorable Matthew Rodriguez, Secretary, Cal-EPA
Miriam Ingenito, Deputy Secretary, Cal-EPA
The Honorable Debbie Raphael, Director, DTSC
Odette Madriago, Acting Deputy Director, DTSC
Jeff Wong, Office of the Chief Scientist, DTSC
Cliff Rechtschaffen, Office of the Governor

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November 1, 2010

Via Federal Express

Mr. Jeff Woled, Regulations Coordinator
Office of Legislation & Regulatory Policy
Department of Toxic Substances Control
California Environmental Protection Agency
1001 I Street
P.O. Box 806
Sacramento, California 95812-0806

Re: Comments on the Safer Consumer Product Alternatives Draft Regulation

Dear Dr. Movassaghi:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the *Safer Consumer Product Alternatives* (SCPA) draft regulation issued on September 14, 2010 to implement Article 14 of chapter 6.5 of division 20 of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI).[1] These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry. This group has a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.[2]

Food packaging is an essential tool in ensuring the safety and quality of food. Materials that contact food are carefully designed to prevent the transfer of their components to food and to have no effect on the contacted food. These materials are also designed with technical properties that preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-

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[1] These comments follow up on our August 18, 2009 meeting with Dr. Maziar Movassaghi, and our comments of November 4, 2009 on the "Straw Proposal."

[2] Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, and the Recycled Paperboard Technical Association.

life of products. The U.S. Food and Drug Administration (FDA), using the legislative authority granted by the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act), has established a comprehensive regulatory scheme to ensure the safety of food-contact materials from both a public health and environmental perspective. This regulatory scheme is wholly consistent with the goals and purposes of the GCI, thus the duplication of this regulatory scheme by the SCPA would impose substantial burdens that do not benefit public health or environmental safety. One consequence of these additional burdens will be the inhibition of technological innovation and the development of safer and more environmentally friendly food packaging materials.

Our comments support the conclusion that food-contact materials are subject to a comprehensive regulatory program that protects the public health and environment from any adverse impacts that could potentially occur due to the use of food packaging materials. Through a combination of federal and state laws, the use of chemicals in food contact materials is controlled throughout the full life cycle of these products. As a result, if the SCPA continues to include food-contact materials, these products would be subject to duplicative and conflicting regulatory programs, in violation of section 25257.1(c) of the GCI. Furthermore, this wasteful, duplicative regulation will divert DTSC's finite resources from those substances that truly present a risk of harm to consumers. Therefore, DTSC should revise the SCPA to exclude food contact materials from the scope of the regulation, thereby preventing this duplicative situation and avoiding the waste of scarce public resources on these products, without providing any benefit to public health and safety.

We also are concerned that, although the SCPA is well-intentioned, the regulation's reach extends significantly beyond the authority established by the GCI. If enacted as proposed, the SCPA would implement a broad range of evaluation and reporting requirements for both DTSC and industry. We foresee two consequences of these new requirements. First, we are concerned that the scope of the regulations as proposed will create such an immense administrative burden on DTSC that it will not be feasible for the Agency to comply with the deadlines established in the SCPA. The regulation contains an abundance of new responsibilities for DTSC, many of which require time-consuming and difficult scientific evaluations. We believe that DTSC is not equipped, with financial support or personnel, to administer these responsibilities. This will result in long delays and regulatory uncertainty that will be detrimental to industry and consumers. Second, the regulations as proposed are so complex and unclear that the financial and administrative burden placed on industry will force industry and safe consumer products out of the California market.

We present our comments in three sections: (1) comments regarding concerns specific to food packaging materials; (2) comments regarding the SCPA generally; and (3) comments regarding specific sections of the SCPA.

I. Food Packaging Materials Specific Concerns

We have several concerns that relate specifically to the regulation of food-contact materials under the SCPA. As it currently stands, the SCPA includes food packaging and other food-contact materials within the scope of the consumer products that are intended to be covered by the regulation. We believe this will result in regulatory duplication, as food packaging materials already are regulated throughout their life cycle through a combination of federal and California state programs. Such duplication is prohibited by section 25257.1(c) of the California Health and Safety Code. Additionally, the exemptions available for certain chemicals are vague, and likely to be difficult for DTSC to administer on a chemical by chemical basis. As a result, we do not believe that the inclusion of food-contact materials within the scope of the SCPA will further the goals of the legislation. Moreover, this action could inhibit the development of new food packaging materials that ensure the safety of food and prevent food waste due to spoilage.

A. Food Packaging Materials Should Be Exempted From the SCPA to Prevent Duplicative Regulation

It is our position that food-contact materials are fully regulated throughout their life cycle, primarily by the FDA, and that the regulation of these materials is not legally permitted under the SCPA because of the proscription of section 25257.1(c) of the California Health and Safety Code. This section restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI.[3] Using the life cycle segments described in section 25253(a)(2)[4] of the GCI, we demonstrate below that food packaging materials are regulated throughout their entire life cycle by a combination of federal and California regulatory programs. We believe, therefore, that food packaging materials should be wholly exempt from the SCPA as this the further regulation would represent regulatory duplication that is prohibited by the GCI.

We note, as a preliminary matter, that the SCPA references life cycle analysis (excluding multimedia life cycle evaluations) in several different sections. The first, in the definitions section, describes the "life cycle" segments as "design, raw materials, resource inputs,

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[3] Section 25257.1(c) states, "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."

[4] The enumerated segments are as follows: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts (including sensitive subpopulations); environmental impacts; and economic impacts.

manufacture, transportation for distribution, use, operation, resource consumption, waste generation, maintenance, and ultimate disposition."[5] Another variant of the life cycle analysis is present in SCPA § 69305.4(a)(5), in reference to the life cycle analysis that is required as part of the Tier II AA Work Plan. Specifically, this section identifies the following life cycle segments: raw materials mining; intermediary material processes; manufacturing and packaging; distribution, transportation and marketing; use; product end-of-life; and reuse and recycling. These two variants are thus similar, but by no means identical.

The third variant, the language of which is duplicated several times in the SCPA,[6] makes its first appearance in Section 69302.1(a)(1) and notes that the life cycle analysis necessary to obtain an exemption from the chemical prioritization process requires addressing "the same public health and environmental threats [as in] . . . article 14 of chapter 6.5 of division 20 of the Health and Safety Code, and this chapter," or in other words, the GCI.[7] If the Agency determines there are "significant gaps, for one or more life cycle segments" DTSC will not grant the exemption. Yet, the SCPA fails to define those "public health and environmental threats," and "life cycle segments" to which it refers. Looking to the GCI instead, the Code vaguely references "critical exposure pathways" and "life cycle assessment tools," without providing further detail. Attempting to determine exactly what "threats" should be addressed in the life cycle analysis, and for which "segments" there may be gaps is, therefore, virtually impossible. As a result, companies do not have a consistent set of life cycle segments by which to perform their various required analyses. DTSC must decide on a single set of determinative life cycle factors for industry to consider and analyze. As it currently stands, compliance with the life cycle analyses listed in the SCPA is not practically feasible.

As there are several variants of life cycle analysis in the SCPA, for the purpose of these comments and for lack of better guidance, we are utilizing the factors enumerated in GCI § 25253(a)(2).

1. Life Cycle Segments Comprehensively Regulated by FDA

FDA, through the FFDCA,[8] regulates food packaging materials through almost all of the life cycle segments established in GCI § 25253(a)(2). Specifically, the FFDCA establishes a premarket approval requirement for components of food packaging materials that may become significant components of food. In addition to the health and safety concerns with the use of the

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[5] SCPA § 69301.2(a)(44).

[6] SCPA §§ 69302.1(a), 69302.3(h), 69303.1(a), and 69303.3(h).

[7] We note that in no place does the GCI refer to or use the term "public health and environmental threats."

[8] 21 U.S.C. §§ 301 *et seq.*

product, FDA also considers the potential environmental impact that may result from the use of a new food packaging material.

a. FFDCA Regulatory Framework

The regulation of food-contact materials was established by Congress as part of the 1958 Food Additives Amendments.[9] These amendments require FDA to regulate food-contact materials as food to the extent that there is any migration or exposure to the components of the packaging (or other materials used in contact with food). More specifically, Section 201(f) of the FFDCA defines food to mean "articles used for food or drink for man or other animals," including "articles used for components of any such article" (*i.e.*, food additives). The FFDCA further defines a "food additive," in Section 201(s), as a substance that is reasonably expected to become a component of food under the intended conditions of use, with certain statutory exceptions.[10] Thus, to the extent that there is any migration, FDA regulates a food-contact material in the same manner as any substance that is directly and intentionally added to food. Food additives, including food-contact materials, are subject to premarket authorization by FDA before they can be marketed, unless the use of the substance qualifies for one of the limited exceptions provided under the FFDCA. Accordingly, unless an exemption applies, a person intending to market a new food-contact material must first seek clearance from the FDA.

Like substances directly added to food, FDA regulates components of food packaging materials by the promulgation of food additives regulations, which set forth the conditions under which a particular substance may be used. FDA's food additive regulations may be found in Title 21 of the Code of Federal Regulations, Parts 170-189. For each of the clearances in these regulations for a food-contact substance FDA has conducted a detailed review of the substance's safety. In addition, as part of its promulgation of a new food additive regulation, FDA (as required by the National Environmental Policy Act[11]) conducts an environmental assessment of the proposed applications to determine if there would be any environmental impact from the manufacture and use of a new substance or whether the use and disposal of the new product would adversely affect the recycling of post consumer materials.[12,13]

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9 Pub. L. No. 85-929, 72 Stat. 1784 (1958).

10 As detailed below, examples of substances that are exempt from the definition of food additive are substances that are generally recognized as safe (GRAS) or prior-sanctioned for their intended use by FDA before January 1, 1958.

11 42 U.S.C. §§ 4321 *et seq.*

12 FDA has published guidance documents discussing the information and data that must be included for its environmental review. *See* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at

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Congress provided FDA with authorization to use a new regulatory procedure for the review of new food-contact substances and new uses of food-contact substances when it enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).[14] FDAMA added Section 409(h) to the FFDCA authorizing the Food Contact Notification (FCN) program. The FCN program has been operational at FDA since 2000, and now FDA reviews the overwhelming majority of food-contact substances under this program. Under the FCN program, manufacturers must submit information on the identity and use of the food-contact substance, along with information supporting the conclusion that the substance is safe for the intended use. While the system does not result in the promulgation of a new food additive regulation, the safety and environmental evaluation standards are the same as for the food additive petition process. (Arguably, FDA's evaluation of food-contact substances under the FCN program is even stricter than it was before the FCN program was available, as the Agency added additional chemistry and toxicity data requirements when it established guidelines for the new program.) If FDA does not object to a manufacturer's FCN, the proposed substance, along with the terms and conditions under which it may be used, is published on FDA's website along with the identity of the notifier.[15] FCNs are proprietary to the notifier and may only be relied upon by the notifier and its customers. Manufacturers who produce the same material must submit their own notification to FDA.[16]

(...continued)
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm *and* "Environmental Assessment Technical Assistance Handbook" at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm084224.htm.

[13] An article describing FDA's food additive approval process and safety evaluation was recently published by the former director of FDA's Center for Food Safety and Applied Nutrition and the former Director of the Office of Food Additive Safety. While the article focuses on food ingredients, *per se*, FDA regulates the safety of food-contact materials in a similar manner, thus, the article is instructive of the Agency's safety assessment. *See* "FDA's food ingredient approval process – Safety assurance based on scientific assessment" A.M. Rulis and J.A. Levitt, *Regulatory Toxicology and Pharmacology* 53 (2009) 20-31.

[14] Public Law No. 105-115, 105th Congress (Nov. 21, 1997).

[15] Effective notifications are published on FDA's website at http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm.

[16] Additional information on the FCN process and FDA's regulation of food-contact materials can be found in a recent chapter in a book published by the Food and Drug Law

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Once a material is cleared by FDA, the Agency continues to monitor public information and safety that may question whether the use of the material continues to be safe. Under the FCN, notifiers are required to submit to FDA any new toxicological data or other information that may come to their attention that could affect FDA's decision that the use of the substance is safe.

b. Data Required for FDA's Review

To evaluate the safety and environmental aspects of the use of a new food-contact substance, FDA requires a manufacturer to submit extensive data to the Agency. FDA has published guidance documents regarding its requirements for the data and information that must be included in a food additive petition or FCN.[17] These data include:

(1) a full chemical description of the food-contact substance, its impurity profile, and details regarding its manufacture;

(2) information on the technical properties of the substance for its intended use;

(3) data demonstrating the amount of the substance that may migrate from the article to food;

(4) calculations of the estimated dietary exposure to the substance and its impurities based on its anticipated use;[18]

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Institute. *See* D.W. Hill and R.A. Bond, "Chapter 4: Food and Drug Packaging," in the Food and Drug Law Institute's *Food and Drug Law and Regulation.*

[17] FDA, "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" (Sept. 1999, updated Apr. 2002), at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm and "Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations" (Apr. 2002, updated Dec. 2007) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm.

[18] The dietary exposure is calculated by multiplying the amount of a component expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing the additive. This fraction is known as a "consumption factor." These calculations invariably represent a conservative estimate of the dietary exposure of the additive because they are based on the assumption that the component will always migrate at maximum levels, and that all food-contact materials of a given type will be made using the subject substance.

(5) all available toxicological data that the notifier has in its possession or that is publicly available must be provided for the substance and its impurities;

(6) certain minimum toxicological data, the volume of which depends on the estimated dietary exposure from the proposed use; FDA's tiered requirements for toxicological data for substances with a potential dietary exposure between 0.5 parts per billion (ppb) and 50 ppb mandate two *in vitro* genotoxicity studies demonstrating that the substance is not mutagenic or genotoxic; for substances with dietary exposures above 50 ppb, FDA requires a third genotoxicity study in the form of an *in vivo* chromosomal aberration study, and two subchronic feeding studies, generally one in a rodent species and one in a non-rodent species. For substances with exposures above one part per million in the diet, FDA requires a full panoply of toxicological data, including the data identified above as well as from a chronic two-year bioassay, a one-year feeding study in a non-rodent species, and multigenerational reproductive and developmental toxicity studies. Of course, if any of these studies indicate a hazard trait or toxicological endpoint of concern, FDA may require additional studies to demonstrate that the proposed use will be safe;[19]

(7) data that allow FDA to consider the potential environmental impact that may result from the clearance of a new food-contact material;[20] unless the proposed use of the food- contact substance qualifies for an exemption, petitioners and notifiers must submit information that the proposed manufacture of the food-contact substance will not affect compliance with any federal and state environmental laws related to any discharge to the environment, such as air and water emissions.

To put these toxicity thresholds into perspective, 1 ppm is equivalent to one drop of water diluted into 50 liters (roughly the fuel tank capacity of a compact car), 1 ppb is equivalent to one drop of water diluted into 250 chemical drums (50 m^3), and 1 part per trillion (ppt) is equivalent to one drop of water diluted into 20 Olympic-size swimming pools (50,000 m^3). The toxicity

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[19] *Id.*

[20] FDA's categorical exclusions are set forth at 21 C.F.R. §§ 25.30-34. The Agency set forth its rationale for why certain applications are exempt from the need for an environmental assessment in the Federal Register notice promulgating this rule. *See* 62 Fed. Reg. 40569-40600 (July 29, 1997). *See also* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm

studies required by FDA are all for chronic (i.e., long term) exposures. The rationale for requiring chronic toxicity data is that for substances entering the diet at such miniscule levels, acute toxicity almost never is a concern (that is, virtually nothing will be acutely toxic at low parts per billion levels). On the other hand, it is possible, at least in theory, for carcinogenic effects to be elicited at low dietary levels; hence, the toxicity endpoint of greatest concern for low-exposure substances is carcinogenicity. The genotoxicity screening assays are intended to provide an indication as to whether a given substance is likely to be a carcinogen.

Further, we note that information also must be submitted on the environmental fate resulting from the use and disposal of the food-contact substance, demonstrating that it will not affect the environment. In particular, information must be submitted that evaluates any potential environmental impact when the substance is disposed of, such as landfill leachate, incineration and the potential air emission and ash disposal from incineration. Any environmental impact that may result from manufacture, use, or disposal, such as aquatic toxicity or toxicity to terrestrial organisms, must be addressed.

FDA pays particular concern to any impacts that the proposed use of the substance may have on the ability to recycle post consumer packaging materials. If there is a concern that the new substance may create problems with the recycling processes currently being used, FDA will require further data and information or limitations to ensure that the proposed use will not create an adverse economical or technical impact on the ability to recycle food packaging materials.

In sum, FDA has in place a comprehensive and robust system of regulation for food-contact materials that establishes a large margin of safety. The regulations proposed by DTSC to implement the GCI would duplicate this system. FDA's regulatory scheme is consistent with the purposes of the GCI. Thus, the inclusion of these products in the SCPA would contravene the limitations proscribed by Section 25257.1(c) of the Health and Safety Code and would not promote the safety or environmental goals of the GCI.

c. Exceptions from Premarket Review

As noted above, there are limited exceptions to the need to obtain a food additive regulation or an effective FCN for the proposed use of a new food-contact substance. First, FDA may exempt a material from the need for a regulation of FCN under its Threshold of Regulation exemption procedure. FDA's Threshold of Regulation procedure, which is codified at 21 C.F.R. § 170.39, allows the Agency to exempt a substance from the need for a regulation or FCN if the proposed use of the substance meets certain criteria:

(1) the substance must not be a carcinogen and may not contain any carcinogenic impurities with a TD_{50} (*i.e.*, median toxic dose) value less than 6.25 mg/kg body weight per day;[21]

(2) the proposed use of the substance must not result in a dietary exposure exceeding 0.5 ppb or, if the substance is currently regulated for direct use in food, the proposed increase in the dietary exposure must be less than one percent of the established acceptable dietary intake (ADI) for the substance;

(3) the substance has no technical effect in the food; and

(4) the proposed use of the substance may not have a significant impact on the environment.

FDA adopted the Threshold of Regulation procedure after reviewing a large number of published studies indicating that there was little toxicological concern from the exposure to noncarcinogenic substances at levels below 0.5 ppb in the diet.[22] FDA reserves the right to determine if substances qualify for the exemption and provides response to companies submitting such a request.

The FFDCA also provides certain exceptions to the definition of a food additive that also apply to food-contact materials. Specifically, the Act excepts those materials that are considered to be generally recognized as safe (GRAS) or that were sanctioned by either FDA or the United States Department of Agriculture (USDA) prior to the adoption of the Food Additives Amendment in 1958. Food additives, as well as food-contact materials that qualify under these exemptions, are not technically subject to premarket review by FDA, although in many cases companies request FDA's review.

The FFDCA exception for GRAS substances as provided in Section 201(s) states that such a determination requires a general recognition "among experts qualified by scientific training and experience to evaluate [the additive's] safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use." FDA has promulgated regulations setting forth the criteria that the Agency regards as necessary to establish that the use of substance is GRAS. These eligibility requirements provide that a

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[21] The TD_{50} is the chronic dose level that would induce tumors in half the test animals at the end of a standard lifetime for the species.

[22] 60 *Fed. Reg.* 36595, July 17, 1995. A full report and all of the individual papers written as part of a study examining this issue were published in the August 1990 issue of *Regulatory Toxicology and Pharmacology*. *See* Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).

general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."[23] Moreover, FDA has clarified that "scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation."[24] The main toxicological data and other information that support a GRAS determination must be published, generally in peer-reviewed scientific journals.

FDA has a procedure to review and sanction GRAS determinations through a GRAS Notification process.[25] In addition, the Agency has listed or affirmed some materials as GRAS in Parts 182, 184, and 186 of the food additive regulations. A determination may be made without FDA review that a substance is GRAS, provided that sufficient published toxicological data exist that establish a general scientific recognition that a substance's use is GRAS. The standards for such a self-determined GRAS assessment are robust. As stated by two former FDA officials, Drs. Alan Rulis and Joseph Levitt, "many people mistakenly associate GRAS with a sort of "second" tier of safety protection based on a less-than rigorous standard compared to petitioned food additives. This is not true. In fact, the safety standard applicable to GRAS food ingredients is the *same* as for food additives; namely reasonable certainty of no harm."[26] The former directors went on to say that "[i]n fact, the GRAS criteria are in some ways more difficult to satisfy than the food additive criteria because of the additional requirement of public availability of the data and general recognition and acceptance of a safety conclusion based on those data."

The FFDCA also expressly exempts those materials that were sanctioned by USDA or FDA in letters issued by these Agencies before the passage of the Food Additive Amendments in 1958. In the experience of our members, the substances covered by prior sanctions and still used in commerce are limited, and many of the substances were subsequently petitioned or notified to

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[23] 21 C.F.R. § 170.30(a)(2).

[24] 21 C.F.R. § 170.30(b).

[25] *See* FDA, GRAS Notification Program, at http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm.

[26] *See* A.M. Rulis and J. Levitt, p. 26.

the FDA. FDA very strictly interprets previously issued prior sanction letters, and limits the scope of the exclusion by construing prior sanctions as narrowly as possible.[27]

Substances also may be used without express premarket approval from FDA if they can additionally be shown to not migrate from the food-contact article. The standard for this assumption is strictly interpreted by both the Agency and industry. In general, a showing of no migration must be based on an analytical sensitivity demonstrating that there would be no migration at a level equivalent to 50 ppb and often lower in some situations.[28] The basis of the exclusion from premarket clearance is that, given the very low migration of the substance to food, the resulting dietary exposure among consumers will be negligible.

In sum, the exemptions from premarket approval for food-contact materials are strictly limited by the FFDCA. Only those materials that are subject to published toxicological data and generally accepted by the scientific community as safe may be considered to be GRAS and used without FDA review. Those substances covered by prior sanctions are limited, and the substances used in food-contact materials that do not migrate to food result in no exposure to consumers. In addition, these substances when used in food-contact articles are still subject to FDA regulation under Section 402 of the FFDCA.[29] Under no circumstances may any substance cause a health or safety concern when used as intended and may not affect the taste or odor of the food. Thus, it is our opinion that the substances that qualify for these limited exceptions do not result in exposures of concern and, therefore, subjecting them to the scope of the GCI would not promote the purposes of the statute. Including such materials within the scope of the GCI will duplicate the existing regulatory scheme which Congress and FDA have established.

d. The Current Regulation and Evaluation of Food-Contact Materials Is Consistent with the Hazard Category Endpoints

The SCPA aims to prioritize all chemicals used in products in California for a list of Chemicals of Concern, based on the "hazard trait" exhibited by that chemical.[30] "Hazard trait" is defined so as to eventually refer to the hazard traits identified by the Office of Environmental Health Hazard Assessment (OEHHA) as part of its implementation of the Toxics Information Clearinghouse, that is required by GCI § 25256.1. On August 10, 2010, OEHHA released a pre-

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[27] *See* 456 F. Supp. 207, 209 (d. Neb. 1978), *aff'd sub nom. United States v. Nielsen* (8th Cir. 1979), cert. denied 444 U.S. 832 (1979). *See also*, 21 C.F.R. § 170.38(d).

[28] The resulting dietary exposure for most food-contact substances, even if there were some migration below the level of detection, would be less than 0.5 ppb, a level below FDA's threshold of toxicological concern.

[29] 21 U.S.C. § 342(a)

[30] *See* § 69302.1(a).

regulatory draft proposal of the hazard traits by which a chemical would be evaluated to determine whether it belongs on the list of Chemicals of Concern. As a general matter, we consider the pre-regulatory draft to be as vague and ambiguous as the SCPA. Specifically, the OEHHA pre-regulatory draft calls for a new classification system for chemicals, ignoring established, internationally-recognized systems, recognizes numerous types of toxicity data on an individual basis, when many would be better suited to categorization, and includes types of emerging toxicity traits for which there is a distinct lack of scientific consensus.

These concerns are exemplified by the inclusion of epigenetics as a recognized hazard trait. Epigenetics is a new field of toxicological analysis. As such, it has no reference database by which to judge any analysis, or historical controls for comparison. Furthermore, the definition in the pre-regulatory draft proposal is overly broad and would be better suited as part of a discussion of systemic toxicity, as opposed to an endpoint of itself. Finally, epigenetics as a toxicological field is not yet the subject of scientific consensus—resulting in OEHHA unilaterally establishing a new hazard trait that has not been accepted by the wider scientific community. We consider epigenetics to be one example of the many problems with the pre-regulatory draft's list of hazard traits.

Because we consider that the hazard traits proposed by OEHHA are inappropriate for analyzing the toxicity of a substance, we have instead chosen to discuss various hazard traits using the categories established in the October 1, 2009 "Straw Proposal" for the implementation of the GCI. The hazard categories listed in this proposal for the evaluation of chemicals of concern were: (1) acute toxicity, (2) eye irritation, (3) genetic toxicity and mutagenicity, (4) reproductive toxicity, (5) carcinogenicity, (6) endocrine disruption, (7) respiratory sensitization, (8) skin sensitization, (9) bioaccumulation, (10) acute aquatic toxicity, and (11) hazards to the ozone layer. As discussed above, in the course of its evaluation for a food-contact material, FDA requires the submission of a substantial amount of toxicological data to support the safe use of a product. We will compare the Straw Proposal's hazard traits to the data required by FDA to demonstrate that all significant hazard traits are regulated by FDA.

(1) Acute Toxicity, Eye Irritation, Skin Sensitization, Respiratory Sensitization

The acute exposure endpoints identified in the hazard criteria are not relevant endpoints for exposures from food packaging materials. Substances used in food-contact materials are generally of low acute toxicity and are trapped within a matrix (*e.g.*, a polymer, coating or paper) that prevents their migration and limits exposure to levels that are not relevant for acute exposures. While FDA requires the submission of acute toxicity data when available, the Agency generally is not concerned with acute, single-dose toxicity data and, rather, is more concerned with potential carcinogenicity effects or other endpoints from repeated-dose studies.

(2) Genetic Toxicity and Mutagenicity

FDA requires genetic toxicity and mutagenicity testing for any chemical substance with a potential dietary exposure above 0.5 ppb. In addition, if structural alerts suggest that a substance may have genetic or mutagenic attributes, FDA may request that additional data be provided. Any GRAS determination must consider these toxicological endpoints, as well. In the case of materials that do not migrate, there would be no exposure, although the level of analytical sensitivity needed to determine whether the "no migration" threshold would be lower than 50 ppb also is based on these genotoxicity concerns.[31] In our experience, if a substance is determined to be mutagenic or genotoxic in screening tests, FDA will require (a) data demonstrating whether these affects are likely to be observed *in vivo*, (b) a cancer bioassay to resolve whether the material is a carcinogen, or (c) proof that potential dietary exposure will be insignificant even if the material is later determined to be a carcinogen; generally, this would be at a level that would not exceed 50 parts per trillion, 0.05 ppb, in the diet.

(3) Reproductive Toxicity

FDA requires that reproductive and developmental toxicity data be submitted for substances when the dietary exposure may be significant for these toxicological endpoints. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for reproductive or developmental toxicity, the Agency may request additional data. As with genotoxicity data, any GRAS determination must consider these toxicological endpoints as well. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.[32]

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[31] The use of 50 ppb in this context is a concentration that could migrate from the package, not a level of dietary exposure. The resultant level of dietary exposure from food is determined by the consumption factor and would be at least an order of magnitude less, or even more in some cases.

[32] In a 1999 paper, Dr. Ian Munro and colleagues established a safety evaluation procedure for use by the Joint Food and Agricultural Organization/World Health Organization of the United Nations (FAO/WHO) for flavoring substances implementing a threshold of toxicological concern approach involving a number of toxicological endpoints.[32] The study authors concluded that "toxicity endpoints, such as developmental toxicity, neurotoxicity, and immunotoxicity demonstrate considerably higher human exposure thresholds than the threshold value [established using carcinogenicity data], making it highly unlikely that these non-cancer endpoints are a relevant concern in applying the threshold concept." *See also*, Kroes, R., Galli, C., Munro, I., Schiltwe, B., Tran, L.-A., Walker, R., and Würtzen, G. (2000) "Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A Practical Tool for Assessing the Need for Toxicity Testing," *Food and Chem Toxicol*; 38: 255-312. The Kroes

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(4) Carcinogenicity

The FFDCA prohibits the use of carcinogenic food additives, including substances used in food-contact materials that become components of food. Specifically, Section 409(c)(3)(A) of the Act (also known as the "Delaney Clause") states that no food additive shall be deemed by FDA to be safe if the additive is found "to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of safety of [the additive], to induce cancer in man or animal."[33] Thus, it is not possible to use a substance considered to be a carcinogen that would be a food additive when used in food-contact materials.

The Agency has established standards for the presence of any carcinogenic impurities that may be present in food-contact materials. The standard that FDA has established for these materials is known as the "constituents policy."[34] FDA sets an extremely strict standard for carcinogenic impurities. The Agency uses data from animal carcinogenicity studies, together with extrapolation procedures, to calculate the potential risk from the estimated daily exposure to the carcinogenic impurities as a result of the particular use. In order to determine that there is a reasonable certainty of no harm, FDA requires that the dietary exposure to a carcinogenic

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(...continued)
study reviewed an expanded databases to establish if additional toxicological endpoints were more sensitive than the carcinogenic endpoints of a variety of chemical substances. The report indicates that none of the specific non-cancer endpoints (*i.e.*, developmental toxicity, developmental neurotoxicity, and immunotoxicity) was more sensitive than cancer endpoints for the same substances. The results of a more recent analysis were published by Kroes and colleagues in 2004. The authors conclude that, based on their examination of metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific toxicological endpoints, including neurotoxicity, teratogenicity, developmental toxicity, and immunotoxicity, carcinogencicity is the most sensitive toxicological endpoint. *See* Kroes, R., Renwick, A.G., Cheeseman, M., Kleiner, J., Mangelsdorf, I., Piersma, A., Schilter, B., Schlatter, J., van Schothorst, F., Vos, J.G., and Würtzen, G. (2004) "Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet," *Food and Chem Toxicol*; 42: 65-83.

[33] FFDCA § 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A).

[34] 47 Fed. Reg. 14,464 (Apr. 2, 1982). Although this Advanced Notice of a Proposed Rulemaking was withdrawn by the agency in a November 26, 2004 Federal Register notice (69 Fed. Reg. 68,831, 68,831), the impetus of the withdrawal was administrative only, and FDA has since made clear that the constituents policy remains a valid means by which it evaluates minor carcinogenic impurities of food additives.

impurity must not exceed the calculated upper-bound lifetime risk from all sources of exposure and be lower than a risk of 1 in 1 million.[35]

(5) Endocrine Disruption

The proper assessment of the endocrine disrupting potential of a particular chemical is a topic of much current discussion. Whether the *in vitro* endocrine disrupting effect exhibited by a chemical at the extremely low doses of oral exposure associated with food packaging actually translates to an adverse physiological effect is in our opinion, at best, very controversial. Moreover, the health effects of chemicals acting through an endocrine mode of action should generally be captured by traditional toxicological tests, which are designed to detect adverse health effects acting through any means, including interaction with the endocrine system.

FDA and other bodies around the world that regulate food-contact materials are monitoring current scientific information on this subject. At this time, however, no regulatory body in the world that is responsible for food safety has established separate endocrine disruption data requirements for food-contact materials. Instead these regulatory bodies rely on information from reproductive, developmental and other well established, validated toxicology studies to understand the potential health effect of chemical regardless of their mode of action. While industry and government continue to monitor this issue, it is our opinion that there is not sufficient scientific information or agreement on the data at the present time to establish endocrine disruption as a regulatory criterion.

(6) Bioaccumulation

FDA considers the biopersistence and bioaccumulation of a proposed food-contact substance as part of its evaluation of food additive petitions and FCNs. If a substance is suspected of being bioaccumulative, the Agency requires further data on its absorption, distribution, metabolism and elimination to determine the potential bioaccumulation in the body. Any GRAS evaluation of a substance would also take this outcome into account. With regard to the other materials that may not be subject to FDA's review, the Agency considers that a daily exposure of 0.5 ppb in the diet is an insignificant addition to the diet from a cumulative exposure standpoint (except for carcinogens). If a substance is present at levels below 0.5 ppb, its bioaccumulation potential is considered to be insignificant.

(7) Acute Aquatic Toxicity and Hazards to the Ozone Layer

As stated above, FDA requires in its review of food-contact materials that the substance not have an adverse environmental impact during its manufacture, use, and disposal. In addition, the manufacture of food-contact materials—like any other consumer product—is subject to

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[35] *Id.* at 14,468.

federal, state, and local environmental laws that govern discharges to the air and water (*e.g.*, the laws administered by the California Air Board and Office of Environmental Health Hazard Assessment). Most importantly, because of their inert design there is not likely to be any exposure from a food-contact material that could have an effect on aquatic toxicity or the ozone layer at any level of concern. The possible levels of migration of a substance from a food-contact article are very low, generally in the part per million range or lower, and these toxicological endpoints are simply not relevant to packaging or other food-contact articles.

2. Regulation of Other Life Cycle Segments

As described above, the FFDCA regulates a significant portion of the life cycle segments of food packaging materials. As a result, there are only five remaining segments to which the FFDCA does not reach: materials and resource consumption; water conservation; production, in-use, and transportation energy inputs; energy efficiency; and economic impacts. We believe that food packaging materials are fully regulated during these life cycles by California regulatory programs, or are otherwise not subject to California jurisdiction.

The life cycle analyses contemplated in the SCPA are comprehensive; the consequence is that the regulation reaches many activities that take place outside California. While (for the sake of current argument) we do not take issue with California regulating resource consumption activities that take place in-state, we note that many of the activities contemplated as part of the life cycle analysis occur outside of California and are, thus, not subject to DTSC's jurisdiction. However, for purposes of these comments, we will assume that the full life cycle of a product occurs in California.

a. Resource Consumption

We have grouped two consumptive segments, "Materials and resource consumption" and "water conservation," in this category. These consumptive activities are covered by a variety of California regulatory programs. Specifically, materials and resources consumed in California are regulated by various California agencies, such as the Department of Conservation (mining and oil, gas, and geothermal energy management), the Department of Forestry and Fire Protection, the Natural Resources Agency (water, energy, minerals, coastal and marine life), and the California Environmental Protection Agency (air quality, soil quality, and waste recycling and reduction). Any impact on worker safety is regulated by the Division of Occupational Safety and Health in the Department of Industrial Relations. Collectively, California's agencies regulate all aspects of resource consumption that could potentially impact public health or the environment in California.

b. Energy Use

This category also groups together two segments, production, in-use, and transportation energy input, and energy efficiency. Similarly to resource conservation, energy use in California

is regulated by a plethora of agencies. Of note, the California Climate Action Team's[36] efforts to reduce energy emissions, the Energy Commission's energy efficiency programs, and California's Public Utilities Commission's energy efficiency programs combine to address the energy impacts of any industrial activities for food packaging in California.

c. Economic Impacts

Although all of the life cycle segments listed in the H&S code are vague to a certain extent, this segment is by far the most unclear. We consider the economic impacts of any public health or environmental threat are already encompassed within the prior segments.

The above discussion demonstrates that food-contact materials are regulated throughout all life cycle segments. DTSC should, therefore, exempt food-contact materials from the requirements of the SCPA.

B. The SCPA is Preempted by Federal Law

Although we believe that the regulation of food-contact materials is prohibited by the duplication provision of the Section 25257.1(c), there are also serious questions whether the SCPA would be preempted by Federal law. The Supremacy Clause of the Constitution of the United States grants to Congress the power to preempt state law. U.S. Const. art. VI, cl. 2. "[S]tate law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). The same is true of state law that conflicts with federal regulation. *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes."). Where the State does not completely exclude federally licensed commerce,[37] the test for preemption "is whether both regulations can be enforced without impairing the federal superintendence of the field."[38]

Of the three types of preemption (*i.e.*, express, conflict and "field" preemption), only two are relevant here—conflict preemption and field preemption. Conflict preemption exists if a private party's compliance with the state and federal laws is impossible, or the state or local law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *California v. ARC America Corp.*, 490 U.S. 93, 100 (1989). *See also Dowhal v.*

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36 Composed of CalEPA, the Business, Transportation and Housing Agency, the Department of Food and Agriculture; the Resources Agency, the Air Resources Board; the Energy Commission; and the Public Utilities Commission.

37 "That no State may completely exclude federally licensed commerce is indisputable." *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963).

38 *Id.*

Smithkline Beecham Consumer Healthcare, 88 P.3d 1, 7 (Cal. 2004). If a conflict is found "a holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Florida Lime,* 373 U.S. at 142-43.

Field preemption exists "where the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Fidelity Fed. Sav.,* 458 U.S. at 153. Similarly, the federal law or regulation "may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

As detailed above, FDA has established a comprehensive regulatory framework for food-contact material. The scope of FDA's regulations leaves no room for the SCPA to regulate food-contact material. The SCPA unduly interferes with the well-established federal regulatory scheme and would likely be held preempted by a court.

Additionally, the proposed regulations contain a provision under which certain chemicals or products would be prohibited for use in California.[39] If any of the chemicals that would be prohibited have been approved by FDA for use in food-contact material, such prohibition would be preempted under principles of conflict preemption because in such a case, the SCPA would have banned a chemical that FDA previously had cleared for use in food-contact materials. When a federal and state law are in direct conflict, the state law must yield to the federal law. *ARC America Corp., supra.*

C. Non-Listing of Priority Chemicals Due to Regulatory Duplication

As noted above, food packaging materials are subject to a combination of federal and state programs that regulate these products throughout their life cycle, thus they should be wholly exempted from the requirements of the SCPA. However, if DTSC decides that food packaging materials should not receive a blanket exemption, many manufacturers instead are likely to avail themselves of the exemption provided in section 69302.1(a)(1), whereby a chemical that exhibits a hazard trait and would otherwise be a Chemical of Concern, may be exempted from SCPA's reporting requirements under the regulatory nonduplication exemption. Under this alternative, DTSC will need to review each individual chemical that exhibits a hazard trait to determine whether it is regulated throughout its life cycle. This would be a time- and resource-consuming effort if food packaging materials were the only products of concern, but they are not; there are likely to be thousands of exemption requests from chemicals used in all types of products.

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39 *See* SCPA § 69306.5(b).

Furthermore, as noted above, both the SCPA and GCI are unclear as to the "threats" that are to be addressed in the life cycle analysis to obtain this exemption. We consider that the only "threat" to be evaluated under this analysis is the hazard trait that caused the chemical to considered a Chemical of Concern. For example, if a substance is listed as a Chemical Under Consideration because it is a reproductive toxicant, it should be this trait (and this trait only) that should be evaluated under the life cycle analysis. It would unnecessarily expand the scope of the SCPA to require a full life cycle analysis for any and all potential threats, when it is not those threats that are considered to be the "hazard trait." Furthermore, several of these life cycle segments (energy use, resource consumption) are irrelevant to the determination of whether a chemical exhibits a hazard trait. We consider, therefore, that these life cycle segments (as discussed above in § I.A.2) are also irrelevant to the determination of whether a chemical is already fully regulated.

D. The Burden of Proof

To qualify for either of the exemptions in section 69302.1, the person requesting the exemption must demonstrate that the chemical meets the requirements "by clear and convincing evidence to the Department's satisfaction." With regard to the regulatory nonduplication exemption, the Department will review the existing regulatory programs with reference to a full life cycle analysis, and if "significant gaps" are identified in the regulatory programs, the DTSC may regulate the product through those segments. This section also contains a rebuttable presumption that the exemptions do not apply, unless otherwise proven.

DTSC has failed to provide a rationale for this high burden of proof. In its Initial Statement of Reasons (ISOR) accompanying the SCPA, DTSC simply states that this standard is necessary to show that the burden of proof for the exemptions is on the applicant. We do not take issue with DTSC placing the burden of proof on the applicant; however, we do not believe that the "clear and convincing" standard has any rational relationship to the requirements for the exemption. The determination of whether a chemical is fully regulated by existing federal or California programs is a factual inquiry—either the chemical is regulated or it is not. It is difficult, therefore, to understand why DTSC has imposed a legal evidentiary standard on a factual inquiry. Furthermore, the imposition of the clear and convincing standard goes beyond the authorizing legislation, and is not necessary. Indeed, GCI § 25257.1 provides a strong prohibition against regulatory duplication, which the "clear and convincing" standard would appear to contradict by placing a significant barrier before a chemical could be exempted from the SCPA. Thus, we believe that this evidentiary standard to obtain an exemption from the SCPA is inconsistent with the spirit of the authorizing legislation and is not necessary.[40]

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[40] *See* Gov. Code §§11349.1, 11349.3.

Finally, DTSC applies the "clear and convincing" standard inconsistently within the SCPA. The regulatory nonduplication exemption appears in its pertinent form four different times in the regulation.[41] In sections 69302.1 and 69303.1, both the regulatory nonduplication and exposure pathway exemptions are available, and the clear and convincing standard applies. In sections 69302.3 and 69303.3, however, only the regulatory nonduplication exemption is available, and there is no requirement that the nonduplication be shown by clear and convincing evidence. The SCPA is unclear, therefore, when the clear and convincing standard applies, and even if the standard itself is tied to the exposure pathway exemption only, rather than both exemptions.

E. Exposure Pathway and Regulatory Duplication

SCPA § 69302.2 requires DTSC to prepare two lists relating to the threats posed by a given chemical – a list of Chemicals under Consideration and a list of Priority Chemicals. As part of its preparation process, DTSC must identify the hazard trait(s) exhibited by the chemical, and the potential exposure pathways for each chemical. It is possible that DTSC could choose to list a chemical based on a hazard trait for which the exposure pathway is through the consumption of food packaged in a food-contact material. As discussed above, FDA thoroughly regulates food contact materials and their components thereof throughout the product's life cycle. Therefore, if DTSC listed a chemical in such a scenario, DTSC would be exceeding its authority in violation of Section 25257.1(c) of the California Health and Safety Code, which prohibits regulatory duplication.

F. *De Minimis*

The second exemption available for some SCPA requirements is the *de minimis* exemption.[42] "*De minimis*" is defined as "a concentration less than or equal to the lower of: (1) 0.1% by weight; or (2) the lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination." As it relates to food packaging materials, it is very unclear to what the 0.1% by weight threshold refers. This threshold could be interpreted to apply to the components of a finished food contact article, a chemical that comprises one ingredient of a component, or the amount of the chemical that could migrate from the finished food contact article into food. FDA considers this latter measurement most important from a health and safety perspective.

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[41] §§ 69302.1(a), 69302.3(h), 69303.1(a), 69303.3(h). There is also a regulatory nonduplication provision contained in § 69306.7(a), but this provision applies to a regulatory response required by DTSC, as opposed to the regulation of the product, itself.

[42] The application of the *de minimis* exemption is found in § 69305.3, although the definition of "*de minimis*" is found in § 69301.2(23) and (24)

Occasionally, FDA sets limits on the amount of a chemical that may be used in a finished product. For example, in 21 C.F.R. § 178.2010 ("Antioxidants and/or stabilizers for polymers"), FDA has set use limits for a commonly used antioxidant known as Irganox 1010.[43] FDA has determined that the use of Irganox 1010 at these levels is safe from both a public health and environmental perspective. It would be inappropriate, and potentially preemptive, for the SCPA to establish regulatory thresholds contrary to those established by FDA.

There are a number of other concerns with this exemption. First, the exemption is only available for Priority Products that contain a Priority Chemical at or below the *de minimis* threshold. The ISOR states that this provision is necessary "to allow DTSC and manufacturers to focus their resources on those Priority Products that pose the greatest threats to public health and the environment."[44] If this is the case, we question why the exemption should be limited solely to Priority Products. We believe that DTSC should also allow the exemption for Products Under Consideration. If a Priority Chemical is not going to present a threat to public health or the environment when used at *de minimis* levels in a Priority Product, it will present no greater threat when used at the same level in a Product Under Consideration. It would be logical to apply the *de minimis* exemption to both lists of products. Furthermore, it would permit some manufacturers respite from burdensome assessment and reporting requirements when their product is not expected to pose a threat to public health or the environment.

Second, the exemption has to be granted by DTSC, rather than allowing industry to make a self-determination. This will create a time- and resource-consuming administrative burden for DTSC for a factual enquiry that requires no regulatory assistance. Whether a Priority Chemical is present in a Priority Product at more than 0.1% is a matter of fact, not interpretation. Industry should, therefore, be permitted to take a self-determined *de minimis* position as to the composition of its products. It is unnecessary for DTSC to require industry to submit substantial amounts of costly paperwork for a substance that DTSC has acknowledged is used at a level that does not constitute a threat to public health or the environment.

Finally, the language of the definition itself is very vague. The *de minimis* level may be set at "The lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination." These thresholds "include, but are not limited to" seven different existing reference databases. When a list of potential sources is not limited in scope, it makes it difficult, if not impossible for industry to be on notice

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[43] Listed in 21 C.F.R. § 178.2010 as "Tetrakis [methylene(3,5-di-*tert*-butyl-4-hydroxyhydro-cinnamate)] methane (CAS Reg. No. 6683-19-8)."

[44] *See* Initial Statement of Reasons (ISOR), p. 76, ll. 27-29.

of the requirements with which it must comply, and by what standards DTSC will judge a *de minimis* level request.[45]

II. General Comments

The SCPA's stated objective is to "create a systemic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety."[46] While industry's paramount interest is the health and safety of the products that they produce, our members are concerned that the SCPA is extremely broad and goes well beyond what is necessary to implement the requirements of the GCI.

A. Scope of Information

We are concerned that the scope of information sought by DTSC is not within the ability of industry to provide. We consider this problem from two perspectives. The first concern is the sheer volume of information that DTSC proposes to require under the SCPA, and the second concern is the complexity of obtaining the necessary information from all participants in the supply chain for a product.

According to section 69301.6, DTSC may request a responsible entity to provide (1) chemical and product data, (2) information describing the types, categories, and classes of products that contain Priority Chemicals, (3) identification of intentionally-added chemicals and chemical ingredients, including quantities used in a product, (4) chemical and product market data, (5) analytical protocols, and (6) information on reformulation or redesign of a product. We are concerned that DTSC does not fully appreciate the difficulties involved with obtaining much of this information. To illustrate, using a hypothetical scenario: Company wishes to package its potato chips in Supplier's plastic bag. The plastic bag is a multi-layer film, comprised of three different layers, each bound together with an adhesive. Each layer is composed of a different type of plastic. Each plastic is formulated with a base resin, and a variety of processing aids and additives that give the plastic its technical properties. Each base resin is a formulated product manufactured with processing aids and additives. Furthermore, each adhesive is a formulated product. The compositions of the film layers and adhesives, the plastics, the base resins, the processing aids, and the additives are all trade secret information. Most of these substances are present in the finished packaging at extremely low levels, but the SCPA would require

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[45] *See Tidewater Marine Western, Inc. v. Bradshaw*, 14 Cal. 4th 557, 568-69 (1996) ("One purpose of the APA is to ensure that those persons or entities whom a regulation will affect have a voice in its creation, as well as notice of the law's requirements so that they can conform their conduct accordingly.) (internal citations omitted).

[46] *See* 45-Day Public Notice and Comment Period for Proposed Rulemaking, page 7.

responsible entities to obtain an enormous amount of data regardless of the level of the substance used or the potential exposure.

Moreover, obtaining the requested information will be a complex process of revealing business relationships and trade secret information. In many cases, due to intra-industry trading, this may even involve disclosure of trade secrets to a direct competitor. This will be an extensive burden for a responsible entity, without providing a commensurate benefit to public safety, considering that these materials have already been determined by FDA to be safe for their intended use.

B. Feasibility of the Regulation

We also are highly concerned that DTSC has given itself more responsibility than is feasible to manage. The SCPA requires a substantial number of evaluation, reports, and applications, all of which must be submitted to, and reviewed and evaluated by DTSC, with DTSC then providing, and enforcing, a regulatory response. Specifically, DTSC is required to undertake the following:

- Review and evaluate petitions to designate chemicals on one of the chemical/product lists
- Develop and update lists of
  - Chemicals of Concern
  - Chemicals Under Consideration
  - Priority Chemicals
  - Products Under Consideration
  - Priority Products
- Review, evaluate, and reevaluate requests for exemptions
  - Regulatory duplication
  - No exposure pathway
  - *De Minimis*
- Review, evaluate, and respond to the different types of AAs:
  - AA Work Plans
  - Tier I AA (review only)
  - Tier II AA
- Review and evaluate applications for AA accreditation
- Review and evaluate Chemical/Product Removal Intent/Confirmation Notifications
- Develop and enforce appropriate regulatory responses
- Review and evaluate claims of trade secret information and confidentiality

We note that these are only the "big ticket" items, and do not include other requirements, such as updating the DTSC website, drafting guidance documents, and consulting with small businesses. Based on this list, even if the SCPA were to apply only to food packaging materials,

it would require a legion of chemists and toxicologists to review, evaluate, and respond to the mountains of paper that DTSC will need to handle.

C. Scope of the regulation

If finalized in their current form, the regulations will impose heavy assessment and reporting burdens on industry that are beyond the authority established in the GCI. DTSC had previously indicated that the evaluation and reporting requirements of the alternatives assessments (AAs) would be imposed solely on Priority Products. In the SCPA, the scope of the AAs has been significantly expanded. For example, the designation of a chemical merely as a Chemical under Consideration may result in the need for expensive and time consuming AA. The SCPA requires a Tier I AA for products containing a Chemical under Consideration or Priority Chemical. This will be a substantial burden on industry because, given the number of factors that the Department may consider when compiling the list of Chemicals under Consideration, the amount of products containing a Chemical under Consideration is likely to be very large and, thus, AAs will be required for many products currently on the market in California. Of course, for those products designated as Priority Chemicals or Priority Products, the assessment and reporting burdens are significantly greater. If DTSC implements the SCPA as is, the practical result is likely to be the withdrawal of a substantial number of products from the California market as companies choose to withdraw from the market rather than undertake the costly AA requirements when these products have already been subject to review by FDA. For example, FDA has reviewed and evaluated almost 1000 FCNs, while the Agency's indirect food additive regulations clear the use of over 3000 substances.[47] These substances have already undergone an extremely time-consuming and expensive evaluation,[48] thus the prospect of repeating the process under the SCPA is likely to result in these products leaving the California market. This result is clearly not to the benefit of either industry or California consumers.

III. Section Specific Concerns

(1) § 69302.1

As an alternative to the life cycle exemption, manufacturers may wish to utilize the "no exposure pathway" exemption also present in SCPA § 69302.1(a). To obtain this exemption, there must be no exposure pathway by which a chemical may pose a public health or environmental threat during the useful life or the end of life management. However, the term "exposure pathway" is not defined in the regulation. It is possible for a chemical to be bound

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47 *See* http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=iaListing. This FDA database contains 3,237 records.

48 Before the FCN program went into effect, it was common for FDA to take several years to review a Food Additive Petition. Indeed, some product reviews went on for over 10 years.

up in a product so that there is no threat to public health or the environment during the product's useful life or at end-of-life; however, this enquiry is very product-specific.

(2) § 69302.3

This section provides the factors that DTSC may consider when determining whether to place a chemical on the list of Chemicals under Consideration. This section provides for over 100 factors ranging from chemical properties to public health impacts to existing data on exposure potential, without providing any indication or guidance as to which factors are weighed more heavily. DTSC should indicate the relative priority of these different factors.

(3) § 69303.2

Paragraph (a) requires that a product containing a Priority Chemical will be designated as either a Product under Consideration, or a Priority Product. Logically, there should be one set of factors that would lead to this determination. However, this paragraph presupposes that a chemical will be designated under either of these categories by evaluating whether a product would be a Product under Consideration or a Priority Product under the factors specific to those designations.

(4) § 69305.4

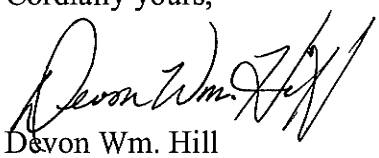
Paragraph (a)(3) requires, for a Tier II AA Work Plan, the submission of information on the supply chain for a product, including "any other person in the supply chain for the product." This requirement is very vague, as it could be read to mean any person who has supplied a component of a product, and their ingredient suppliers, and so on. This information would be very time consuming to obtain, so DTSC should clarify what it means by "any person."

IV. Conclusion

Food packaging is important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products to reduce food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food-contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI. In the opinion of our members, a separate duplicative regulate scheme would inhibit technological innovation and development that is important to ensure the safety of food and provide consumers with even safer and more environmentally friendly food packaging materials. Thus, the further regulation of food-contact materials under the GCI is prohibited by Section 25257.1(c) of the Health and Safety Code.

For the reasons set forth above, we respectfully request that the DTSC exclude food-contact materials and substances used as components of food-contact materials from the scope of any regulations promulgated to implement the GCI.

Cordially yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

cc: The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
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December 3, 2010

Via Electronic Mail and Regular Mail

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Re: Comments on the Revised *Safer Consumer Product Alternatives* Draft Regulation

Dear Mr. Woled:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the revised *Safer Consumer Product Alternatives* (SCPA) draft regulation (hereinafter SCPA 2) issued on November 16, 2010 to implement Article 14 of chapter 6.5 of division 20 of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI). These comments are being submitted on behalf of the Food Packaging Coalition ("the Coalition"), a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States, as well as trade associations that represent the food industry. The members of the Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.[1]

The comments provided herein follow up on the Coalition's comments submitted November 1, 2010, on the first draft of the proposed *Safer Consumer Product Alternatives* regulations (hereinafter "SCPA 1"). Our comments in this letter focus solely on the changes made to the draft regulation published on November 16, 2010.[2] Nonetheless, we hereby reiterate and incorporate by reference the comments from the Coalition's November 1, 2010 submission, a copy of which is enclosed.

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[1] Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, the Recycled Paperboard Technical Association, the American Chemistry Council Plastics Foodservice Packaging Group, and the Flexible Packaging Association.

[2] All section references are to SCPA 2.

As a general matter, we appreciate DTSC's efforts to streamline and clarify the regulations. SCPA 2 is easier to read and understand, and is a substantial improvement over SCPA 1. There are, however, some areas for which the Coalition believes that DTSC has not fully considered the potential implications of SCPA 2 on food packaging materials. We provide comments on these areas, below.

I. Regulatory Nonduplication

In the Coalition's November 1 submission, we stated our position and provided information to support the fact that food-contact materials already are fully regulated, by the U.S. Food and Drug Administration (FDA), to protect the safety of the public health and environment. Therefore, the regulation of these materials is not legally permitted under SCPA 2 because section 25257.1(c) of the California Health and Safety Code prohibits regulatory duplication.[3] We further discussed the regulatory nonduplication exemption set forth in various sections of SCPA 1.[4]

The Coalition considers several of the changes made in SCPA 2 with regard to the regulatory nonduplication exemption to be improvements. To start, the nonduplication exemption has been significantly simplified by the fact that it is now positioned at the beginning of the regulation (*see* § 69301(b)(5)), as opposed to being scattered throughout the implementing regulation. In addition, the nonduplication exemption has been clarified so that the analysis of whether the SCPA would comprise duplicative regulation for a given Chemical of Concern is determined by whether the hazard trait that otherwise would cause the chemical to be listed as a Chemical of Concern is already regulated by another federal or California regulatory program.

While we appreciate these changes, the Coalition would like to reiterate its position that food packaging materials should be wholly exempt from the final regulation. As fully described in the Coalition's November 1 submission, FDA has established a comprehensive regulatory framework for food-contact materials that leaves no room for regulation under the SCPA. Our prior analysis clearly demonstrates that FDA and California governmental agencies regulate all of the public health and environmental threats that are of concern to DTSC. Therefore, we urge DTSC to make this exemption explicitly clear in the final regulations.

If DTSC does not agree to fully exempt food packaging materials from the final regulation, the Agency should justify why it does not consider the SCPA duplicative regulation. Industry should not be required to go on a "fishing expedition" in order to identify any gaps in FDA's regulations. In SCPA 1, Section 69302.1(c) stated that "Any person requesting the Department to make a determination [regarding the regulatory nonduplication exemption] shall

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[3] GCI Section 25257.1(c) states, "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."

[4] Although represented best in SCPA 1 § 69302.1(a)(1).

bear the burden to prove by clear and convincing evidence to the Department's satisfaction that [the regulatory nonduplication exemption] applies to the chemical in question." Thus, it was clear that industry had to demonstrate to DTSC that a product was already fully regulated for a hazard trait by a combination of federal or California programs. In SCPA 2, this language has been removed. The exemption in SCPA 2 now simply states that "The requirements of this chapter do not apply to a chemical or consumer product that the Department has determined is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination, address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the basis for the product being listed as a Priority Product." DTSC should, thus, be required to make explicitly clear its rationale for why food packaging materials should not be exempt.

Furthermore, the revised language in SCPA 2 appropriately places the burden of this exemption on DTSC. The removal of the language of SCPA 1's Section 69302.1(c) is indicative that DTSC has taken on the burden of informing industry of the public health and environmental threats and exposure pathways for which DTSC is asserting jurisdiction. (DTSC's jurisdiction would be based on the premise that no federal or California program regulates a given Chemical of Concern's hazard trait for a particular threat to public health or the environment.) Second, the language of SCPA 2 supports this conclusion, as Section 69301(b)(5) simply states that the requirements of the SCPA do not apply to Chemicals of Concern or Priority Products "that the Department has determined" are already regulated, thereby indicating that DTSC will bear the burden of the determination of whether Chemical of Concern's hazard trait is already properly regulated.

In addition, the language of the GCI legislation also supports this conclusion. California Health and Safety Code[5] Section 25257.1(c) provides a strong prohibition against regulatory duplication, stating that "the department *shall not duplicate* or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article" (emphasis added). This mandate against regulatory nonduplication adds further support for the conclusion that DTSC should have the burden of establishing the absence of existing regulation for a given hazard trait.

Finally, it is more appropriate for the burden to placed on DTSC. DTSC will be establishing a list of Chemicals of Concern and Priority Products. For each Chemical of Concern, DTSC must identify the hazard trait that is the basis for the listing. It would be logical for the Department to inform industry, at the same time DTSC issues the list of Priority Products, of the rationale for why the Priority Product is not exempt from the requirements of the

[5] The GCI legislation is codified at Health and Safety Code §§ 25251 – 25257.1.

regulation by identifying the hazard traits and exposure pathways that are not already regulated by FDA or California agencies.

The Coalition proposes below a modified SCPA 2 Section 69303.2(b) (dealing with the development of the list of Priority Products), that we believe would address our concerns:

> "Prior to finalizing the Priority Product list, the Department shall make the proposed list available on its website, for public review and comment, along with supporting documentation, including the Department's rationale, data and data sources, subject to article 9. The supporting information shall include:
>
> (1) ~~a~~An identification of the hazard trait(s) exhibited by, and potential exposure pathways for, each Chemical of Concern that is the basis for a product being listed as a Priority Product; and
>
> (2) For food packaging materials, the Department's rationale for its determination that the hazard trait(s) and potential exposure pathways that are the basis for the chemical being listed as a Chemical of Concern are not regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate."[6]

II. No Exposure Pathway

In addition to the nonduplication exemption, SCPA 2 has also retained the exemption by which products containing Chemicals of Concern may be exempt from the Alternative Assessment requirements, if DTSC has determined that there is no exposure pathway for the Chemical of Concern that would pose a threat to the public health or the environment. Similarly to the regulatory nonduplication exemption, the no exposure pathway exemption has been significantly simplified by its consolidated placement at the beginning of the regulation (*see* § 69301(b)(6)). By contrast, however, the "clear and convincing evidence" standard has not been removed. The Coalition is concerned that DTSC has failed to provide a rationale for this high burden of proof, and is imposing an unnecessarily stringent standard on industry. The Coalition recommends that, instead, DTSC utilize a standard of "weight of the evidence based on validated scientific data." It is always difficult to prove a negative, thus, requiring manufacturers to prove the absence of an exposure pathway by a "clear and convincing" standard is overly burdensome. We believe that a weight of the evidence standard is sufficiently rigorous to determine whether

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[6] The remaining text of this paragraph may be redesignated as paragraph (c), and all following paragraphs also should be redesignated accordingly.

there is significant exposure to the chemical from its intended use. Thus, the revised Section 69301(b)(6)(B) would read as follows:

> (B) Any person requesting the Department to make a determination pursuant to subparagraph (A) shall bear the burden to prove that, based on validated scientific data, the weight of the evidence demonstrates that subparagraph (A) applies to the product in question.

In addition, DTSC has retained the requirement that the exemption shall be determined based on "an evaluation of reasonably foreseeable uses, misuses and abuses of the product, and reasonably foreseeable proper and improper end-of-life management of the product." The Coalition believes that this standard should be limited to reasonably foreseeable uses. A food packaging material manufacturer should not be required to speculate on all the misuses and abuses to which their product could be subjected. It is difficult for any manufacturer to speculate on how a product could be misused, and placing the burden of safety for uses which a product is not intended would be a substantial and unfair burden on industry. Furthermore, in the event that a consumer does misuse or abuse a food container, it is not likely that the package itself will pose a new or significant safety concern, because the misuse or abuse would not likely change the intrinsic nature of the food container. The human and environmental exposure to the Chemical of Concern would not be increased by the misuse because, as noted by Dr. George Gray in his peer review (page 5), there is "little opportunity for exposure if the chemical is sealed, bound to a matrix or otherwise unavailable," as is the case with substances in food packaging materials. Instead, the contents of the misused package are what would be relevant from a health and environmental standpoint.

III. *De Minimis* Exemption

Another exemption available from some SCPA 2 requirements is the *de minimis* exemption.[7] "*De minimis*" is defined, in part, as a concentration less than or equal to 0.1% by weight. This part of the exemption is unchanged from SCPA 1. As the Coalition discussed in its comments for SCPA 1, it is unclear as to what the 0.1% by weight threshold refers. For food packaging materials, this threshold could be interpreted to apply to the amount of the chemical by weight of the consumer product as a whole, the amount of the chemical in relation to the finished package, or the amount of the chemical that could migrate from the finished food contact article into food. We believe that the exemption should be clarified so that, for food packaging materials, the exemption threshold applies to the amount of any chemical that could migrate from the package into food. This measurement is the most important from a health and environmental safety perspective, because it is based on the potential exposure that could result.

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[7] The application of the *de minimis* exemption is found in § 69303.2, although the definition of "*de minimis*" is found in § 69301.1(26).

It is not the presence of a chemical in a food packaging material that is of interest; instead, it is the level of migration of the chemical from the food packaging that would give rise to an exposure to a particular substance.

Although the 0.1% by weight threshold is unchanged from SCPA 1, DTSC has made other beneficial changes to the *de minimis* exemption. Most notably, industry now has the ability to make a self-determination as to whether a Chemical of Concern is present in a product at a level above the *de minimis* threshold. The Coalition considers this to be an appropriate revision, on the basis that a manufacturer is in the best position to have information on the composition of its products.

However, although industry now makes a self determination as to whether a product is eligible for the *de minimis* exemption, DTSC has added a notification requirement to this exemption (*see* § 69303.2(d)(3)(A)), whereby the Priority Product's manufacturer submits a "De Minimis Exemption Notification" to DTSC. As part of this Notification, the manufacturer must submit, for a formulated product, the maximum concentration of each Chemical of Concern in the product that is the basis for the Priority Product listing, and a description of all data and other information used by the manufacturer to determine and substantiate this concentration. Furthermore, DTSC has limited the exemption for formulated products by requiring the aggregation of Chemicals of Concern that exhibit the same hazard trait. Thus, if a Priority Product contains multiple Chemicals of Concern that exhibit the same hazard trait, the concentration of these Chemicals of Concern in the Priority Product must not total more than 0.1% in order for the Priority Product to qualify for the *de minimis* exemption.

The Coalition considers that the aggregation of chemicals with the same hazard trait is inappropriate from a toxicological perspective. DTSC is equating the aggregation of hazard traits with the aggregation of the risk that multiple chemicals exhibiting the same hazard trait will result in a particular toxic event. This often is not the case. For example, a product may contain two chemicals that exhibit the broad hazard trait of carcinogenicity, but that act by dissimilar biochemical mechanisms. Although exposure to each chemical may result in the same toxicological endpoint (cancer), there is no cumulative effect from both chemicals because the biochemical mechanism is different. Each of the two chemicals has its own biochemical mechanism that causes the toxic event. By contrast, two chemicals may cause cancer through the same biochemical mechanism; in this case, it may be appropriate to aggregate the exposures, as there could be a cumulative risk of the chemical exposure resulting in the same toxic event. It is important to note, however, that there may be uncertainties and complexities associated with aggregating exposures to chemicals that work through similar biochemical mechanisms, because such chemicals may still have differences in their toxicokinetic profile (such as in their absorption, distribution, metabolism, and excretion (ADME) profile, for example, or in their Physiologically Based Pharmacokinetic (PBPK) models). Therefore, only those Chemicals of Concern that exhibit the same hazard trait, and for which there is evidence that the biochemical

mechanism of exposure and the toxicokinetic profile are the same, may be subject to aggregation.

IV. Adverse Public Health Impacts

DTSC has added a new definition to describe "adverse public health impacts" (*see* § 69301.1(6)). Adverse public health impacts are one factor that DTSC will use in its evaluation of the relative threat of different chemicals to determine which chemicals will be placed on the list of Chemicals of Concern (*see* § 69302.2), and again in its evaluation of the relative threat of a Priority Product (*see* § 69303.2). Adverse public health impacts are defined as "impacts that directly or indirectly cause any of the following effects on human health: (a) acute toxicity; (b) carcinogenicity; (c) developmental toxicity; (d) reproductive toxicity; (e) epigenetic toxicity; (f) genotoxicity; or (g) organ, tissue or cellular toxicity not otherwise described above. We are concerned with two of these categories—epigenetic toxicity, and the catch-all, "organ, tissue, or cellular toxicity not otherwise described above."

The Coalition's comments for SCPA 1 described for DTSC the problems with using epigenetics as a toxicological endpoint of concern. We would like to reiterate again that the inclusion of epigenetics is inappropriate because it is a new field of toxicological analysis. As such, it has no reference database by which to judge any analysis, or historical controls for comparison. In his peer review, Dr. William Farland suggests that epigenetics is a valid endpoint, as long as it is toxicity-related. However, this suggestion assumes that we know which "epigenetic" changes are implicated in the etiology of disease; this is not yet the case. The appropriate toxicological endpoint for such effects would instead be the more conventional endpoints, such as reproductive or development toxicity or carcinogenicity, which are already listed. Thus, as epigenetics is an unproven and ambiguous area of toxicology, the Coalition believes it should be removed from the definition of an adverse health impact. Furthermore, no other regulatory agency (of which we are aware) uses such an ambiguous and amorphous endpoint for regulatory decision making purposes.

In addition, the catch-all provision of "organ, tissue, or cellular toxicity not otherwise described above" should be removed from the list of adverse impacts, because it is ambiguous, and fails to put industry on notice of the appropriate toxicological endpoints of concern.[8]

V. Chemical Removal Notice

SCPA 2 has added a requirement that, when submitting a Chemical Removal Notice under Section 69303.2 (d)(2), the manufacturer is required to certify that the Chemical of

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[8] In addition, similarly to epigenetics, the use of cellular toxicity as an endpoint is toxicologically ambiguous. Some studies address cytotoxicity, however, the impacts on living systems is, at best, speculative and has not been validated. Thus, cellular toxicity should not be considered to be an appropriate toxicological endpoint.

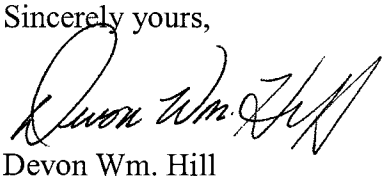
Concern has been removed "without adding another chemical or increasing the concentration of a chemical contained in the product or component to compensate for the removal or reduction of the Chemical(s) of Concern" (*see* § 69303.2(d)(2)(A)). In many cases it would be unlikely that a Chemical of Concern can be removed from a product without replacing it with another chemical that can provide equivalent functional performance. However, it would be reasonable to require that no additional Chemicals of Concern are used to replace the one that was removed. Thus, the Coalition believes that this section should be revised to read as follows:

> "(A) A statement certifying that any and all Chemicals of Concern that are the basis for the Priority Product listing have been removed from the product or component, whichever is applicable, or reduced to a level that meets the criteria specified in paragraph (3)(d), without adding another Chemical of Concern ~~chemical or increasing the concentration of a chemical already contained in the product or component~~ to compensate for the removal or reduction of the Chemical(s) of Concern that caused the listing of the product as a Priority Product".

* * *

We appreciate this opportunity to comment on SCPA 2, and we look forward to working with DTSC on the continued implementation of the GCI. Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely yours,



Devon Wm. Hill
Counsel to the Food Packaging Coalition

Enclosure

cc (via email only): The Honorable Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
Scott Reid, Cabinet Secretary, Office of the Governor
John Moffatt, Legislative Affairs, Office of the Governor
Maziar Movassaghi, Acting Director, DTSC
Jeff Wong, Chief Scientist, DTSC
Odette Madriago, Chief Deputy, DTSC
Hank Dempsey, Special Advisor, DTSC

December 19, 2011

Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Comments on Informal Draft Regulations - Safer Consumer Product Alternatives

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The $2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over $1 trillion in added value to the nation's economy.

GMA was an original supporter and is an active leader in the development of California's Green Chemistry Initiative (GCI) and advocated for the passage of AB1879 and SB509 as key elements in establishing authority to identify, assess, and manage high priority chemicals and to establish a portal for chemical safety information. We appreciate the opportunity to submit the following comments in response to DTSC's October 31, 2011 Informal Draft Regulations for Safer Consumer Products. We recognize the extensive DTSC staff efforts that have gone into these revisions from the 2010 efforts. In particular, we appreciate and strongly support Director Raphael's direction to make the Safer Consumer Products regulation practical, meaningful and legally defensible. Applying and balancing these concepts can be a pathway to achieving the Green Chemistry Initiative's objectives.

GMA filed substantial comments to the Proposed Regulation throughout the process thus far, which we incorporate by reference here. (For a copy of our comments, please see: http://www.gmaonline.org/issues-policy/product-safety/chemicals-management/green-chemistry/state-comments/).

The latest iteration of the draft regulations contains a number of strategic choices that will help create a program to improve public health and the environment for all Californians:

- It appropriately focuses on consumer products and not commercial products, bulk chemicals and manufacturing operations;

- DTSC indicates that in the first round it will select 2 to 5 Priority Product (PP)/Chemical of Concern (CoC) pairs. GMA has advocated for and supports this approach to enable focused learning and building on success in the initial stages of implementation.
- DTSC's approach to the process is described as "mandating the question" (i.e., the Department picks Priority Products/CoC pairs), not "dictating the answer" (i.e., the Department does not select the alternative). Rather, companies are expected to conduct the Alternative Assessment.
- The draft Alternative Assessment (AA) section has some important features that are critical to maintain: the ability for a company to propose an alternate AA process that meets the intent and outcomes of DTSC's AA process; the flexibility to use any appropriate AA methodology; the capability to focus the AA on relevant factors, case-by-case; the elimination of 3rd party verification and the ability to use in-house expertise in developing AA's.
- On data requirements, DTSC has chosen to allow submitters to provide quantitative and qualitative information. Where information is lacking, there will be no obligation to fill data gaps initially. However, as a regulatory response, the Department may require the data should there be remaining concerns. This option would allow for timely completion of AA's, and focus any new data requirements on truly critical needs.

However, there are numerous concerns in the current draft that if not addressed will prevent the program from being deliberate, focused, and achieving its full potential. There also remain several continuing scientific concerns. Additionally, some aspects of the draft will not only be impractical and unworkable, but may stifle innovation due to the potential for a regulatory treadmill and may result in arbitrary decisions. Beyond these, the draft would impose unnecessary costs and administrative burdens on companies doing business in California and will require a large DTSC staff to manage the paperwork and process, even if the number of products is limited. Following are some issues of major concern to GMA, addressed more fully in the attached detailed comments:

- The definitions for reliable information and the lack of defined thresholds for measurable hazard traits will weaken the effort to make this a meaningful scientific program.
- The regulatory duplication provisions include an unnecessary and unauthorized criterion for determining the scope and application of the Safer Products regulation.
- Proposed *de minimis* levels are inconsistent with those set elsewhere in federal and international chemical control systems and made more impractical with stringent add-up provisions in the AA section.
- The proposed establishment of a chemical of concern list containing well over 4000 chemicals is not a process for selecting chemicals of concern (as statutorily prescribed for), 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 of authoritative bodies.
- A non-quantitative product prioritization process, so-called a narrative process, as proposed is not suitable for identifying high priorities that will make meaningful improvements to public health and the environment in California.
- Although there are many positive aspects of the draft Alternative Assessment process, there a number of critical workability concerns - timelines are too short; the

requirements wander away from a strict focus on the Chemical of Concern, serving as the basis for designating a product as priority, with the potential for establishing a regulatory treadmill; and the expertise of company experts is not valued in conducting AA's.

- The regulatory response provisions include no criteria for determining the level of response action the Department would take and for what reasons.
- The regulations would create an enormous paperwork burden for the Department and regulated entities.

California deserves a credible, workable, and successful program that can achieve this part of the Green Chemistry Initiative's objectives, to complement the other five planks of the Initiative. GMA strongly supports many of the improvements in this version of the draft regulations but still has many important concerns. There is much work remaining for the draft regulations to achieve the balance of being practical, meaningful and legally defensible. GMA is a member of the Green Chemistry Alliance (GCA) and supports the Alliance's forthcoming detailed comments. In addition, GMA is a member of the Food Packaging Coalition (FPC) and supports the Coalition's comments.

The Grocery Manufacturers Association remains committed to assisting the Department in developing and implementing a Green Chemistry program that will not only achieve the Green Chemistry Initiative's objectives, but that will also be a model for the U.S. and elsewhere. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,

John Hewitt
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cc Secretary Matt Rodriguez, California EPA
Miriam Ingenito, California EPA
Director Debbie Raphael, DTSC
Odette Madriago, DTSC
Jeff Wong, DTSC
Cliff Rechtschaffen, Office of the Governor

Detailed Comments

§69501.2 Definitions
Definitions for "adverse impacts", "bioaccumulation" and "reliable information" although modified, remain scientifically inadequate. Thresholds must be included to account for potency in implementing all aspects of the regulations. Suggested revisions to other terms in the Definitions section of the informal draft regulations are provided below as well.

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 "chemical ingredient". The following revision is suggested:
"Chemical ingredient" means a chemical **that serves an intended function** in a consumer product.

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. The following revision is suggested:
"Legal requirements" means specifications and/or performance standards that **a chemical or** a product is required to meet by federal or California law.

Safer alternative – "Safer alternative" means an alternative that, in comparison with the existing Priority Product, ~~reduces, avoids, or eliminates the use of, and/or potential exposures to, one or more Chemical(s) of Concern, so as~~ **is determined by the Alternatives Assessment** to reduce potential adverse public health and environmental impacts.

Adverse Impact – Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, and waste/end-of-life related to hazard traits. Many traits are traditional endpoints addressed in state, federal and international chemical programs. However, there are several critical concerns in these definitions.

Scientific Frontier –The first is that some factors are scientific frontier issues—for instance epigenetic toxicity—that are not settled science and lack widely accepted evaluation methodologies, but are included in OEHHA's hazard traits and by reference in these regulations. We have argued that such traits do not belong in these regulations and should be removed. Peer reviewers suggest that "epigenetics" is a valid endpoint as long as it is toxicity-related. However, this makes the implicit assumption that we know which "epigenetic" changes are implicated in the etiology of disease and that is not yet the case. Since epigenetics is an unproven and ambiguous area of toxicology, GMA believes it should be removed from the definition of an adverse health impact.

Thresholds –An overriding concern with the adverse impact and chemical property definitions is that there are no threshold levels to provide a context for what is of concern. All chemicals, including water, have toxic impacts across a variety of hazard traits at some measurable level. The absence of thresholds in the regulations suggests that every substance could be considered a Chemical of Concern or be included for the purposes of *de minimis* determination, Alternative Assessment and Regulatory Response because it has some impact, no matter how small or large, regardless of potency. Thresholds are a part of chemical control systems worldwide as a means

to help identify priorities, particularly in the PBT and chronic toxicity arena. The definitions should include thresholds and clearly convey the potential for adverse impacts in the context of thresholds.

Bioaccumulation – GMA has previously noted that the proposed definition for bioaccumulation was inconsistent with nationally and internationally accepted definitions, which specifically include thresholds. Peer reviewers have also commented on this issue. It's not clear why such an important chemical property, with a long history of federal and international standard setting and chemical control actions, should be defined with a unique to California approach. This will disconnect the state from the capability to use any existing data and scientific approaches, slowing Green Chemistry progress as the Department attempts to translate all of the extensive information, learnings and actions from global programs into a California-unique approach. This is particularly troubling given that this trait is among several targeted for more stringent *de minimis* levels, and the fact that no threshold is identified for a property that yields a measured, non-zero value. GMA reiterates the recommendation that the bioaccumulation definition be changed to be consistent with definitions in the following:

> **EPA policy statement entitled 'Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances' (64 Fed. Reg. 60194; Nov. 4, 1999).**
>
> Stockholm Convention on Persistent Organic Pollutants http://chm.pops.int/default.aspx

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 sources as *de facto* "reliable" is scientifically bankrupt and has the potential to drive controversy into a program that is intended to be science-based. In particular, (C) "Published in scientifically peer reviewed reports or other literature" is problematic. First, "other 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) "Reliable 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 DTSC 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 "reliable information". GMA believes they should not automatically be considered as such.

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

GMA reiterates our recommendation that the department provide separate definitions for "Information Sources" to include the diverse sources listed in (66) and (67) and then to determine reliability by subjecting those studies to this definition for "Reliable Information" based on the OECD Manual:

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

§69501 Regulatory Duplication
Under the draft regulations, regulatory duplication provisions of the statute apply and the product will be excluded from the program if DTSC 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.

GMA supports the first criterion and believes that it should be the sole factor in determining regulatory duplication.

The second criterion is not intended by the legislature. It is not authorized by the statute nor is it necessary. It is 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 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 any regulatory response 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 seems to be addressing.

§69502 Chemicals of Concern

The Draft Regulation envisions an approach that would announce well over 4,000 chemicals of concern at the effective date of the Regulation, resulting from the merging of all the items on 22 diverse lists. Contrary to the overall direction for developing these regulations, the approach is not Practical, not Meaningful and not Legally Defensible. There are several major concerns with this approach:

- The statute requires that DTSC establish a <u>process</u> to prioritize chemicals of concern. The proposed approach does no prioritization 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 in 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 US commerce[1]; 80% were not reported as manufactured or imported into the US in 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 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 chemicals of concern 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. GMA recommends the following approach to prioritize chemicals of concern. This can be completed in a timely way—within 90 days of the publication of the regulation—and not slow progress in implementing the regulations. The Department should:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes

[1] 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.

with the opportunity for stakeholder input and comment (specific recommendations below);

- Merge those lists to generate a set of "chemicals under consideration";
- 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.

This approach has several benefits: it can be done quickly without diverting DTSC's other efforts to implement the regulation; it produces a large list of "chemicals under consideration" 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 DTSC's further work, but that will be more likely to prompt action in the marketplace beyond just DTSC's 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 DTSC represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment, a number do not. In addition, some lists are selected based on exposure. GMA believes that lists should be those that are developed to identify chemicals with significant hazards. Appendix A provides GMA's detailed recommendation and rationale on which sources are appropriate and which should be dropped from consideration.

There are some sources that DTSC has not included that GMA would recommend. The Stockholm POPs list for PBTs has been developed through extensive global discussion and consensus. http://chm.pops.int/Convention/ThePOPs/tabid/673/Default.aspx . 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, DTSC would pick up all chemicals on which decisions had been made at the effective date of the regulation. http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec_en.asp

§69503 Product prioritization

GMA supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of DTSC scientists. In previous comments, we have supported and recommended a 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. DTSC must employ a rigorous scientific process for selecting chemical of

concern/priority product pairs. GMA prepared an in-depth report and suggestions on a quantitative process that would ensure such an outcome and that had been successfully been employed internationally. This is posted on DTSC's website under the headline "Chemical/Product Prioritization Resources"
http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm

Unfortunately, these ideas do not seem to be employed in the Draft Regulations. Instead, a "Narrative Standard" is envisioned. The process outlined has three aspects.

- (a) Consideration of a wide set of potential adverse impacts and exposures, the availability of information, and the protections addressed and afforded by other regulatory programs.
- (b) Consideration of Key Prioritization Criteria
- (c) A description of a process for moving through selection that evaluates products based on the factors in (a) to identify high priority products. That evaluation can be adjusted based on the ready availability of a safer alternative and the scope of other product regulatory programs. Finally, the list is reviewed for consistency with (b).

The Draft product prioritization process is problematic in a number of ways.

- 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 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 Chemical of Concern 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 GMA 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 "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 and vice versa. GMA strongly encourages inclusion of "level" of exposure in this provision.
- GMA 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 "reviewed for consistency" in (c). Instead they 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 Chemical of Concern in the product has significant potential to cause adverse public health and environmental impacts; and
    - There is significant potential for exposures to the Chemical of Concern in product in quantities that can result in adverse public health or environmental impacts.

  GMA'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 should be prioritized as high priority that meet just one or two of these criteria. 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 DTSC to base decisions on both hazard and the potential for exposure. If a product is intended for consumers AND made with a Chemical of Concern 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 petroleum-based consumer products that are formulated but which 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. DTSC 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. Keeping in mind that formulated products can be packaged in a variety of ways and delivered in many forms—gas, liquid, foam, gel, powder, granule and solid—GMA recommends that (5) be re-written to parallel (4) by dropping (A), (B) and (C) and stating:
    - ***For 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***.
- The Draft regulations have abandoned any focus on intentional ingredients, those chemicals purposefully included in a product to perform a function. GMA 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. DTSC 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 while controlled, are not economically feasible to remove. To ensure that prioritization is focused on substituting chemistries that are most likely to have the greatest potential risk to the public, GMA recommends that DTSC consider only chemicals that have been both intentionally added and are above the *de minimis* level when making product prioritization decisions.

§69501.2, 69503 and 69505 De Minimis

GMA has consistently advocated for the inclusion of a *de minimis* threshold in the Proposed Regulation with a default level of 0.1%. With ever improving analytical capability and ever-lower detection limits, vanishingly small and insignificant levels can be identified. These are great for generating headlines, but meaningless in protecting public health. *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. GMA believes 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, GMA has supported the concept that DTSC 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 DTSC'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. GMA does not agree with this direction and requests that the Department reconsider establishing the *de minimis* at 0.1% for all hazard traits. In addition, GMA does not support the concept that the *de minimis* should be based on adding the concentrations of multiple Chemicals of Concern. Firstly, no other *de minimis* systems in the world employ this approach. This suggested approach would add an additional order of magnitude of conservatism, rendering it significantly more precautionary. Secondly, as discussed in California's Green Ribbon Science Panel (GRSP), the complexity of the evaluation on similar mechanisms and determining whether there is co-activity are extremely difficult and not appropriate for this regulation.

Some stakeholders have suggested that "0" is an appropriate *de minimis*. "0" is impractical, is a technically impossible regulatory standard to measure and comply with, and provides no additional benefit to public health and the environment.

§69505 and 69508 Alternative Assessment/Certification

Alternative Assessment (AA) in the Research and Development Paradigm. 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**, cost to consumers, processability or manufacturability, 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 "pick and choose" between AAs and mandate a particular alternative but rather evaluate AAs to ensure 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 for 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 <u>gradual</u> and <u>measured</u> 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.
- Ensure that an alternative formulation is legal, especially when considering patent issues and other state and federal regulations.

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 DTSC 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

I. 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. In addition, 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 are clear 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 6 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 3-5 years or more, often with many failed alternatives cast aside at different points in the product development process.[2]

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

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[2] 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 new chemical PMN is required (as the PMN work may sometimes 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 chemical of concern. 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.)

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. 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. A significant question is whether DTSC anticipates the workplans to include all of the requirements of the Preliminary AA report or is DTSC's expectation to simply have an outline of a company's plan— i.e., the approach they plan to take, identifying the major blocks of work and specifying the timeline for submissions to DTSC (including both any interim as well as Final reports). The proposed 60 days is sufficient if the workplan is an outline of a company's plan. If the AA workplan is intended to capture more than just an outline, in which the company has to essentially demonstrate that the tools, methodologies, etc. to be used by the company to do the AA will provide similar information as DTSC's AA stages do, the responsible entity should be given 6 months to submit an AA workplan (NOT 60 days) for the alternate process. Also, there needs to be adequate allowance for extending timeframe to complete Stage 2 AA depending on the complexity of the product and the type of substitution. Responsible entities could still however be held accountable (via a regulatory response) to pursue viable alternatives through further research and development.

As mentioned above, there will be situations where a collaborative approach is the best approach to pursue alternatives. Flexibility in timing and 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 3-4 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 "flame retardants in circuit boards," which is ongoing after more than 6 years, is instructive. Despite a widespread, committed level of interest and effort by the industry in this public-private partnership, there is not yet a fully demonstrated 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 on 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 workplan and regular reports to provide the department with updates on progress.

II. SCOPE of AA process – Stage 1, Stage 2, and Consortia/Anti-Trust:

IIA. Stage 1 AA:

Showstoppers. 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 "potential" 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 "showstoppers" for which further evaluation is not necessary, thereby focusing limited resources on truly potential alternatives. An alternative may have showstoppers, and thus, not be viable for a number of reasons, whether the alternatives are eliminated on product safety, on technological feasibility, economic feasibility, and other factors (e.g., environmental footprint), etc. GMA 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, describing the rationale for the decision. In addition, the hazard comparison as suggested in the Preliminary stage should serve primarily as an initial screening tool, focused on quickly identifying showstoppers and narrowing the list of potential alternatives to those that are truly viable.

GMA recommends the following language be added to the draft regulations:

(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.

IIB. Stage 2 AA:

(i) **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 "scope creep", the focus of any assessment should be restricted to the CoC that is the reason for the designation of the priority product.

(ii) **Relevant Factors.** As mentioned previously, the AA should identify "relevant" 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 "demonstrable" inappropriately implies that even the slightest impact or change would be relevant. What would constitute a "demonstrable contribution" to increasing or decreasing adverse impact AND a "demonstrable 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, GMA recommends that, in the same spirit of AB1879 with the goal of significantly reducing adverse impacts, "demonstrable" should be replaced with "**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.

GMA recommends the following revision be made to the draft regulations:

§ 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 and important. 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).**

GMA recommends the following language be included in the regulations:

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

(iii) **Focus on Designated Chemical of Concern and Alternatives.** The scope of the alternatives assessment is broadened substantially when multimedia life cycle impact and chemical hazard considerations are being requested not only for the CoC and its potential substitutes but also for ALL chemical ingredients and any CoC 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, significantly extending the time necessary for AA completion and diverting resources from focusing on the real purpose of the AA.

To ensure that such unauthorized "scope creep" does not occur, it is important to maintain focus of the Alternatives Assessment on the CoC/PP pair and their potential alternatives and to evaluate only substantial changes to the alternative formulation in which <u>other CoC</u> may have been newly added. It is unnecessary, burdensome, and inefficient to require reporting on all chemical ingredients within the product (and/or

alternative), thus detracting from the goal of the statute of identifying, prioritizing, and evaluating prioritized CoC that may significantly adversely impact public health/environment.

GMA recommends that the language be revised to:

§ 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**…**

(iv) On the determination of the "technological 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 "functionally acceptable" alternative, *affordability*, and the *purchase price differential* to the consumer. However, these don't directly address the "technological 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.

GMA recommends that the language in § 69505.4.(a)(2)(B)3. be revised to:

§ 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**, including not only the actual cost difference but also any difference in the processing/manufacturing conditions,** 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.

(v) **Externalized Costs.** Regarding economic impacts (§ 69505.4.(a)(2)(C)), the implications of "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 manufacture 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.

IIC. Consortia/Anti-Trust:

Consortia. 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 human and environmental toxicity, exposure patterns and safe practice considerations only. In contrast, the scope of the AA as described by DTSC 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 (Section 69505.4(a)(2)(B)3. and (C)), and discussion of business plans (Section 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 Sections 69505.4(a)(2)(B) and (C), and 69505.4(c). This will still test the more restrictive US 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 Section 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.

To authorize such programs and ensure they are effective, the Department needs to consider what will be necessary to support them and how the regulations can help to enable success.

GMA recommends the following language be added to the draft regulations:

(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.

III. Alternatives Assessment Reports

(i) **Focus on Designated Chemical of Concern and Alternatives.** Regarding list of chemical ingredients in Priority Product (PP) and potential alternatives, sections (i.e., § 69505.5.(h)(2)(C) within the "Supporting Information" section AND § 69505.5.(l)(4) within the "Selected Alternative" section) that make reference to the need for a complete list of all chemical ingredients within the PP beyond the designated CoC 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.

(ii) **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. often make and market products for all of North America, compliance with Canada's requirements may also be necessary (e.g., a New Substance Notification (NSN)).

(iii) **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. GMA recommends that all language relating to product contents beyond the CoC that was the basis for the listing be deleted from this Article. We propose that the language be revised to reflect this:

> "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."

IV. Regulatory Treadmill

GMA 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.

As 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 legislative oversight hearing on Green Chemistry, Dr. George Daston (P&G) commented that "definitive results" would be a successful criterion, without the need for further regulation of the alternative.

This regulatory treadmill will kill innovation, diverting company resources to continuously assess a product that is already safe, preventing the development of other improvements in safety, cost and sustainability. 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 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 and improve the safety profile for public health and the environment. When definitive results have been achieved, the Department should declare success and move on.

V. Quality Assurance for Alternatives Assessment

(i) 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. Key technical skills beyond exposure assessment that are required to develop safe and effective products for consumer use include toxicology, environmental toxicology, chemistry, chemical engineering, microbiology. In addition, the process will require the help of those knowledgeable in finance/accounting, life cycle analysis, and consumer and clinical testing.

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 all expectations

and requirements for the AA have indeed been addressed. 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.

(ii) Certified Assessors

In-house company experts with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead alternative assessment projects 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 safety and 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 have the necessary in-depth understanding 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. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors' work products) that is being certified. DTSC 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.

(iii) Audit

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

§69506 Regulatory Response

The Green Chemistry Alliance is providing detailed suggestions on this article and GMA supports those comments.

GMA emphasizes that while the types of regulatory responses follow those named in the statute, we are concerned that there are no criteria indicating what level of response action the Department would take and for what reasons. Regulatory responses vary from "No Additional Response" to "End-of-Life Management", "Product Sales Prohibition" and "R&D Project". These are grossly different actions and should be taken in markedly different situations that should be able to be described or categorized in advance. Not doing so provides the Department with unfettered authority and opens it to charges of arbitrary and capricious action. We suggest that clear criteria and considerations for different regulatory responses be outlined in the regulations. In addition, the Department should clearly document the reasons for each Regulatory Response action.

On the End-of-Life Management response, in the case where this affects multiple responsible entities, there are potential anti-trust concerns with organizing programs to accomplish these objectives. To authorize such programs and ensure they are effective, the Department needs to consider what will be necessary to do so and how the regulations can help to enable success.

In parallel with comments on Alternative Assessment references to Regulatory Responses, there should be no Regulatory Responses beyond those relating to the CoC that was the basis for the Priority Product selection. The scope of the effort should be focused only on the CoC/Priority Product pair and not be broadened. This is currently not the case in No Additional Response, Product Information for Consumers. GMA recommends that all language relating to product contents beyond the CoC that was the basis for the listing be deleted from this Article.

§69510 Trade Secrets and Intellectual Property

The Green Chemistry Alliance is providing detailed suggestions on this Article and GMA supports those comments.

Protection for Trade Secrets is a core component of this law and is supported by existing California statute and regulations. GMA emphasizes that product formulae information in particular is a critical part of a company's trade secrets. The names, concentrations, and physicochemical properties of ingredients in formulae will inevitably be claimed secret under this provision and are the result of investments in innovation. The time-frames for such claims will regularly extend well beyond a few years—such innovations are often core to a product's success for decades. Each innovation can build on and enhance previous innovations and must be protected from disclosure to competitors. It should come as no surprise that substantial portions of AA reports, especially data-based, detailed comparisons, will be redacted for these reasons and more.

Aside from trade secrets, manufacturers should not have to jeopardize their ability to file patents, particularly under the new "first to file" patent regulations to be in effect soon. One key tenet of the new legislation is that the priority date for a patent claim will be awarded to the "first to file" a provisional patent application, not the "first to invent (previously substantiated with a standard affidavit of, for example, a witnessed lab notebook)". Thus, if a manufacturer's alternative is declared in the report and disclosed publicly, the manufacturer's invention would be precluded from intellectual property protections. Disclosure of proprietary raw material considerations, compositions, processes, use methods, technology, etc. must keep the filing of patents in mind. Even the disclosure of a particular raw material as an alternative to a chemical

of concern in a particular product could be considered the sort of public disclosure that impacts patent rights, if not in the U.S., then potentially in other jurisdictions since it becomes public knowledge at that point. Allowances for **confidential** disclosure with the agency must be made.

Appendix A. GMA 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 Traits	GMA Recommendation
(a)(1)(A)	California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity	Toxicological Hazard Traits: · Carcinogenicity · Reproductive Toxicity · 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: · Carcinogenicity · Reproductive Toxicity · 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: · Bioaccumulation · Persistence	**√ Use. Previously recommended by GMA. In 2009, GMA recommended using the <u>393 priority PBiT chemicals</u>, 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: · 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: · Bioaccumulation/Persistence · 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: · Endocrine Toxicity	**Not authoritative body; work discredited by EU's highest scientific advisors (NAS equivalent). No deliberative scientific process with stakeholder input. No EU <u>regulatory attention for 5 years.</u>**
(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: · Carcinogenicity · Reproductive/Developmental Toxicity · 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: · 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: · Toxicological Hazard Traits · Environmental Hazard Traits · 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: · Toxicological Hazard Traits · Environmental Hazard Traits · 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: · Bioaccumulation/Persistence · 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: · Bioaccumulation/Persistence · 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: · 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: · Bioaccumulation · Persistence · 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: · 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: · Reproductive Toxicity · 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: · 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.**

(IC)49-DuPont

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December 16, 2011

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Debbie Raphael
Director, Department of Toxic Substances Control
P. O. Box 806
Sacramento, CA 95812-0806

Re: October 31, 2011 California Safer Consumer Products Informal Draft Regulations

Dear Director Raphael:

E. I. du Pont de Nemours and Company (DuPont) submits these comments in response to the California Department of Toxic Substance Control's (DTSC) October 31, 2011, version of the California Safer Consumer Products Informal Draft Regulations.

DuPont has been bringing world-class science and engineering to the global marketplace in the form of innovative products, materials, and services since 1802. The company believes that by collaborating with customers, governments, and NGOs we can respond creatively to challenges in the marketplace, such as the current societal shift toward a demand for products that demonstrate sustainability throughout the life cycle.

We appreciate that the October Informal Draft reflects positive changes to the previous draft version. However, several critical areas and systemic themes remain where further revisions and fundamental recognitions are necessary to create a practical, meaningful, and legally defensible regulatory program. After careful review from our technical, business and policy experts, we offer the comments in Attachment 1. In addition, DuPont supports the comments offered by the American Chemistry Council on this topic.

Thank you for the opportunity to comment on this very important matter. DuPont looks forward to continued collaboration with DTSC and our fellow stakeholders to develop and implement a workable Safer Consumer Products Regulation.

Sincerely,

Caroline Silveira

Caroline Silveira
Government Affairs Manager, Western Region

Attachment 1: DuPont Comments on October 31, 2011, California Safer Consumer Products Informal Draft Regulations

1) **We believe the proposed regulation would result in significant unintended consequences.** DuPont and many other companies do extensive work to understand the safety-in-use of their products, including identifying trace levels of Chemicals of Concern (COCs) in the products they make and in the raw materials they purchase. These companies often do in-depth risk assessments, including studying the hazards of the COCs and the extent to which consumers might be exposed to them, to confirm that the COCs do not present a significant hazard to consumers at the levels in which they appear in the final products. Other companies that do not do such in-depth chemical or safety analyses may believe that their products do not contain COCs simply because they have not tried to determine if they are present in their raw materials or in their synthesized products. The proposed regulation may prevent those companies that have done extensive risk assessments to confirm the safety of their products from continuing to offer those products in California, while allowing other companies that have NOT exercised diligence in proving the safety of their products to continue selling their products. This unintended consequence undermines the regulation's intent to improve the safety of consumer products. In fact, the de minimis quantities that have been proposed are so low that only companies that pay close attention to trace impurities in their raw materials and their synthesized products are likely to know that COCs are even present in the final product.

2) **Insufficient time to consider reformulation.** Once the Priority Product list is finalized and published, there appears to be very little opportunity for companies to reformulate products containing COCs without being obliged to significant reporting requirements (e.g., Priority Product Notification or De Minimis Notification, Preliminary Alternative Assessment, Final Alternative Assessment). We recommend companies be given a reasonable amount of time to reformulate before they are subject to reporting or formal alternative assessments. Sufficient time is needed to identify new chemistries, test and validate the resulting product quality, gain acceptance from downstream customers and implement technology changes that are often required.

3) **Proposed exclusion of unintentional by-products.** If a COC is added to a product deliberately, there may be opportunities for the COC to be replaced by an alternative chemical that provides equivalent performance but with more favorable safety, health, and environmental characteristics. However, many products contain COCs only as impurities from raw materials or from by-products of the reactions that create the final products, and the COC usually cannot reasonably be removed from the raw material or final product. In these cases, the idea that the COC can be replaced with an alternative chemical with more favorable health or environmental characteristics does not apply, since it would be impossible to remove the COC without replacing the raw material or the synthesized chemical with not-in-kind chemistry.

   Furthermore, the very low de minimis quantities that have been proposed for COCs (0.1% or 0.01%) make it likely that entire classes of chemicals that provide significant benefits in consumer products may no longer be used because they contain trace levels of COCs that might exceed the proposed de minimis quantities when

formulated into consumer products. Consider that these de minimis levels represent a threshold that would require greater than 99.99% purity, which would be unreasonable.

4) **Information requirement should be limited only to information on COCs.** Trade secret concerns can arise when companies are inadvertently forced to disclose information about critical raw materials unrelated to COCs. If the Alternative Assessment is required for detailing the substitution of a raw material containing a COC as a by-product or impurity, with a raw material that does not contain this COC as a by-product or impurity, companies will have significant trade secret concerns with disclosing the types and trade names of raw materials being considered as alternatives to the raw materials already being used. It will be difficult for companies using raw materials containing COCs as by-products or impurities to do the alternative assessment, as the raw material supplier is the one with knowledge about how the material is manufactured, and how the COC is being introduced.

5) A transparent process for determining priority products must be added. As enacted by Assembly Bill 1879 (2008), Health and Safety Code Section 25252 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. Such a process is not included in the informal draft regulation. The list of COCs is anticipated to be approximately 3,000 compounds, and the universe of consumer products containing these COCs is, therefore, likely to be very large. Even following the factors specified in proposed section 69503.2, it is not specified, as required by law, what process will be used to narrow the universe of products containing COCs to the department's stated goal of just 2 to5 Priority Products.

6) **By-products should be subject to higher de minimis levels.** Section 69503.4(c)(3)(A)(d) indicates that a higher de minimis level may be specified if "a processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended." Therefore, a higher de minimis level is allowed not based on the hazard that the COC presents, but based on the fact that the COC is a result of necessary processing steps and is not desired or intended in the final product. This same rationale should be applied to COCs that are unintended by-products of chemical reaction steps, since the COCs in this case are a result of necessary processing steps and are not desired or intended in the final product. Therefore, the following language should be added to the draft regulation: "69503.4(c)(3)(A)(e): An unintended by-product of a synthetic reaction, and the presence of this by-product is not desired or intended."

7) **Determination of COC concentration should allow information provided by suppliers and/or calculated values when appropriate.** In 69503.5(a)(6)(A), the draft regulation requests "a description of the information used to detect and measure this concentration." For cases in which one company's raw material contains a COC as a by-product impurity, and a second company formulates this raw material into a final product, the company formulating the final product may not know how the raw material supplier detects and measures the concentration of the COC and, in some cases, may not be able to obtain this information from the raw material supplier. In this case, the following wording is more appropriate: "a description of the information used to determine the presence of the COC and its concentration", since this would allow the formulating company to declare that the raw material supplier stated that the COC was present at a particular concentration in the raw material.

In addition, it should be acceptable to calculate the concentration of a COC in a priority product based on information provided by raw material suppliers on the level of by-product impurity COCs in their raw materials and the concentration of that raw material in the priority product without additional testing by the user.

8) **Retailers are not the appropriate parties to be conducting AAs.** Retailers are not likely to know whether a product does or does not contain COCs at levels above the proposed de minimis levels, since the de minimis levels are well below levels at which OSHA requires that the COC be reported on the MSDS, and consumer product labeling regulations may not require the COC to be reported on the product label. Retailers have neither the information nor the expertise to conduct AAs.

9) **Product recall is overly burdensome and an inappropriate response under this regulation**. In recognition of the extreme difficulty and disruption that product recalls bring to the supply chain, which places implementation responsibility on a large variety of stakeholders, product recall should only be initiated in cases where imminent danger to human health is posed by a consumer product. This is not an appropriate action to apply to consumer products that have been sold and used in the marketplace without imminent threat.

10) **Data sources and interpretation for Alternatives Assessment should be clearer.** The Alternatives Assessment framework is substantially clearer than previous versions. However, the lack of detail about how the AA data will be collected and interpreted makes it difficult to comment on its practicality. For instance, it is difficult to know what sources to explore to satisfy the requirement that "The responsible entity shall include in the AA consideration of any identified existing potentially viable alternatives" (69505.3). The lack of detail also makes it difficult to know if the proposed timelines to deliver a preliminary or final AA are reasonable. Without understanding the data that will be required, one cannot speculate on the time it would take to provide that data.

11) **Guidance materials should be compiled and reviewed by multiple stakeholders.** In section 69505 (a), it is stated that the Department will make guidance materials available to assist persons in performing AA in accordance with the regulation. This guidance material will be the basis for the currently missing detail, and it will be essential that it be (1) compiled by a group of experts with experience in conducting such assessments, importantly including industry participants and (2) subject to stakeholder review and approval.

12) **The certification and accreditation requirements for individuals conducting alternatives assessment are unnecessarily arduous and will create implementation difficulties. In addition, reviewers should be held to equal standards.** Experts who have met education or work requirements and who maintain a standard of ethical professional conduct should be sufficiently equipped to provide robust Alternative Assessments. These same requirements should be imposed on entities providing review.

AmericanCoatings ASSOCIATION

(IC)50- American Coatings Association

December 29, 2011

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RE: Comments of the American Coatings Association on the October 31, 2011 *DRAFT* California Safer Consumer Product Alternatives Regulations

To Whom It May Concern:

The American Coatings Association (ACA) is submitting these comments on the latest draft of the California Safer Consumer Product Alternatives Regulations. ACA is a voluntary, nonprofit trade association representing some 350 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. Our membership represents over 90% of the total domestic production of paints and coatings in the United States. Our membership includes paint and coatings manufacturers, raw materials suppliers, distributors, as well as approximately 2,000 coatings formulators and scientists.

The manufacture, sale, and distribution of paints and coatings is a $20 billion dollar industry in the United States. Our industry operates in all 50 states, and employs over 60,000 people engaged in manufacturing and distribution. The state of California currently represents approximately 18% of our domestic coatings sales market.

ACA appreciates the opportunity to submit these comments to DTSC. The current draft is clearer and more precise than prior department versions in certain areas, allowing the regulated community a better picture of the direction and department intent in implementing the enabling statute. Also, the administrative process DTSC is employing has been open and receptive to input from all stakeholders, and ACA appreciates the time and consideration that has been taken to try and establish a workable regulatory framework. ACA provides these comments in the same spirit, seeking to identify the critical remaining issues that must be addressed collectively to advance the effort <u>while striving to be practical, meaningful, and legally defensible.</u>

First and foremost, any eventual regulations will need to be clear and concise if the department wishes to remain true to stated purpose of the regulation listed in Section 69501 on page 4 of the draft:

- **Prioritize** consumer products containing **"Chemicals of Concern"**
- Identify **potential chemical alternatives** for "Priority Products"
- Determine how best to **limit potential exposures or the level of potential adverse impacts** (posed by the Chemical of Concern in the product)
- Specify the **regulatory response** that will be imposed on completion of an alternative assessment

We raise these points because, quite frankly, they have not been adequately addressed in the draft. In some cases, they have been ignored completely, a fact we attribute to the department taking a "narrative standard" approach. Rather than explicitly spelling out the required steps in the regulatory process, DTSC has chosen to offer a general narrative of what it will do and how industry should respond during the regulatory process. This may lead to inconsistent compliance across priority product manufacturers and across industries.

Without adequate efforts to address these bulleted items, the entire regulatory effort will be subject to challenge as **actual** proposals are published that impact **actual** products. To emphasize this point, DTSC need only consider that any product drawn into the eventual regulatory process will be one that is currently viable in the marketplace, meeting customer demands for quality and performance, and offered at a price that makes it economically viable. In the case of paint and coatings products, we might add that we are confident that our entire product stewardship effort, from formulation to product labeling (including hazard precautionary, and use instructions) to use and end-of-life management is offering consumers safe products that are used safely. We expect that other consumer product manufacturers would feel the same way about their products.

For this reason, it will be necessary for the department to truly focus its efforts on products that pose a well-defined, significant risk to human health and the environment. A "narrative standard" cannot seek to regulate the marketplace in California on the principle that the department "will know it (risk) when they see it." The hallmark of any successful regulatory initiative at the federal, state, or local level is a clear definition of the standard of care being imposed to address risk.

The regulated community could possibly look at the draft as setting a very loose framework for the department to operate within, and expect that the department's professional staff would only seek to apply the "narrative standard" for well-defined risks and clear proposed rules subject to notice and comment review. However, to provide certainty, to help direct research funding, to pursue well-defined technology roadmaps and directed innovation, and to ensure customer preferences are being met, the consumer products industry needs more certainty from the regulations and from DTSC.

ACA is providing focused comments on several critical areas of the draft that we hope will help DTSC understand the needs of the regulated community. These include:

1. Prioritizing the Chemicals of Concern (COC) List
    a. Details of the EPA Prioritization Policy
    b. Renaming the prioritized version of the COC List (Candidate List)
    c. Stressing that "real action" by DTSC only comes with naming of a product/chemical combination
2. Taking a Different Approach to De Minimis
    a. Use OSHA HazCom rules
    b. Stronger language on changes to de minimis level (arising from actual product/COC pairings)
    c. Drop or simplify the de minimis notification requirement
3. Priority Products Prioritization
    a. Clarifying DTSC concerns about formulated products, when the product is intended

to be dispersed as an aerosol or a vapor

4. Acknowledging Reformulation Efforts in Advance
   a. "Ride the Back" of industry innovation/product stewardship efforts
   b. Recordkeeping aspects of current draft provide opportunity for DTSC to post public progress reports
5. Changing the "Narrative Standard" to a "Performance Standard" to Provide Certainty
   a. "Hazard" and "Risk" are both inherent in the regulations – Acknowledge both!
   b. Re-writing of the "narrative standard" can achieve this!
6. Encouraging Collective Action on Alternatives Assessment
   a. Not clear in current draft…Canada, EU, and others have accommodated collective action (such as efforts under the DSL Challenge and REACH SIEFs)
   b. Purpose here might be to solicit information first on "potential" priority products before "moving out" with a proposal
7. Need Longer Timeline for Completion of Priority Product Notification, De Minimis Exemption Notification, Preliminary and Final Alternatives Assessment Reports
   a. Need more time for formulated products
8. Inflexible and Unfair Product Information Requirements
9. Exempting Existing Statutory Requirements for End-of-Life Management
   a. Exemption language for PaintCare® and similar programs required by statute
10. Trade Secret Process Contrary to California Law

Our overarching message in these comments is that we advocate the use of a risk-based, scientific approach for advancing green chemistry principles that will enhance the public's trust in government agencies to protect people and the environment. With that said, below are our comments on the latest draft of the Safer Consumer Product Alternatives Regulations.

Respectfully Submitted,

/s/	/s/
Stephen R. Sides	Stacey-Ann M. Taylor
VP, Science, Technology, and Environmental Policy	Counsel, Government Affairs

1. Prioritizing the Chemicals of Concern List (Section 69502.2)

a. Details of the EPA Prioritization Policy

While the draft has flagged a more finite "set of lists" to serve as the initial Chemicals of Concern list, the sheer number of chemicals (over 3,000) and the wide range of inherent hazard categories would seem to preclude its practical use for engaging industry in proactive reformulation efforts. Quite simply, the draft proposes a list that, absent any type of prioritization effort, would not move industry to act. ACA members view this as unfortunate, and we see this as an unintended consequence that can be rectified in any of a number of ways. Referring to the current draft list as a "Candidate Chemicals of Concern List", "Potential Chemicals of Concern List", or Chemicals of Interest List, while seemingly a semantic difference, would be step in the right direction, if coupled with some simple prioritization criteria the department may use to focus regulatory attention on actual Chemical of Concern/Product pairings.

The US EPA has recently indicated it intends to apply a new approach to identify priority chemicals for review and possible risk management action under TSCA. In announcing this new approach, the US EPA was quick to state that "identification of a chemical as a priority chemical for review would *not* itself constitute a finding by the agency that the chemical presents a risk to human health or the environment." We would hope that DTSC would have similar views with respect to its own proposed list.

Similarly, ACA also believes that identification of a Chemical of Concern would not preclude DTSC from undertaking a full risk assessment when seeking to identify potential health and environmental risks arising from its use in commerce. This will require that the chemical identified be well-characterized for hazard and have information indicating exposure potential in the product.

US EPA also plans on using some well-regarded prioritization factors when seeking to identify true chemicals of concern, and we offer them here for emphasis:

- Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects).
- Chemicals identified as persistent, bioaccumulative, and toxic (PBT).
- Chemicals identified as probable or known carcinogens.
- Chemicals used in children's products.
- Chemicals most commonly used in consumer products.
- Chemicals detected in biomonitoring programs.

US EPA has also provided sources for each of these prioritization categories that could be used to align with the DTSC effort, promote consistent practice and industry consideration, and capture any potential synergies in the program's implementation.

US EPA Data Sources for Identification of Priority Chemicals

Factor	Data Sources	Definition
PBT	TRI Persistent, Bioaccummulative and Toxic (PBT) Rule Great Lakes Binational Toxics Strategy Canadian Categorization EPA Region 5 PBT Identification Project (Syracuse Research Corp.) Chemicals proposed to UNECE LRTAP POPs and Stockholm Convention on POPs	P, B, and T as defined in the specific data source
Carcinogenicity	Integrated Risk Information System (IRIS)[1] International Agency for Research on Cancer (IARC) National Toxicology Program (NTP) California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)	**IRIS**: A or B1, or known or likely to be carcinogenic to humans **IARC**: 1 or 2A **NTP**: known or reasonably anticipated to be carcinogenic to humans **CA**: Known to the state to cause cancer
Potential Children's Health Concern	Voluntary Children's Chemical Evaluation Program California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986) IRIS NTP CERHR Monographs	**VCCEP**: Named in program **CA**: Known to the state to cause reproductive toxicity **IRIS**: Non-cancer RfD or RfC is based on repro/dev effects **NTP**: "Some concern," "concern," or "serious concern" for effects on fetuses, infants, or children at current human exposures; or effects on offspring from exposure of pregnant women; or repro effects in exposed adults
Children's Product Use	Washington State Children's Safe Product Act[2] Inventory Update Reporting (IUR, 2006)	**WA**: Listed in the Children's Safe Products – Reporting rule **IUR**: Any report that used in products intended for use by children
Consumer Product Use	Inventory Update Reporting (IUR, 2006) National Institutes of Health (NIH) Hazardous Substances Data BankDanish Consumer Product Studies	**IUR**: Any report of "consumer/commercial" use **Others**: Identified as being in consumer product
Human Biomonitoring	National Health and Nutrition Examination Survey (NHANES)	Reported in any of the data sources

[1] Recent efforts in the U.S. Congress have mandated a series of reforms for the current IRIS database, and DTSC should utilize content that aligns with these required reforms.

[2] ACA does not fully agree with the arbitrary way in which Washington has selected some chemicals, but we include the list here in an effort to be fully descriptive of EPA's prioritization scheme.

	National Human Adipose Tissue Survey (NHATS) National Human Exposure Assessment Survey (NHEXAS) Total Exposure Assessment Methodology	

EPA is also planning to use established sources for information to be considered in identifying potential exposures (including public health and environmental impacts of exposures/discharges/releases).

Other Data Sources for Screening Priority Chemicals for Assessment

Exposure and Use Information	
Data Type	**Data Source**
Uses	Inventory Update Reporting and Chemical Data Reporting (IUR/CDR) Premanufacture Notice (PMN) Database (confidential) High Production Volume (HPV) Challenge Submissions Screening Information Data Sets (SIDS) Documents National Institutes of Health (NIH) Household Product Database NIH Hazardous Substances Data Bank
Environmental releases	Toxics Release Inventory (TRI) National Emission Inventory (NEI) Database U.S. EPA Preliminary Assessment Information Reporting (PAIR) Organization for Economic Cooperation and Development (OECD) Emission Scenario Documents NIH Hazardous Substances Data Bank
General human exposures, including indoor air contaminants	Children's Total Exposure to Persistent Pesticides and Other Persistent Organic Pollutants (CTEPP) Study Brown et al., Indoor Air, 4:123-134, 1994. Daisey et al., Atmospheric Environment, 28 (22): 3557-3562, 1994. Kelly et al., Environmental Science & Technology, 28(8): 378A-387A, 1994. NOPES Final Report, EPA/600/3-90/003 (NTIS PB90-152224), January 1990. Samfield, M.M. Indoor air quality data base for organic compounds. Govt. Reports Announcements & Index (GRA&I), Issue 12. EPA-600-R-92-025 (NTIS PB92-158468), 1992. Shah and Singh, Environmental Science & Technology, 2(12): 1381-1388, 1988. Sheldon et al., Indoor Pollutant Concentrations and Exposures, California Air Resources Board, Contract A833-156, Final Report, January 1992. Shields, et al., Indoor Air, 6:2-17, 1996.
Worker exposures	Inventory Update Reporting and Chemical Data Reporting (IUR/CDR) National Occupational Exposure Survey (NOES) Occupational Safety and Health Administration (OSHA) monitoring studies Preliminary Assessment Information Reporting (PAIR) OECD Emission Scenario Documents NIH Hazardous Substances Data Bank
Environmental exposures	Contaminant Exposure and Effects-Terrestrial Vertebrates database (CEE-TV) EPA Environmental Monitoring and Assessment Program (EMAP) EPA's Databases on Monitoring and Assessing Water Quality List of Drinking Water Contaminants and their Maximum Contaminant Levels (MCLs) National Air Quality System (AQS) U.S. EPA National Contaminant Occurrence Database (NCOD) U.S. EPA

	Current National Recommended Water Quality Criteria U.S. EPA National Water-Quality Assessment Program (USGS NAWQA) EPA Fish Tissue Studies National Sediment Inventory (NSI) Tissue Data National Status and Trends Program (NSTP) National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data U.S.G.S.
Hazard Information (Data on all toxicological endpoints)	
Providers/ Data Source	**Description**
National Library of Medicine Databases	http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp Accessed through ChemID Plus, searching on a chemical name or ID produces results that are linked to all NLM databases, including: • Biomedical Citations From PubMed • Toxicology Citations From PubMed • Registry of Toxic Effects of Chemical Substances (RTECS) • NLM TOXLINE on TOXNET • Agency for Toxic Substances and Disease Registry (ATSDR) Medical Management Guidelines • ATSDR Public Health Statements • ATSDR Toxicological Profiles • ATSDR ToxFAQS
TSCATS	The Toxic Substance Control Act Test Submission Database http://www.syrres.com/esc/tscats.htm EXIT Disclaimer
USEPA - Office of Pesticide Programs	http://www.epa.gov/pesticides/reregistration/status.htm http://www.epa.gov/opprd001/inerts/decisiondoc_a2k.html
USEPA - Ambient Water Quality Criteria Documents	http://www.epa.gov/waterscience/criteria/wqcriteria.html
USEPA - Drinking Water Standards Health Effects Support Documents	http://www.epa.gov/safewater/standards.html
USEPA - ECOTOX Database	http://www.epa.gov/ecotox
IPCS Concise International Chemical Assessment Documents (CICADs)	http://www.inchem.org/pages/cicads.html

b. Renaming the Prioritized Version of the Chemicals of Concern List

ACA believes that the prioritized version of the Chemicals of Concern list should be given a new name that is more reflective of the fact that, in general, chemicals would be chosen from the prioritized version of the list first for regulation. A name such as “Priority Chemicals List” would be appropriate.

c. Stressing that "real action" by DTSC only comes with the naming of a product/chemical combination

ACA staff was pleased to hear DTSC staff acknowledge publicly during the recent workshop that, in general, only 2-5 chemical/product combinations would be chosen for regulation each year. While we understand that DTSC does not want to include such specific information in the actual regulation so as not to completely restrict the department's regulatory authority, we would still encourage DTSC to include in the regulation that "only a limited number of chemical/product combinations will be put through the regulatory process each year." We believe that consumer product manufacturers are entitled to a realistic portrayal of this regulatory process, and they need to understand the true scope of the initial program.

2. Taking a Different Approach to De Minimis (Sections 69503.4 and 69503.5)

a. Use OSHA HazCom Rules

The current de minimis level that operates most broadly in commerce is based on the OSHA Hazard Communication Standard requirements for development of Material Safety Data Sheets (MSDSs). The de minimis level is 1.0 percent, except if the listed toxic chemical is an OSHA-defined carcinogen. The de minimis level for OSHA-defined carcinogens is 0.1 percent. US EPA has also embraced the OSHA HazCom de minimis levels for its required reporting under community right-to-know regulations.

Arbitrarily requiring a 10 fold reduction in the De Minimis level for certain categories of hazards (i.e. to 0.01%) would offer no basis for pre-emptive industry assessments. When coupled with a large "Chemicals of Concern" list, the resultant uncertainty would not foster any industry action. It is simply not possible to test every potentially covered product, for every potential "Chemical of Concern" (as DTSC seems to imply is required for the de minimis to apply), to a level of detection consistent with a 0.01% or 100 ppm de minimis.

b. Stronger language on changes to De Minimis level (arising from actual chemical/product pairings)

By establishing the 1.0/0.1% OSHA HazCom de minimis level for the general COC list, it is certainly within DTSC's regulatory authority to decide on a lower De Minimis level for a specific chemical/product combination. If the OSHA De Minimis is used, DTSC would need to add language indicating that the department will *only* consider lowering the standard de minimis level once a specific chemical/product combination is chosen for regulation.

c. Drop or simplify the de minimis notification requirement

DTSC should follow other regulatory schemes and drop the requirement that manufacturers with products falling under the de minimis exemption must notify the department. If a notification is to be required, DTSC should first remove the implication at Section 69503.5(a)(6) and (a)(7) that only analytical testing results are appropriate substantiation that a product meets the de minimis standard. Manufacturers commonly rely on supplier certifications regarding purchased material content to understand product ingredients and impurities, and do not routinely test every single shipment of purchased materials or finished goods. Given the sheer number of "Chemicals of Concern", and considering various regulations and customer restricted/banned substances lists, testing for all of these is cost-prohibitive. Responsible manufacturers certainly augment supplier information with testing when knowledge of the chemistry of the product indicates probable presence of chemicals of concern, or when there is just cause to doubt the veracity of the supplier certification. But to require all products containing the COC below de minimis to be tested is a waste of resources when knowledge of suppliers, product formulation or construction,

expected chemistry, and supplier certifications provide a high degree of assurance that the COC is below de minimis.

If a notification is to be required, DTSC should exempt from the de minimis notification requirement those priority products that do not contain the COC. By "does not contain", we mean those products to which the COC is not intentionally added and is not expected to be present at trace levels. Otherwise, DTSC will be inundated with notifications of products that happen to be in the priority product category but are truly outside the scope of the alternatives assessment requirements. This would be an especially costly endeavor with little health or environmental benefit if the department persists in requiring testing data as part of de minimis notifications (see above). An exception to this exemption could be made where the COC is a known contaminant of other raw materials or components. By including that information in the priority product list publication, DTSC will make it clear to users of those raw materials/components in priority products that they will need to submit a de minimis notification in those circumstances.

3. Priority Products Prioritization (Section 69503.2)

a. Clarifying DTSC concerns about formulated products, when the product is intended to be dispersed as an aerosol or a vapor

We would like to see DTSC further clarify the section on Priority Products Prioritization. Section 69503.2(b)(2) should be changed to clearly state what we assume is DTSC's intent---that products used by consumers on a daily basis such as personal care products and cleaning products are a key prioritization criteria. While dispensing form is a consideration in assessing exposure potential, the key criterion remains exposure. Section 69503.2(b)(4) should be changed to "For both assembled and formulated products, the product contains one or more Chemical(s) of Concern that may present potential exposures through inhalation, dermal, or oral contact in quantities that can result in adverse public health or environmental impacts." Section 69503.2(b)(5) is especially confusing and should be deleted.

4. Acknowledging Reformulation Efforts in Advance (Section 69501)

a. "Ride the Back" of industry innovation/ product stewardship efforts

Since DTSC will use its website to post a "Failure to Comply List" of manufacturers who don't meet the new regulatory requirements (Section 69501.3), then DTSC should also have an area of its website dedicated to acknowledging manufacturers who reformulate their products in advance of being required to do so by DTSC.

b. Recordkeeping aspects of current draft provide opportunity for DTSC to post public progress reports

ACA strongly urges the department to consider embracing previously identified clarifications to the Chemicals of Concern list, prioritization, and a more reasonable De Minimis exemption that would provide certainty and encourage innovation towards green products. To this end, the reporting aspects of the current draft could be used to provide public information on the nature and the extent of progress by product manufacturers. This would obviously have to be done without infringing upon confidential business information protections, but it would be good for DTSC to keep the public apprised of industry compliance efforts.

5. Changing the "Narrative Standard" to a "Performance Standard" to Provide Certainty

a. "Hazard" and "Risk" are both inherent in the DRAFT regulations---Acknowledge both!
The draft mentions both intrinsic hazard as well as exposure pathways, which we all know is involved in calculating risk. We understand that DTSC considers this regulation to be the first hazard-based environmental regulation of its kind. However, the calculation of risk is a key part of the effort to protect public health and the environment from toxic chemicals. Therefore, we believe these regulations must emphasize using risk-based science to determine potential regulatory responses.

b. Re-writing of the "narrative standard" can achieve this!
The concept of a "narrative standard" is not foreign to the regulated community. However, the federal OSHA Hazard Communication Standard, published in 1983, introduced the concept of a *"performance standard"* whereby the basic outcome (fulfilling the worker's "right to know") was provided and the mechanisms to reach that end were left to those putting hazardous substances (and mixtures) into commerce. Similarly, DTSC should state the basic outcome(s) it seeks by promoting a *"performance standard"* and allow product manufacturers the opportunity to devise a compliance approach. The current draft offers little insight on the outcome measures that would demonstrate a successful program, and relies heavily on the department being engaged throughout a largely administrative "alternatives assessment" process that offers the regulated community no certainty that a viable consumer product can continue to be offered.

6. Encouraging Collective Action on Alternatives Assessments (Section 69501.3)

a. Not clear in current draft…Canada, EU, and others have accommodated collective action (such as efforts under Canadian DSL Challenge and EU's REACH SIEFs)
ACA notes the current draft is somewhat unclear as to how DTSC would respond to a collective approach to development of the required Alternatives Assessment (AA). We want to ensure that an AA submitted by a trade association or consortium is indeed a **complete** alternative to an AA submitted by an individual company, rather than an additional data gathering exercise for industry. We also note that the purpose of a trade association or consortium might only be to solicit information first on "potential" priority products before "moving out" with a proposal to individual companies. ACA members have often worked collectively to develop critical information sources for regulatory actions. In California, ACA members were successful in establishing a "Safe Use Determination" for crystalline silica in house paints working closely with OEHHA under the enabling Proposition 65 regulations. ACA would hope that similar cost-savings and efficient methods could be facilitated with clearer language in future versions of the proposed regulations.

b. Anti-trust language to allow collective action
This language would be necessary for multiple product manufacturers or a third party representing the product manufacturers to collectively undertake the alternative assessment for a consumer product and/or fund such activity, particularly if the funding mechanism was based on market share. In addition, if there is an aggregated externalized cost identified, it would protect the identification of such collectively by competitors.

Note: This suggested anti-trust language may need to be inserted into a brand new section. It should be examined by DTSC Counsel for form and sufficiency.

"(a) Except as provided in subdivision (c), action taken solely to comply with this chapter, including alternative assessments and identifying potential alternatives for Priority Products, undertaken by multiple responsible entities or a third-party organization funded by participating responsible entities is not a violation of the statutes specified in subdivision (b).
(b) The following statutes are not violated by an action specified in subdivision (a): (1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code). (2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).
(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of consumer products, except for aggregate externalized costs, or the output or production of consumer products, or any agreement restricting the geographic area or customers to which consumer products will be sold."

7. Need Longer Timeline for Completion of Preliminary and Final Alternatives Assessment Reports (Section 69505)

a. Need more time for formulated products
With respect to Priority Product Notification and De Minimis Exemption Notification, the current draft requires notification within 60 days of the product being listed as a priority product. This short timeline is of particular concern for formulated products like paints, because formulated product manufacturers in many cases will be required to rely on the actual chemical or chemical mixture manufacturers that supply their raw materials for information. Those chemical manufacturers may not respond in a timely manner and may request that some of the information be kept confidential (in which case it isn't clear how a formulated product manufacturer should proceed). This would place a formulated product manufacturer in immediate non-compliance through no fault of their own, if they can't identify all of the COCs in their products down to 0.01% or 0.1% within 60 days. Therefore, we would like to see at least 180 days allowed for compliance with these requirements.

With respect to the Preliminary AA, the current draft requires submission of the Preliminary AA Report no later than six months (180 days) after the product is listed on the final Priority products list. We respectfully suggest that this time period should be increased to at least 12 months, given the possibility that a manufacturer may have numerous formulations or variations of the same product and each product may require its own AA. Also with respect to the Preliminary AA, manufacturers will need more time to pursue the route of collective action, as such industry consortia can take time to form.

With respect to the Final AA, the current draft requires final submission of the Report no later than 12 months after DTSC issues a notice of compliance for the Preliminary AA. Again, it is conceivable that a single manufacturer will have to submit multiple AAs and we believe manufacturers should be allowed at least 18 months to comply.

8. Inflexible and Unfair Product Information Requirements (Section 69506.3)
The very large number of chemicals of concern listed, plus the cumulative definition of de minimis (the total concentration of all chemicals of concern exhibiting the same hazard trait, environmental, or toxicological endpoint, and mode of action), means that most products will require extensive labeling. It is unclear if DTSC has considered how that requirement will interfere with existing labeling regulations that already strain limited label space, especially for smaller-sized products. DTSC's suggested alternatives (an accessible manual or point-of-sale posting) are inflexible given the sheer variety of products that may be subject to alternatives assessments over the years.

If an alternative is not selected, DTSC should require identification only of the COC that caused the priority product listing in the first place. If an alternative is selected that contains other listed COCs, only that COC that serves the same function as the replaced COC should be required to be identified. Otherwise, the manufacturer will be placed at an unfair disadvantage relative to competitive products that did not happen to contain the COC that caused the priority product listing, but may contain other COCs.

9. Exempting Existing Statutory Requirements for End-of-Life Management (Section 69506.4)

a. Exemption language for PaintCare® and similar programs required by statute
The draft regulations require manufacturers of selected consumer products to "fund, establish, and maintain an end-of-life management program for the product." In 2010, legislation was passed in California establishing such a program for the paint industry. The program is called PaintCare®. Since PaintCare® is already established by statute, there is no reason for DTSC to subject the coatings industry to additional regulatory requirements in this area. ACA respectfully requests that DTSC include the following language in the regulations that specifically exempts PaintCare® and any other end-of-life management programs that are established by statute.

Amend S. 69506.4. (a):
(a) Except as provided in section 69506.2 <u>and 69506.4 (e)</u>, a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that both of the following requirements are met:

Add a new S. 69506.4 (e):
(e) A responsible entity otherwise subject to the requirements of this section shall be exempt from an end-of-life management regulatory response if the responsible entity is participating in an end-of-life management or extended producer responsibility program that is currently required pursuant to a different California statute or regulation.

10. Trade Secret Process Contrary to California Law (Section 69510)

This section of the regulations should focus on the interrelationship between the new Safer Consumer Products Regulations and the preexisting California laws on trade secrets.

California Civil Code Section 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.

Therefore, in order to establish that information submitted is a trade secret under California law, one should allow that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by DTSC under California Health and Safety Code Section 25257(d) should logically begin by looking at those two questions.

Another issue that arises relative to trade secrets is whether the information is readily ascertained by proper means (e.g. reverse engineering). If information can be readily determined through legitimate analysis or examination and study of a product, that information is probably not a trade secret.

Thus it would be reasonable to approach the question of supporting a claim of trade secrecy by asking the submitter to provide information relevant to items (1) and (2) above and relevant to the difficulty of discovering the information through analyzing the product. Much of the current draft regulation in Section 69510 is not needed in order to show that submitted information meets the definition of a trade secret under California law, and those items should not be required of the person (company) claiming the trade secret rights.

Further, given that under Section 69510(f) of the draft regulations trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient, there is no reason why the lengthy and intrusive list of questions in the draft regulations is necessary. Answering all of those questions for each trade secret claimed will be a burden requiring needles expenditure of resources by trade secret owners, adding to the cost of consumer products.

It is worth pointing out that the California statute which the draft regulations purport to implement states in Section 25253(c):

> (c) The department in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

The current draft regulations fail to fulfill the aspiration set forth in the statute. In their treatment of trade secrets, they do not ensure a process that is easy to use, nor are they simplified tools that manufacturers, distributors, retailers, and consumers can use.

founded 1881

(IC)51- Consumer Healthcare Products Association

December 28, 2011

California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
Mr. Jeff Woled, MS 22A
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Dear Mr. Woled,

On behalf of the Consumer Healthcare Products Association (CHPA), a 131 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers, I'd like to thank you for the opportunity to comment on the proposed Chapter 55 Safer Consumer Products Informal Draft Regulations (R-2011-02) of October 31, 2011.

First, we echo the concerns expressed by the Green Chemistry Alliance and their effort to create a science-based framework for state regulation which strikes a balance between the needs of the environment, and California consumers.

Additionally, we ask that OTC's be exempted from these informal draft regulations entirely as suggested by Section 69501 4(A) and Section 69506.7. These sections specifically mention removing applicability of these regulations to any consumer product already regulated by one or more federal and/or other California State regulatory programs.

Unfortunately, the language in the proposal is much narrower than what is provided for in the implementing statute. Section 25257.1(c) of the California Health and Safety Code provides that "[t]he department shall not duplicate or adopt conflicting regulations for product categories already subject to pending regulation consistent with the purposes of this article." Therefore, if a product category is regulated by a federal or state agency for the same impact or risk as the concern that is being addressed under DTSC's proposal, the product category should be *automatically* exempted from regulation.

In the case of the OTC medicine industry, CHPA believes the proposed regulation is clearly duplicative and conflicting, as OTC products are already regulated by the federal Food and Drug Administration (FDA) for human health

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or environmental health concerns. For example, OTC drug products must conform to either new drug applications or monographs issued by the FDA. Each monograph applies to a specific drug category (e.g. antacid, internal analgesic, external analgesic) and prescribes detailed conditions to which the drug product must conform in order to be legally marketed, including active ingredients, labeling statements, warning statements, and the like. Active ingredients that are included in a monograph have undergone extensive review for human health effects by experts in what is known as the OTC Drug Review. And further, as with all human drugs, the FDA already has authority to require an environmental assessment for OTC drugs (See 21 C.F.R. Part 25). Therefore, it is inappropriate for the Department of Toxic Substances Control (DTSC) to give itself additional authority in this regulation.

Similarly, under the Dietary Supplements Health and Education Act, the FDA has several post-marketing responsibilities to ensure the safety of dietary supplements. Among those is enforcement of the final rule on dietary supplement Good Manufacturing Practices (GMPs), released on June 25, 2007. This rule establishes uniform standards needed to ensure quality throughout the manufacturing, packaging, labeling, and holding of dietary supplement products.

OTC and dietary supplement manufacturers request regulatory certainty to ensure consistent product development and maintain quality and safety standards. These products provide real and significant health benefits to consumers at minimal costs. They are formulated and manufactured under extremely controlled environments that are also governed by FDA. Manufacturers of OTC's need the confidence that they will not be subjected to a patchwork of state requirements that could conflict with already existing federal obligations.

Subjecting these products to additional regulation could result in restrictions on ingredient use that is inconsistent with the federal determination. Thus, at a minimum, OTC drugs should be excluded from the scope of the proposed regulation for purposes of human health and environmental health issues. In addition, dietary supplements should also be excluded from the scope of the regulation.

While proper disposal of unused medicine is important, CHPA also opposes the labeling requirement in Section 69506.3(1)(D). Product labeling is already oversaturated with required language and additional content would only serve to reduce text size to an unreadable level for most consumers.

Additionally, CHPA disagrees with the requirements laid out in Section 69506.4. The vast majority of pharmaceuticals in the environment are from human use and metabolites of medicines – not from the improper disposal of medicines. Consumers have more effective means of ensuring safe medicine disposal which not only protect the environment, but also prevent illegitimate access to drugs, decrease potential of abuse, and limit accidental poisonings. Disposal in household trash is the most convenient and environmentally responsible way to dispose of unused medicines. Proper disposal in household

trash is environmentally responsible and more convenient for consumers than a drug take back program, which increases the likelihood of compliance. CHPA supports SMARxT Disposal (www.smarxtdisposal.net), a campaign designed to educate consumers about proper disposal procedures for unwanted medicines, and the American Medicine Chest Challenge (AMCC). SMARxT Disposal is an initiative of the U.S. Fish and Wildlife Service, the American Pharmacists Association, and PhRMA and is in accordance with guidelines issued by the White House Office of National Drug Control Policy. The AMCC is a comprehensive public health initiative to educate the public about safe disposal and the dangers of medicine abuse, which gives consumers the choice of dropping off their unwanted medicines at a local collection site during a national take-back day, or at home using the SMARxT Disposal Program.

Finally, CHPA supports the inclusion of Trade Secret Protection in Article 10. OTC and dietary supplement formulations are frequently trade secrets and in some cases patented. However, the proposal requires a producer or responsible entity to provide a significant amount of chemical and product data and information, as well as the quantity of intentionally-added chemical ingredients. We are also concerned that the proposal would allow DTSC to subjectively make determinations of the validity of a claim for trade secret. The regulation must include stronger safeguards and assurances that product formulations and trade secret information will be adequately protected.

In sum, CHPA believes these concerns pose significant obstacles to establishing a workable, meaningful framework for consumer health and environmental protection in California. We urge DTSC to give serious review and consideration to these comments, as well as the comments submitted by the Green Chemistry Alliance, during the rulemaking process.

CHPA appreciates the opportunity to contribute to the development of the Safer Consumer Product Alternatives Regulation.

I am more than happy to speak to you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,

Carlos I. Gutiérrez
Director, State Government Relations

JDMT, Inc

(IC)52- JDMT, Inc

December 29, 2011

California Department of Toxic Substances Control
Attn: Heather Jones - Safer Consumer Products Regulations - MS 22-A
P.O. Box 806
Sacramento CA 95812-0806
via email: gcregs@dtsc.ca.gov

SUBJECT: Comments to "Green Chemistry Regulations"
Draft Regulations for Safer Consumer Products, R-2011-02

Dear Ms Jones:

The Department of Toxic Substances Control (DTSC) has developed draft regulations providing Safer Consumer Products as required by Health and Safety Code sections 25252 and 25253 and intended to: (1) establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized; and (2) develop criteria by which chemicals and their alternatives may be evaluated and reduce exposure to these chemicals and the hazards posed by them.

The proposed Draft Regulations stem from Assembly Bill 1879 giving the California Environmental Protection Agency greater authority to regulate toxins in consumer products, and Senate Bill 509, which authorized development of an online Toxics Information Clearinghouse to provide Californians with information on hazardous chemicals. The draft regulations establish methods to identify and prioritize chemicals of concern in consumer products and to outline the four-step process developed in the regulatory language, provide the manufacturer, seller and consumer responsibilities and consequences, and describe approaches to the daunting task of cataloguing and maintaining chemical and product information.

The DTSC has requested stakeholder comment by December 30, 2011 in order that all comments may be considered during finalization of the regulatory package being proposed for adoption. This document constitutes our comments to the proposed draft regulations, beginning with General Comments to the overall structure and implementation. The draft regulations are presented as DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS, CHAPTER 55. SAFER CONSUMER PRODUCTS; our Specific Comments herein are ordered according to the Code section and subsection designations, with section titles for clarity.

General Comments

(1) The main body of the draft regulatory package consists of a detailed mechanism by which an enormous amount of data is to be collected and analyzed, and from which the DTSC and certified assessment entities are to implement control on an on-going basis. The sheer scale of this as a data management task needs to be subjected to predictive modeling to

determine the escalating magnitude of the task as time progresses. From this modeling effort, the agency then may assess the necessary data management construct in advance, and determine whether sufficient resources (human and capital) are now and will be available in the future to adequately manage the task.

(2) One area of the draft regulations is particularly troubling: the entire suite of provisions mandating product "end-of-life" management crosses jurisdictional boundaries and imposes DTSC oversight on issues of solid and liquid waste management already under the purview other state agencies. For example, the California Department of Resources Recycling and Recovery (CalRecycle) is deeply engaged in Product Stewardship program development, and the extension of manufacturer responsibility, including proper product end-of-life management. These comments will isolate a number of the specific areas of conflict proposed in these draft regulations, but we request that a thorough assessment be conducted on the impact and portent of this proposed DTSC expansion of oversight will have on on-going programs of this nature in other agencies of purview.

(3) The proposed regulations require that companies attempting commerce in California must assume a defensive stance, clearly a disincentive to doing business in this state compared to other states. This negative aspect can be counter-balanced by developing and initiating a strong incentive program rewarding companies that indeed seek to bring new, safer chemicals and formulations into California. An organized and funded incentive mechanism would speed the time required to make green alternatives technically and economically available on the state's marketplace.

(4) In the current economy, well-meaning "Green Chemistry" actions may well cause more harm than good by placing costly barriers in front of California commerce with particularly damaging impacts upon emerging companies. This issue was advanced during repeated public hearings before both the California Environmental Policy Commission (CEPC) and the DTSC. Our firm also provided such comment; see our comments to CEPC dated October 24, 2010 (http://www.terutalk.com/pdf/20101023JDMT_Comments-CEPC_Green_Chem_Regs.pdf) and our comments to DTSC dated October 31, 2010 (http://www.terutalk.com/pdf/20101031JDMT_Comments-DTSC_Green_Chem_Regs.pdf).

(5) In the latter set of comments we provided four key Recommendations. We would like to emphasize and reiterate the last of these previously-submitted Recommendations as pertinent for inclusion in these comments:

Expand upon the outreach and educational aspects of the process to include careful and transparent examination of how and where information a company may feel is proprietary might be divulged as a result of these processes. Provide sufficient assistance and time between notification of impending mandate to divulge sensitive information and the first incidence of compliance, based upon the company's own determination of that sensitivity. A simplified process for claiming an interim confidentiality status would be of value.

Specific Comments

Article 1. General.
§ 69501. Purpose and Applicability.
Subsection (4) (A): The determination of applicability indicates the chapter does not apply if a consumer product is regulated by federal or California programs that "address the same

adverse public health and environmental impacts and exposure pathways…" and "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 was listed as a Priority Product." This section requires that DTSC arrive at a subjective decision regarding not only the toxicity of a particular chemical or formulation, but on the adequacy of control on that material by other agencies of purview. This hazards a boundless and subjectively determined authority for the DTSC, sanctioning expansion of oversight regardless of the state and or federal structures already in place.

§ 69501.2. Definitions.
Subsection (a) (4): "Adverse environmental impacts" should not be defined as restricted to "Adverse air quality impacts, Adverse ecological impacts, Adverse soil quality impacts, or Adverse water quality impacts" (subsection (a)(4) (A) through (D)), but rather defer to the categorization of environmental impacts within the California Environmental Quality Act (CEQA), and the process of determination under CEQA as "Negative Impact" (not "Adverse Impact"). This definition introduces a separate and conflicting pathway for impact assessment and determination, which should definitely be avoided.

This comment applies to each Definition in this section where the term "Adverse" has supplanted the CEQA term "Negative", and where these regulations imply environmental impact should be determined in any manner outside of CEQA or the National Environmental Policy Act (NEPA) if under federal jurisdiction.

Subsection (a) (7): The currently proposed definition regarding "Adverse waste and end-of-life impacts" suggests strongly that the DTSC would have purview through these regulations over any manner of Priority Product end-of-life waste management, recycling, resource recovery and or disposal, without any determination that the consumer product constituted a toxic or hazardous substance.

Such DTSC management would then theoretically apply to select elements of the common municipal solid waste (MSW) stream as well as to liquid wastes and even storm water discharge. These areas of waste management are already entirely under the purview of other state and/or federal agencies and their own regulatory process. The proposed definition would unduly extend DTSC purview without boundaries, and perhaps more importantly, there is no functional mechanism whereby DTSC staff might actually intercede in the daily management of MSW, wastewater, and storm water to selectively apply a separate set of standards to constituents of those waste streams. Note further that this overlap impacts Article 8, Accreditation Bodies and Certified Assessors, in that such certification would of necessity encompass all of the licensing and certification standards and criteria now applicable to agency management of solid and liquid waste.

§ 69501.5 Chemical and Product Information.
The US Environmental Protection Agency (EPA) has initiated the multi-agency Tox21 program for rapid robot-enabled screening of 10,000 chemicals for potential toxicity (National Institute of Health notice dated December 7, 2011: http://www.nih.gov/news/health/dec2011/niehs-07.htm.) Coordination with this program would clearly be in concert with the proposed regulatory mandate that the DTSC seek to obtain and/or review information necessary to implement this chapter.

Article 5. Alternatives Assessments
See our comments regarding the definition of “Adverse waste and end-of-life impacts”. Guidance for and certification of parties who would attempt an alternatives assessment involving potential adverse impacts from end-of-life product management will need to be well versed in pertinent aspects of solid and liquid waste management. As noted above, this provision creates an unnecessary and potentially dangerous overlap of jurisdiction with waste management authorities, which should be avoided.

§ 69506.3. Product Information for Consumers - the Responsible Party is required to identify "any end-of-life management program for this product, and any end-of-life management requirements specified by law…" during a period when Product Stewardship programs are just beginning to address the broader flow of waste and residual. The piece-meal imposition of requirements on a per chemical basis runs counter to the international trend in product stewardship and will surely interfere with development of whole-product manufacturer responsibility programs.

§ 69506.4. End-of-Life Management Requirements. Does the DTSC assume responsibility for management of literally the entire range of potential Product Stewardship plans and implementation schemes dictated by this far-reaching section?

Under what authority will the DTSC discharge these waste management oversight responsibilities? If solely upon the basis of this draft regulation, a direct conflict with existing purview is being proposed.

Who bears the responsibility to enforce section (a) (2) that requires a responsible entity to "fund, establish, and maintain an end-of-life management program … " for any chemical, compound, or formulation falling under these regulations? These provisions constitute a usurpation of purview that threatens direct conflict within the entire construct of California waste management authority.

Article 8. Accreditation Bodies and Certified Assessors
This section establishes the equivalent of a licensing program that overlaps any number of other areas where activities are restricted to existing certification or licensing, such as for the Registered Environmental Health Specialist and its applicability to assessing and managing the complex issues of solid and liquid waste management.

The DTSC proposal would overlay a more general suite of certification criteria not applicable to specifics within this and other highly detailed training and certification mechanisms, and by doing so, not only allow, but literally *require* that intrusive assessments cross jurisdictional boundaries long established. Nowhere is this more apparent than with the imposition of end-of-life product stewardship plan development and implementation, and Alternatives Assessments by DTSC certified entities. If additional training is required for those certified by other programs, that training should be identified and plans developed to implement training programs. Duplicative certification with mandates for intrusive inspection without regard for existing oversight programs is an administrative breach overstepping DTSC authority.

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We offer these comments as an aid to DTSC's difficult task mandated by promulgated law to develop implementing regulation. We fully understand that interlacing new regulatory

programs of this scope and scale will almost certainly result in questions of overlapping purview and unintended consequences. We have attempted to isolate and clarify where we feel such purview complications and unintended consequences are most likely.

Please contact me at mtheroux@jdmt.net or (530) 613-1712 if you have any questions.

Sincerely,

JDMT, Inc

Michael Theroux
Vice President

cc: (via email)
Elliot Block, Chief Council, CalRecycle - Elliot.Block@CalRecycle.ca.gov
Howard Levenson, Deputy Director, CalRecycle - Howard.Levenson@CalRecycle.ca.gov

CalChamber
CALIFORNIA CHAMBER OF COMMERCE

(IC)53- California Chamber of Commerce

December 30, 2011

Deborah Raphael, Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

SUBJECT: Safer Consumer Product Alternatives – Informal Draft Regulations (October 31, 2011).

Dear Director Raphael:

The California Chamber of Commerce (CalChamber) appreciates the opportunity to submit comments regarding the Department of Toxics Substances Control's (DTSC or Department) Safer Consumer Product Alternatives regulation (SCPA or draft regulations) as released October 31, 2011.

The CalChamber is the largest broad-based business advocate in the state, representing the interests of nearly 15,000 California businesses, both large and small. In fact, about 75% of our members are small businesses. Many of CalChamber's members will be directly impacted by the SCPA regulations, and those businesses not directly regulated will likely experience indirect impact in the form of new costs passed downstream from the consumer product supply chain.

Since the passage of AB 1879 and SB 509 in 2008, CalChamber has been a constructive voice in development of the SCPA. We have remained committed to a process that promulgates the goals and intent of the Green Chemistry Initiative, a science-based process for identifying exposure to the highest priority products containing chemicals of concern (COC), and to an appropriate and economically feasible response. Our hope is to create a program that provides certainty for businesses in an otherwise unpredictable legislative and regulatory environment. We look forward to an approach to chemical management that truly inspires innovation and relies on science, not politics, as the basis for its decision.

We acknowledge some positive changes to the current informal draft iteration, such as certain flexibilities afforded to responsible entities in the Alternatives Assessment (AA) Report, the elimination of the Third Party Verifiers and the Department's stated intention to start with 2 to 5 Priority Products, also been noted in the SCPA Summary. Unfortunately, as written, the informal draft regulations has several unworkable provisions and fail to deliver on the most fundamental aspect of the Green Chemistry Initiative. Rather than to inspire a new era of greener, safer products and technologies, the SCPA continues to disincentivize the innovation and investment necessary to achieve these shared goals. The uncertain regulatory environment resulting from the proposed regulations will make investing, innovating, and simply doing business in California a substantially riskier endeavor. Much like the 2010 drafts, the regulations are written in a way that gives the department near-limitless discretion over a process that will be used to regulate consumer products. Indeed, a fundamental problem with the draft regulations is that DTSC retains so much discretionary power that it virtually eliminates any certainty that a business might have in terms of regulatory treatment.

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On several critical elements of the regulation the Department fails to create rules that provide any level of predictability for regulated entities. Adding to the uncertainty is the draft's expansive COC list, which lacks a chemical prioritization process. Also financially burdensome is the requirement for responsible entities to establish, maintain, and fund an end-of-life product stewardship program for a product identified as a hazardous waste in California. All this amounts to a regulation in which it is nearly impossible to ascertain whether a given product or material will be subject to a long and expensive process.

The following comments address our concerns with the informal draft SCPA regulations that if left unchanged, will threaten to impede the innovation, technology and job creation goals envisioned by the Green Chemistry Initiative. We respectfully submit our comments, which by no means are an exhaustive list of our concerns, with the SCPA draft regulations. Additionally, we echo the comprehensive comments that will be submitted by the Green Chemistry Alliance (GCA). As an active and founding member of the GCA, the CalChamber believes that for the regulations to be successful, the Department must heed the comprehensive recommendations contained within the GCA document.

Chemicals of Concern List

The informal draft SCPA regulations call for an immediate, robust list of Chemicals of Concern (COCs), which the Department estimates will include approximately 3,000 chemicals. CalChamber is concerned that such an expansive list at the outset will only hinder the goals of the Green Chemistry program by creating uncertainty. The expansive COC list is especially problematic because it lacks a prioritization process. As written, it is unclear how the chemicals within the COC list will be prioritized. Without this process, the program is bound to become essentially meaningless, for as long maintained by CalChamber, if everything is a priority, then nothing is a priority. CalChamber strongly urges the Department to effectively prioritize the COC list. With the assistance of the Green Ribbon Science Panel (GRSP), the Department should prioritize chemicals of concern to focus only on those chemicals that pose the greatest hazard and threat of exposure. This focused/prioritized list can be reviewed every three years as described in the regulation. Finally, we urge the Department to ensure that „list of lists' that will be used to generate the COC list is derived based on sound and credible science.

Priority Products/Prioritization

CalChamber is concerned that the informal draft SCPA regulations do not include a process for identifying and prioritizing products. Aside from a list of criteria to „consider,' the draft regulations lack details on how the criteria will be applied or weighted to identify the product/COC combination as it relates to significant threat of exposure and harm. This process should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Reasonable and foreseeable exposure is an essential principle of proper chemical regulation and is recognized nationally and around the world. Without an objective prioritization process, the regulations will be subject to the political influences from which the Green Chemistry Initiative was designed to escape. Regulated entities must have an outlined process for the prioritization of products that are publicly available.

While the summary of the informal draft regulations states that „DTSC anticipates that the initial list of priority products will include 2 to 5 products,' this statement is noticeably absent in the actual informal draft regulation. For clarity purposes and to reaffirm what has been stated both verbally by the Department and in writing in the draft summary, we request that the above summary statement be incorporated into the informal draft regulations. Incorporating this statement will provide much needed certainty, especially since the Department plans to review chemicals and products for prioritization every three years.

Finally, we do not believe the Department has the authority to regulate workplace exposure as a factor for product prioritization. Regulation of workplace exposures are under the jurisdiction of the U.S. Occupational Safety and Health Administration (OSHA) and Cal/OSHA. To avoid regulatory duplication,

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we believe that „worker exposure' consideration should be removed as a priority product factor under the SCPA draft regulations.

De minimis Exemption
While we appreciate the exemption provision for products exhibiting trace levels of a chemical of concern, we believe that the current de minimis exemption is unworkable and goes above and beyond the de minimis thresholds implemented by other existing regulatory programs. We stand by our previous recommendations made in past comment letters that the de minimis threshold be set at 0.1% for chemicals exhibiting the specified hazard traits. Again, this threshold has proven successful as a default and is consistent with current global chemical regulatory programs. The application of a reasonable de minimis threshold exemption is an important element that will help ensure certainty and provide much needed parity in the regulatory process. Another concern is that the draft regulations give the Department complete discretion to declare that, for any priority product, no de minims exemption be given on a case-by-case basis. This provision creates uncertainty and negates the purpose of an exemption all together. We urge the Department to remove this discretionary provision from the regulations.

Finally, the regulations impose an in-depth application process along with detailed data submission in order to justify a de minimis exemption. This onerous requirement defeats the purpose of the exemption provision, undermining the determination that a COC below the threshold level does not pose a concern to human health or the environment and should not be prioritized. This process will be incredibly resource-intensive for the responsible entities, and will certainly overwhelm the Department. Likewise, requiring responsible entities to submit de minimis exemption notifications will only create unnecessary work for both the entity and the Department for chemical/product combinations that pose no real threat.

Applicability and Petition Contents
The SCPA draft regulations identify a detailed petition process for adding a chemical to the COC list. Absent however, is a detailed process for the *removal* of a chemical from the COC list. For parity purposes, we recommend that subsequent iterations of the SCPA regulations include an outlined process for the removal of chemicals on the COC list. Additionally, in an effort to ensure agency oversight and transparency, we recommend that the Technical Review of Petition provision section of the regulations incorporate a public process or a formal notification to the public about the petition requests that the Department may receive for both the addition and removal of a chemical from the COC list.

Alternatives Assessments
We acknowledge some positive changes have been made to the current SCPA iteration relating to the alternatives assessment (AA) process in the form of added flexibilities for regulated entities. Yet, we remain concerned that the AA involves extensive processes with limited timeframes for completion. The 180-day and the subsequent 12-month submission deadlines for the preliminary and final AA reports is not sufficient given the amount of time and resources involved with this in-depth process. While specific industries and companies have made alternative assessments a vital component to a products research and development process for many years, there are several industries and companies, particularly the smaller ones that lack the resources and infrastructure needed to complete such detailed process on-site. For example, these companies will no doubt be required to rely heavily on contractor(s) to finish the assessment within the allotted timeframes. Failing to do so could subject the company to applicable penalties. We recommend that the timeframes be re-adjusted to give a regulated entity ample time to complete the AA assessment. Whether done on-site or contracted out, the AA encompasses an extremely detailed, in-depth process that often times takes years to complete. We urge the Department to not treat the AA process as a one-size-fits all approach. The complexity and time period required for each industry varies as they are each subject to different variables (e.g. product, company, size, etc).

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Regulatory Response
The draft regulations give the Department broad authority to impose a variety of significant regulatory responses on responsible entities. In general, we are concerned that there is no set criteria for how DTSC will determine what is or isn't a proportional regulatory response. It is critical that any response imposed by the Department be proportional to the degree of risk posed by the product in question. Where there is not an objective risk, no regulatory response should be required, a provision that should be made explicitly clear in the current SCPA draft regulations. Significantly burdensome regulatory responses, including "End of Life Management" or "Product Sales Prohibitions", should only be undertaken where there is a demonstrable objective risk that can and must be managed with those options.

- No Additional Regulatory Response Required: As written, this section provides no certainty as to whether or not a selected alternative chemical will necessarily trigger a regulatory response since that alternative must effectively satisfy both sets of criteria outlined in the regulation. Criteria (a) of Section 69506.2, requires that the „selected alternative does not contain a COC in a concentration exceeding the de minimis level….' With a list of over 3,000 COCs, it will certainly be difficult to meet this overreaching requirement. Additionally, criteria (b) of the same section, requires that „the selected alternative does not pose significant potential adverse public health or environmental impacts.' It is unclear how "significant" or "adverse" will be measured. Based upon such onerous and conflicting criteria, the summation that no additional regulatory response is required is flawed.

- Product Information for Consumers: This section is reminiscent of Proposition 65 requirement to label or insert information in the packaging, notifying the consumer that the product contains a priority chemical for which an alternative was not substituted. Research continues to show that beyond immediate hazards, labeling of a product is an ineffective way to warn consumers of potential hazards. We continue to believe that information/disclosure requirements should be done in the least restrictive manner possible. Responsible entities should have alternatives to labeling such as websites, product manuals, or other options that fit the product's market. However, labeling should not be required for a product that meets DTSC's safety standards and does not require substitution.

- End-of-life management requirements: With regard to the end of life management as a regulatory response, the SCPA goes beyond the scope of the statute (AB 1879) and is overly burdensome by requiring public education and take back programs. How does the responsible entity define "roles and responsibilities of manufacturers, importers, retailers, consumers and government"?

  It would appear that this provision is inconsistent with the provision in AB 1879 that prohibits duplicative regulation. Currently, if a product is to be managed as a hazardous waste, a mechanism for handling that waste is already set out in the law. To require a specific method of handling those products (i.e. a take-back program) duplicates the existing provisions in the law. Managing all products as hazardous waste will add significant costs and burdens without providing any benefits to human health or the environment. Additionally, this classification may conflict with Department of Transportation's requirements for storage and transportation of hazardous waste.

- Product Sales Ban: We are concerned with the requirement of an "inventory recall" when the regulatory response calls for a product sales prohibition. This seems to be an extreme and punitive response, especially where there is no safety issue. Additionally, the regulations should provide further information regarding how DTSC will "determine… that a safer alternative exists" and thereby order that the product "shall not be made available for use in California." It is important that such an extreme regulatory measure be implemented only under circumstances

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where gains to public health and the environment will be realized without creating other adverse public health, environmental or economic impacts.

- Other Regulatory Responses: As currently written, this section fails to identify the process by which the Department will select the regulatory responses that are necessary and reasonable to limit exposures. Furthermore, it is unclear when regulatory responses are required, and what would trigger the application of additional regulatory responses. We believe that as with the process for identifying priority products, a process must also be in place that provides certainty to the regulated community whose actions will be regulated. Additionally, the Department must clarify how often it will "periodically re-evaluate" each regulatory response. As regulated entities devote valuable time and resources adhering to the imposed regulatory responses, it seems unfair that the Department retains discretion to require further changes to these responses without necessarily establishing the definition of periodic reviews. Again, regulated entities need certainty or at least sufficient warning of the Department's intention to modify an entity's regulatory response.

Regulatory Duplication
When addressing regulatory duplication, the draft regulations state that the Department *may* exempt a product that it determines is regulated by other federal or state regulatory programs, or international trade agreements. Recognizing duplicative regulations is a key step in the required prioritization process that will determine what chemicals and products will be subject to the SCPA regulatory process. However, the Department essentially nullifies this rule by clarifying that the exemption „only applies if DTSC determines that these other program(s) provide a level of public health and environmental protection equivalent to, or greater, than the protection that would potentially be provided if the product was listed as a priority product.' Again, this exception gives DTSC full applicability discretion, and allows the Department to ignore the presence of duplicative regulations at its own whim. Thus, the only rule businesses can take away from this language is that the Department ultimately decides whether a regulation is duplicative.

Certified Assessors
CalChamber believes that a certification process for assessors of alternatives should be an *option* for regulated entities, *not* a mandate. A regulated entity should be given discretion over the process of certification. Given the breadth of the alternatives assessment, this process should additionally be offered to professionals outside the „scientific' and „engineering' field that posses the relevant experience and education to complete the assessment. Assessors should also not be required to be technical experts in all aspects of an AA, but should instead be capable of managing the AA process to be certain that all applicable parameters are considered.

Trade secrets / confidential business information
Ensuring that confidential business information (CBI) and trade secrets are protected throughout the process is vital to the success of the program, and is essential to ensure innovation and competition in the market. As written, critical confidential business information may not be protected in the process. Instead, the regulations call for a lengthy claim of confidentiality that must be asserted for each chemical, giving the Department the ability to make subjective determinations, at its sole discretion, about whether or not CBI protection is sufficiently justified. If DTSC determines that a trade secret claim is not sufficiently justified, the only recourse a company has to seek relief, is with the courts. Ultimately, there is no certainty provided to regulated entities on protecting the information that gives their product much of its economic value. Again, since this regulatory program is groundbreaking and involves expansive scope and data submission requirements, we urge the Department to make trade secrets and protection of confidential business information, a high priority.

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Economic Impacts
At a time when California needs to kick-start its economy by creating jobs, the proposed draft regulations, much like the 2010 drafts, continue to impose layer upon layer of additional costs on companies when California can least afford it. It is ultimately the Department's responsibility to strike the proper balance between the scope of the program and the resources available for them in order to succeed.

Given that the estimated costs for similar existing regulatory programs are substantial, we believe that it is appropriate for the Department to conduct a periodic economic impact analysis of the SCPA regulations to ensure that the program is economically efficient, and technologically and environmentally sound. A metric for screening all economic impacts is imperative and will necessarily include factors such as costs associated with alternative chemical replacement as well as cost impacts that will ultimately trickle down the consumer supply chain. It is also appropriate for the Department to include market acceptance when screening for economic impacts. Consumer reaction to the potential cost increases resulting from product reformulation will play a major role in the overall fiscal impact of the regulations. We urge DTSC to identify and monitor these and other key indicators, so that any inadvertent problems that may occur can be corrected without further jeopardizing California's economy or environment.

We also urge DTSC to include a periodic review process of the SCPA program via a stakeholder advisory group to ensure the intent and goals of the program are being met efficaciously through the imposition of cost-effective, sustainable, and technologically and commercially feasible requirements. As the Department moves forward, we hope that these and other important issues are addressed with much diligence and oversight via an open forum that allows for public participation and comment in order to ensure transparency in the process and maintain integrity of the program.

<u>Small Business Flexibilities</u>
It is important to recognize that small businesses are the heart of America's economic strength and job creation. Small businesses play an integral role in the state's path toward economic recovery. In keeping this in mind, the SCPA regulations must be drafted in a way that do not unduly burden businesses with excessive, unachievable mandates that will lead to economic impacts such as job losses or other financial constraints. As referenced in the alternatives assessment section above, small businesses will face challenges as they seek to comply with several provisions of the proposed regulations. For example, small businesses do not necessarily have the on-site infrastructure/resource capabilities available to larger companies. Several small businesses will likely be forced to contract these services out, incurring additional costs. Therefore, we urge the Department to be cognizant of the small business impact that may result from the regulations, and to the extent possible work toward mitigating these impacts either through timeline extensions or specific assistance that the Department may provide in an effort to minimize the impact on small businesses as these companies strive to remain competitive in the market. In an effort to avoid running these companies out of business, the Department must provide flexibilities and accommodations necessary for these companies to compete with their larger counterparts. The CalChamber would be willing to provide the Department with further input on how to mitigate the impact on small business.

As written, there are several unworkable, unreasonable provisions in the current SPCA draft regulations. The regulations are filled with uncertainty for California businesses and if left unchanged, threaten to undermine the fundamental goals of the program. The task of chemical management is a long-term endeavor driven by ever-changing developments in science. Regardless of the resources directed toward development of data, there will always be more questions to ask and more data to gather – it is after all the nature of the scientific process. The issue is not whether there is a data gap; but rather, how can the state manage its finite resources to best identify and prioritize the uses of the chemicals of greatest concern in consumer products. We urge the Department to proceed with caution, and recognize the value of harmonizing the program with works previously done in the European Union and other states and countries on chemical use regulation.

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For all of these reasons, and for the reasons articulated in the GCA document that will be submitted separately, we urge DTSC to work toward a process that is reasonable, workable, and that creates certainty for all businesses in the consumer product supply chain, without jeopardizing health and environmental quality or creating greater burdens that will further delay the state's economic recovery.

Again, we appreciate your consideration and the opportunity to comment on the informal draft SPCA regulations. We look forward to further communication as the Department continues to work on the important design elements of the program.

Should you have any questions, please feel free to contact me at (916) 444.6670.

Sincerely,

Brenda M. Coleman
Policy Advocate

cc: The Honorable Matt Rodriguez, Secretary, Cal/EPA
Gordon Burns, Undersecretary, Cal/EPA
Odette Madriago, Acting Chief Deputy Director, DTSC
Martha Guzman-Aceves, Deputy Legislative Secretary, Office of the Governor
The Honorable Joe Simitian, California State Senate
The Honorable Mike Feuer, California State Assembly

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(IC)54- TDC Environmental

tdc
environmental

December 29, 2011

Ms. Debbie Raphael
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Informal Draft Regulations for Safer Consumer Products, October 2011

Dear Debbie:

DTSC has done an amazing job on this informal draft regulation. Together, you and the regulation writing team have constructed a practical regulatory framework for meaningful implementation of AB 1879 and SB 509.

Although the general framework is sound, in reviewing the informal draft regulations, I found areas where the regulation can be improved to make it more scientifically solid and to better address non-human environmental problems associated with consumer products. The areas where I suggest improvements and suggested language are detailed in Attachment A.

Almost half of my comments center on just two sections: the definition of "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" and the Product Prioritization section. I found both of these sections to be scientifically problematic, particularly in the way they address non-human environmental problems. With the proposed wording in these two sections, DTSC would probably have been unable to prioritize most of the environmentally problematic products I have encountered over the last 15 years (see Attachment B). Scientifically, the detail in both of these sections seems unnecessary. Although I am sure that DTSC had good reasons for drafting these sections, both sections seem to function primarily as mechanisms for limiting DTSC's authorities and increasing the evidentiary burden on DTSC when it identifies chemicals of concern and priority products. If non-scientific reasons require DTSC to have highly detailed language in one or both of these sections, I encourage you to ask scientists from state and Federal agencies (particularly the Water Boards, Fish & Game, and U.S. Fish & Wildlife Service) and the Green Ribbon Science Panel for assistance in developing wording that is sufficiently scientifically robust to provide standards that will serve for a great diversity of human and environmental exposures and impacts associated with chemicals in consumer products.

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Finally, although DTSC is not addressing funding at this time, I feel obliged to note my concerns about DTSC's funding to implement these regulations. My professional experience has shown that there are hundreds of products that need regulatory attention to protect public health and the environmental from pollutants in consumer products. The lack of regulation of pollutants in products is costly not only for human and ecosystem health, but also for California state and local governments. For most products (i.e., commodity products), market forces do not reward safer products. This is why regulations are necessary to stimulate innovation, to drive market improvements, and to protect responsible businesses from less responsible competition. If DTSC does not obtain sufficient funding to address a reasonable number of products (i.e., several dozen products annually), I think it likely that market forces, human health and environmental needs, and government budget challenges will force this regulatory process to be bypassed often by the legislature.

It has been an honor to assist DTSC with the development of its landmark program to protect human health and the environment from pollutants in consumer products. I would be pleased to continue to provide whatever support I can toward helping you create a practical, meaningful, and scientifically robust regulatory program. Please feel free to call me at 650-627-8690.

Sincerely,

/s/

Kelly D. Moran, Ph.D.
President

Enclosures: Detailed comments, Product Examples, Conceptual Model Example

ATTACHMENT A: Detailed Comments

Article 1. General - Definitions

Definition of Adverse Air Quality Impact – §69501.2 (2) – This definition omits common indoor and outdoor air pollutants (e.g., formaldehyde from decomposition of chemicals used in furniture construction) and pollutant categories (visibility-reducing particulates). The definition could be improved with the following changes:

(1) Revise the first sentence to read: "Adverse air quality impacts" means air emissions of any of the air pollutants listed below *or their chemical precursors*:
(2) Replace (B) Greenhouse gases, with "chemicals with the Global Warming Potential" hazard trait as defined in §69405.4." This change would allow DTSC to address any newly identified greenhouses gases.
(3) Replace "Compounds" with "Chemicals" throughout (see comment on definition of "chemical" below, this change would allow DTSC to address chemicals that themselves are not air pollutants, but that decompose into air pollutants)

To avoid future problems from the narrow air quality and water quality impacts definitions, I recommend that DTSC clarify in the Initial Statement of Reasons that the intent of the air and water quality impacts definitions is to expand on—and not limit—impacts related to expression of hazard traits defined in Chapter 54.

Definition of Adverse ecological impacts §69501.2 (3) – Recommend clarifying (G) to indicate the effects associated with any of the environmental hazard traits listed in Article 4 of Chapter 54.

Definition of "Adverse environmental impacts" §69501.2 (4) – Recommend adding "Adverse waste and end-of-life impacts" §69501.2 (7), which appears to have been inadvertently omitted. This ensures that impacts associated with end of life and impacts to reuse of solid and liquids that contain the chemical of concern as a consequence of its presence in the product can form the basis for identification of a chemical of concern or a priority product.

Recommend adding "Non-compliance with local, state, or Federal environmental laws and regulations" to this definition. Non-compliance is a straightforward measure of air quality, soil quality, and water quality impacts. Often it is simpler to estimate or demonstrate non-compliance than it is to demonstrate specific environmental impacts individually. Further, some entities may avoid arguing that a product or chemical is causing an environmental impact out of fear of generating legal liability to themselves by putting that argument in writing (this is a particular concern of Clean Water Act permittees, who may be subject to citizen suits). Including environmental compliance in the definition has the added advantage of ensuring that AAs evaluate not only for generic impacts but also specific impacts that are sufficiently important as to be regulated under local, state, or Federal

environmental laws and regulations. Local regulations need to be included because some types of laws, such as local ordinances to implement Pretreatment Programs required under the Federal Clean Water Act, are implemented at the local level to account for differences in locally specific conditions, such as the sensitivity of local surface water ecosystems.

Definition of Adverse waste and end-of-life impacts §69501.2 (7) – Recommend that DTSC modify (C) to read: "*Intentional or unintentional* disposal of the priority product…." This will allow DTSC to address products like lead wheel weights, which are problematic environmentally because they fall off of vehicles (unintentional) and they and their debris are washed into waterways.

Subsection (C) should also be modified to remove the final clause ("and that may result in the release of Chemicals of Concern to the environment."). Interference with operations of these systems is in itself an environmental impact because it is associated with environmental harm—but often harm other than release of a chemical of concern. For example, operational interference at a municipal wastewater treatment plant would ordinarily cause the discharge of partially treated wastewater, which could contain a plethora of chemical and biological pollutants.

Definition of Adverse water quality impacts §69501.2 (8) – Like the air quality definition, this definition identifies only a small subset of water quality impacts; however, the definitions of "adverse ecological impacts" and "adverse public health impacts" capture most relevant environmental endpoints through reference to Chapter 54.

A better definition would be something along the lines of "cause or contribute to violations of water quality standards, adverse effects to aquatic ecosystems, or degradation of any waters, including both surface or ground waters."

The key section of this definition is (E), which captures a critical concept for California and Federal water quality regulatory programs—"Antidegradation." The short set of lists of pollutants that follow does not encompass the range of pollutants that may be subject to Water Board antidegradation policies.

I recommend that DTSC engage the Water Boards' assistance in revising the wording of this section to ensure it will be complete and will stand the test of time.

Definitions of "Assembled product" §69501.2 (12) and "Formulated product" §69501.2 (37) – Although DTSC has attempted to distinguish between these two product categories, the distinction is not nearly as clear as the definitions imply. In many cases, products are a combination of a formulated external element and an assembly beneath. One example of these mixed products includes friction materials like brake pad or clutch pads, which consist of a formulated friction surface mounted on a backing plate with connectors for attaching to a vehicle. Another

example is any assembled product that is covered by a coating, e.g., a painted toy. The primary human and environmental exposure is to the formulated coating.

To address the overlap in these product categories, either the definitions will need to be substantially reworked or the use of the definitions will need to be more carefully delineated at each point where these terms are used in the regulations (the most problematic points are the de minimis exemption and the product prioritization section).

Definition of chemical §69501.2 (16) – Since so many environmental problems are associated with the environmental fate of chemicals, it is essential that the definition of "chemical" capture chemicals for which environmental harm is associated with their inevitable degradates, reaction products, and other transformations in the environment. While there are multiple ways of capturing this critical scientific concept, I suggest use of the definition proposed by OEHHA in Chapter 54 69401.2 (c), which appropriately accounts for metabolites and degradation byproducts (A "chemical substance" is a chemical, chemical compound, chemical mixture, elemental material, particulate matter, fiber, or radioactive agent; its metabolites or degradation by-products.) Because this definition is not quite complete, I suggest adding the following DTSC language to the OEHHA definition: " and a combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature."

If the definition of "chemical" is not revised, changes will be necessary throughout the entire regulation.

Definition of Bioaccumulation §69501.2 (14) – Recommend revising this definition to match the definition in Chapter 54, 69405.2. The definition proposed by OEHHA is scientifically appropriate.

Definition of Economic impacts §69501.2 (27) – This definition should be revised to specifically include both public and private externalized costs, including but not limited to government costs (e.g., waste management, pollution abatement), consumer costs, business costs (businesses other than the manufacturer), and public and private health costs.

Definition of "Environment" §69501.2 (31) – This definition may be too narrow to meet the state's needs. Under CEQA, the environment is defined to include not only the natural environment, but also the human environment. Including human-made portions of the environment would ensure consideration of human-created structures and systems that humans use (such as wastewater collection, sewage treatment, solid waste management, air pollution control, transportation, power generation, and power transmission). Domesticated animals should be added. Because some impacts occur on an ecosystem scale rather than the scale of an individual organism, the environment should be defined to include larger systems in

addition to individual organisms: ecological communities, populations or ecosystems.

Definition of "Environmental Fate Properties" §69501.2(32) – This definition includes an confusingly constructed list, some of which are standard environmental fate characterization values, others of which are non-specific (e.g., "mobility among and between individual components of the environment"). This would work better if DTSC created a list of standard environmental fate tests.

To construct a lit of standard environmental fate tests, I suggest that DTSC look at U.S. EPA's environmental fate data requirements for pesticides (see 40 CFR Part 158). Pesticide data requirements are good examples for DTSC because U.S. EPA's list has been carefully crafted over the last several decades to ensure that sufficient data are available for pesticide regulators and manufacturers to develop an informed understanding of the potential for a chemical to adversely affect humans or the environment. In a quick comparison of DTSC and EPA data requirements, I noted the following standard EPA requirements were not on DTSC's list in this definition: aqueous photolysis half life; soil photolysis half life; photodegradation in air; volatility; leaching and adsorption/desorption as well as the municipal wastewater treatment fate data requirements (activated sludge sorption isotherm; ready biodegradability; modified activated sludge respiration inhibition test; porous pot study).

Another key gap in the list of Environmental Fate Properties is identification of degradates, metabolites, and reaction products that will be formed in the environment in relationship to the use of the chemical. Often the key hazards and most important environmental harm associated with chemical use are due to the chemical substances formed once the chemical is released to the environment. For example

- the pesticide DDT degrades to several more stable (and equally toxic) chemicals in the environment
- the marine antifoulant zinc pyrithione reacts with copper (often present in high concentrations in marinas due to its use as a marine antifoulant) to create copper pyrithione, which is far more toxic to aquatic life than the parent zinc compound
- nonylphenol ethoxylates in detergents degrade to nonylphenol, a water pollutant

Missing these transformations while evaluating a chemical would miss some of its key impacts.

This definition should link to Chapter 54, Article 5 (Exposure Potential Hazard Traits). That article includes several environmental fate properties that should be part of the Safer Consumer Product design process and that are needed for thorough alternatives assessments.

To ensure that the list of environmental fate properties is complete, I recommend consulting with the Air Board, Water Board, DPR (which has substantial experience with environmental fate data needs), DFG, and the U.S. FWS (which has substantial experience using environmental fate data in ecological risk assessments, such as for pesticides).

Definition of "Environmental or toxicological endpoint" §69501.2 (33) – This definition is a bit unclear because it uses the term "endpoint" while Chapter 54 uses the term "hazard trait". All toxicological and environmental hazard traits should be considered "endpoints" for the purposes of these regulations.

Definition of lifecycle §69501.2 (46) — This definition should specifically include reasonably anticipated misuse, incidental activities associated with use (e.g., cleaning after use), and common accidents involving the products. The omission of these inevitable exposure pathways from pesticides reviews has caused endless headaches for regulators and ongoing health and environmental challenges.

Definition of "mode of action" 69501.2 (54) – Recommend deleting this from the regulations. The mode of action of chemicals on various target organisms is relatively rarely known. Understanding the molecular-level details of mode of action should not be a requirement for either DTSC or private company decisions.

Definition of "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical" §69501.2 (67) – This definition greatly (and in my view inappropriately) limits the types of scientific information that DTSC may consider when identifying a chemical of concern or a priority product. Since "reliable information" is already defined to require reasonable quality scientific information for DTSC decisions, is this definition necessary?

The proposed definition creates a particularly high burden for new chemicals, which are often not well characterized and for which chemical analysis methods are often unavailable.

Because I do not believe that it is feasible to create a list of all types of sound scientific evidence for all types of chemical-caused environmental problems, I encourage DTSC to remove this definition from the regulations. Should DTSC feel that it is essential to define this phrase in a manner that specifies (and therefore limits) the types of scientific information that would be allowable for DTSC to use, I recommend that DTSC review the literature to identify a full range of scientific studies examining pollutant exposures across all human and environmental settings, obtain assistance from scientists at other state and federal agencies, and consult with the Green Ribbon Science Panel.

The following questions and comments show why this list seems problematic from the viewpoint of non-human environmental problems:

- Monitoring data – Why are data about the presence of a chemical only reliable if they are obtained from a residential setting? (A) and (B) should be modified to provide that all monitoring data are reliable.

- Environmental monitoring data – "Accumulation" of a chemical in the environment—see (C) and (F)—is not necessary for environmental harm to occur. Most of the Chapter 54 hazard traits are exhibited without accumulation of a chemical—simply the presence of the chemical is usually sufficient. Environmental accumulation is also exceptionally difficult to prove.

- Why would exposures only to aquatic, avian, animal and plant species be considered? Ecosystem exposures, insects, and other organisms (e.g., waste management organisms) should not be omitted.

- Would conceptual models and straightforward calculations be considered "exposure modeling" (G)? These are the types of modeling that are ordinarily available to link consumer products to environmental problems. Full numeric modeling can cost hundreds of thousands of dollars and seems unnecessary to provide the weight of evidence necessary for DTSC decisions in most cases.

- Why is so much information beyond exposure estimates required to demonstrate exposures in solid waste, wastewater or stormwater (H)? Why would exposures occurring in solid waste, wastewater, and storm water collected and managed by non-government entities (e.g., private garbage companies, private property stormwater systems) not be relevant?

- When a chemical interferes with a waste treatment process, the end result may not necessarily be that the same chemical is discharged to the environment. Other chemicals may be discharged at higher concentrations (e.g., bacteria or excess nutrients might occur in wastewater effluent) or a composting facility might not be able to create usable compost (which of course is not "discharged").

While deletion would be the most prudent course in my view, if DTSC needs to revise this definition, the following modifications should be considered in combination with further revisions that should be developed by DTSC in consultation with other agencies and the GRSP:

(67) Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that are established by reliable information:

(A) Monitoring data that shows the chemical to be present in ~~household~~ dust, indoor air, or drinking water, or on interior surfaces;
(B) Monitoring data that shows the chemical to be present in, or released from, products used *in California* ~~in or present in the home~~;
(C) Environmental monitoring data, or environmental modeling results, that indicate environmental *presence* ~~accumulation~~ of a chemical;
(D) California Environmental Contaminant Biomonitoring Program data, Center for Disease Control's National Health and Nutrition Evaluation Survey biomonitoring data, or other biomonitoring data, that show the chemical to be present in human organs, tissues or fluids;
(E) Reliable information that provides evidence that a chemical exhibits the lactational or transplacental transfer hazard trait specified in section 69405.5;
(F) Environmental monitoring data that shows the *presence* ~~accumulation~~ of the chemical in aquatic, avian, animal or plant species *or elsewhere in the environment*;
(G) Exposure modeling that indicates exposure point concentration(s) associated with adverse public health or environmental impacts *or non-compliance with environmental laws*; or
(H) Monitoring data indicating the presence of a chemical ~~or its degradation products~~ in California solid waste, wastewater or storm water streams ~~collected or managed by California State or local agencies in concentrations or volumes that:~~

~~1. Present potential adverse public health or environmental impacts;~~
~~2. May require the expenditure of public funds to mitigate potential adverse public health or environmental impacts;~~
~~3. Increase the costs of reusing or recycling materials containing the chemical; or~~
~~4. Interfere with the proper operation of solid waste, wastewater, or storm water treatment systems and may result in the discharge of the chemical to the environment.~~

Please note that the suggested revisions above assume that the definition of the word "chemical" is revised as recommended (see comments above). If the definition is not revised, then at each instance of the word "chemical", the phrase "chemical, its degradates, metabolites, or reaction products" should be substituted.

<u>Definition of "technologically and economically feasible alternative" §69501.2 (74)</u> – Recommend that subsection (C) be modified to read: "The alternative does not *significantly* increase aggregate externalized costs to consumers, public health, and the environment." This will avoid the potential for negligible cost increases (i.e., one penny) to interfere with desirable changes.

<u>Information Submission Section §69501.4</u> – Based on my previous experience in regulatory programs, I recommend that all submittals should have company Owner Officer Signature (not "authorized representative"). This provides greater

assurance that the company will stand behind and be accountable for the information supplied to DTSC.

Article 2. Chemicals of Concern Identification Process

Initial Chemicals of Concern List §69502.2 (a) – The general size of the initial list of chemicals of concern appears appropriate. The list signals the market that DTSC expects stewardship for all hazardous chemicals, stimulates innovation, and should address pollutants with adverse impacts for both humans and the environment.

The list misses several key pollutants. In my review, I identified three types of pollutants that are not captured in current lists:

(1) Chemicals that degrade into a pollutant, such as nonylphenol ethoxylates (which degrade to the water pollutant nonylphenol),
(2) Chemical families, such as copper compounds and alloys
(3) Chemicals that are hazardous due to their physical structure or size, such as asbestos and carbon nanotubes.

To maintain a manageable listing process, I recommend addressing degradates and families of chemicals (e.g., all copper compounds) through the definition of "chemical" rather than attempting to list every single one.

This section includes few lists of non-human environmental pollutants. To address this gap, I recommend that DTSC evaluate the following lists for potential addition to the regulations:

- Chemicals for which U.S. EPA has promulgated water quality criteria under Section 303(c) of the Federal Clean Water Act;
- Chemicals for which U.S. EPA has established Water quality criteria under Section 304(a) of the Federal Clean Water Act
- Chemicals for which one or more California Regional Water Quality Control Boards has established Water Quality Objectives.
- Chemicals for which California has established Maximum Contaminant Levels or Public Health Goals
- Chemicals for which OEHHA has established Fish Contaminant Goals
- Canada's list of "challenge substances" http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php
- Oregon's P3 list (http://www.deq.state.or.us/wq/SB737/)
- The Stockholm Convention list of POPs

Criteria for additions to the Chemicals of Concern List, §69502.2 (b) – In subsection (b) (1) 6., to ensure that ecosystems as well as individual organisms can be the basis for listing, recommend use of the term "environment" instead of "environmental receptors."

Additions to the Chemicals of Concern list §69502.2(b) – In subsection (1) (b) 3., to ensure that severe effects (e.g., death, severe localized groundwater pollution) that may not be widespread are prioritized, recommend use of "widespread or severe" rather than just "widespread."

Why is exposure a consideration for adding new chemicals of concerns to the list §69502.2 (b) (2)? The initial listing in subsection (a) is based on hazards; why should additions be treated differently? It makes scientific sense to create the chemicals of concern list based on hazards (including exposure potential hazard traits identified in Chapter 54) and to bring in exposure at the product prioritization stage. Calling for exposure information at the time of listing creates a potentially significant barrier to listing new chemicals, for which such information is rarely available (often product use is unknown and chemical analytical methods are unavailable). (See also comments on the definition of "reliable information demonstrating the occurrence, or potential occurrence of exposures to a chemical.")

On the basis of the above comments, the following revisions are suggested:

(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 one or more hazard traits or environmental or toxicological endpoints, as Chemicals of Concern by considering the following factors for which information is available:

(1) Potential Chemical Adverse Impacts.

(A) The potential for the chemical to cause adverse public health and/or environmental impacts, considering:

1. The chemical's hazard traits and environmental or toxicological endpoints, ~~and modes of action~~;
2. The chemical's aggregate effects;
3. The chemical's cumulative effects with other Chemicals of Concern ~~with similar modes of action~~;
4. The chemical's physicochemical properties;
5. The chemical's environmental fate properties; and
6. The populations and/or *environment* ~~environmental receptors~~ that are potentially adversely impacted.

(B) The Department shall give special consideration to the type and severity of potential adverse impact(s) and the potency of the chemical associated with the adverse impact(s) for all of the following:

1. Children, pregnant women, and other sensitive subpopulations;
2. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and
3. Widespread *or severe* adverse public health and/or environmental impacts.

~~(2) Potential Exposures. The potential public and/or environmental exposures to the chemical in quantities that could result in adverse impacts,~~

~~considering relevant reliable information that indicates the possibility for public or environmental exposures to the chemical, and reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical.~~

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

General Comments – The product-based approach that DTSC proposes is both practical and scientifically necessary for Alternatives Assessments (AAs). DTSC's selection of a narrative standard is appropriate because the narrative is the only practical means by which DTSC can deal with the variety of types of environmental problems that these regulations will need to target.

Product Prioritization Criteria §69503.2 (a) and (b) – I recommend that DTSC greatly simplify the criteria in this section. As explained below, this wording of this section would make it difficult for DTSC to prioritize products that harm the environment. The detailed approach would require costly staff work for DTSC to demonstrate how it has considered the multitude of listed factors for each product under consideration. (See also the above comments on the definition of "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical" §69501.2 (67), which would create a portion of the costly staff work in this section.)

The details in this section might pose a practical challenge when the regulations are implemented. DTSC's framework will be most practical if it allows DTSC to tackle a variety of types of problems in a single listing cycle. For example, in one listing cycle, DTSC should be able to list a group of products that includes products that pose children's health hazards (e.g., lead in children's toys), products that contain a pollutant that will be scientifically challenging to replace (e.g., flame retardants), products that create pollution that is costly for California governments (e.g., copper in brake pads), and products with environmental consequences that are infrequent but severe (e.g., chemical toilet additives that cause groundwater pollution).

The specific comments below explain the concerns I have with the wording of this section.

Potential Chemical Adverse Impacts from Chemicals of Concern §69503.2 (a) (1) (A) – Comments above on this text, which also appears in the additions to the Chemical of Concern List section (§69502.2 (b) (1) (A) also apply here.

Priority Products Prioritization - Potential Exposures - §69503.2 (a) (1) (B) – When I compared this list of use patterns and exposure pathways to the list of products in Attachment B, I found that the list does not characterize the nature and range of human health and environmental problems associated with my experience of polluting chemicals in consumer products. The list particularly disfavors non-human environmental pollution problems.

For example, the list includes an item that I believe is intended to capture pollutants used in manners that make them likely to be washed away in urban stormwater runoff. This only applies to formulated products. From the scientific literature, it can be seen that sources of urban stormwater runoff pollution are from both assembled and formulated products. Common urban runoff water pollution sources are construction products (e.g., roofing, paint, asphalt), air deposition (e.g., brake pads), product wear (e.g., tires). If DTSC finds that creating a criterion to address this pathway is necessary, the urban stormwater runoff exposure pathway would better be captured through a phrase like "Used, dispersed, or discharged outdoors or indoors in a manner that creates a pathway for the chemical of concern [or its degradates, metabolites, or reaction products] to reach a storm drain, sewer drain, or surface or ground water."

Replacing the proposed language with a straightforward, clear, narrative standard would be more scientifically robust. For example:

> "(B) Potential Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts."

I am not sure it is possible to develop a practical and scientifically robust list of priority use patterns and exposure pathways. Should DTSC feel that inclusion of specific use patterns or exposure pathways in the regulations is essential, I recommend that DTSC review the literature to identify a broad range of examples of known problem products (see Attachment B), obtain assistance from scientists at other state and federal agencies, and consult with the Green Ribbon Science Panel.

If DTSC elects to revise the existing text, the following comments are applicable.

<u>Cumulative exposures §69503.2 (a) (1) (B) 3</u> – The criteria for cumulative exposures should not be limited to indoors and to humans and only to residential settings. Outdoor human and wildlife cumulative pollutant exposures and non-residential settings (gym, hotel, hospital, stores, etc.) should be equally important. To address this, delete the word "household" the two times it appears in §69503.2 (a) (1) (B) 3.

<u>Types of uses that could result in exposures §69503.2 (a) (1) (B) 4.</u> – The list of considerations in 4. b. essentially covers all human exposures while omitting all non-human environmental exposures. The listing of product uses (the "factors" list in i., ii., and iii.) does not add anything to the prioritization process other than to exclude non-human exposures. The section should be revised to provide equal consideration of product uses for both humans and the environment.

<u>Environmental consideration in §69503.2 (a) (1) (B) 4. e</u>. – This list does not capture the essential characteristics of non-human environmental problems

today, which often do not involve accumulation and persistence, but rather toxicity or sublethal effects like endocrine disruption. On a practical basis, environmental accumulation is very difficult to measure (variability in environmental data makes it difficult to show trends without very large and long-term data sets). Spreading across multiple environmental media should not necessarily be prioritized because problems often occur in only one medium (e.g., water).

Other regulatory programs §69503.2 (a) (3) – AB 1879's provisions to avoid regulatory duplication do not provide that other regulatory requirements related to a chemical be a consideration in prioritization. Most chemical-related requirements that are not tied to a specific product are pollution abatement requirements. Pollution abatement is often more expensive than product reformulation and often externalizes the cost of managing the pollution. Since DTSC seeks to avoid regulatory overlap related to products—and does not seek to preclude prioritization of products that create pollution that must currently be managed through costly pollutant abatement programs, it should modify §69503.2 (a) (3) to delete mention of the regulation of chemical of concern.

Additional Prioritization Criteria – Two key criteria are missing from this section:

- Externalized costs (e.g., costs for disposal, costs for cleanup of dispersed pollutants, cost of other regulatory programs like water pollution control.) DTSC should consider prioritizing externalized costs that are borne by California state and local government agencies and individuals that do not use the polluting product.
- Products associated with violations of environmental laws (e.g., Clean Water Act, Clean Air Act, California hazardous waste disposal laws).

Key Prioritization Criteria – Use patterns for assembled and formulated products §69503.2 (b) (4) and (5) – Why were the proposed criteria in (4) and (5) selected? These combinations of use patterns plus exposure pathways would not prioritize the kinds of products that have previously been linked to harmful pollution (see Attachment B). For example, the following products recently addressed in legislation would not have been prioritized under these criteria: vehicle brake pads (copper emissions are dispersed through the air, not applied to outdoor surfaces), BPA (seeps into liquids or foods, exposure is not through dermal or inhalation exposures), mercury thermometers (mercury is contained until the product breaks), lead in wheel weights (not applied to hard surfaces).

There is insufficient distinction between assembled and formulated products to develop separate criteria.

Summary - Recommended revisions to §69503.2 (a) and (b)

(a) (1) Potential Adverse Impacts and Exposures. The Department shall consider the potential adverse public health and environmental impacts posed by the

Chemical(s) of Concern in a product due to potential exposures during the manufacture, useful life, and end-of-life disposal or management of the product. The evaluation of the potential adverse impacts and exposures shall consider both of the following:

(A) Potential Chemicals Adverse Impacts from Chemicals of Concern.

1. The potential for the Chemical(s) of Concern in a product to cause adverse public health and/or environmental impacts, considering:
   a. The Chemical(s) of Concern's hazard trait(s) and environmental and toxicological endpoint(s)~~, and mode(s) of action~~;
   b. The Chemical(s) of Concern's aggregate effects;
   c. The Chemical(s) of Concern's cumulative effects with other Chemicals of Concern ~~with similar modes of action~~;
   d. The Chemical(s) of Concern's physicochemical properties;
   e. The Chemical(s) of Concern's environmental fate properties; and
   f. The populations and/or *environment* ~~environmental receptors~~ that are potentially adversely impacted.
2. The Department shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for all of the following:
   a. Children, pregnant women, and other sensitive subpopulations;
   b. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and
   c. Widespread *or severe* adverse public health and/or environmental impacts.

(B) Potential Exposures.

OPTION 1 – PREFERRED APPROACH – Replace entire section with:

(B) Potential Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts.

OPTION 2 – ALTERNATIVE (LESS PREFERRED) APPROACH – the following modifications should be considered in combination with further revisions that should be developed in consultation with the GRSP:

(B) Potential Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts, considering:

1. Market presence information for the product;
2. Relevant reliable information that indicates the possibility for public or environmental exposures to the Chemical(s) of Concern in the product, and reliable information demonstrating the occurrence, or potential occurrence, of exposures to the Chemical(s) of Concern in the product;
3. Information concerning the ~~household~~ presence of the product, and other products containing the same Chemical(s) of Concern that is the basis for the Priority Product listing, including the number of such of products,

how common their ~~household~~ presence is, the frequency of use, and the concentration of the chemical in those products; and

4. The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the useful life of the product, considering the following factors:

a. Manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices.

b. The types of uses that could result in public *or environmental* exposure to the Chemical(s) of Concern in the product~~, considering the following factors:~~

~~i. Household and recreational use;~~

~~ii. Sensitive subpopulation potential use or exposure at locations frequented by members of sensitive subpopulations; and~~

~~iii. Workers, customers, clients and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other location.~~

c. Frequency and duration of exposure for each use scenario and end-of-life scenario.

d. Containment of the Chemical(s) of Concern within the product, and engineering and administrative controls.

e. Potential for release into, migration from, or distribution *in the environment* ~~across environmental media, and potential for accumulation and persistence in biological and/or environmental components or systems~~ of Chemical(s) of Concern or its/their degradation products, *reaction products and metabolites*, considering the environmental fate properties of the Chemical(s) of Concern and its/their degradation products*, reaction products, and metabolites*.

(2) Availability of Information. The Department shall consider the availability of reliable information to substantiate the potential adverse impacts and exposures.

(3) Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs, and any applicable international trade agreements ratified by the United States Senate, under which the product ~~or the Chemical(s) of Concern in the product~~ is regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a potential basis for the product being listed as a Priority Product *and the costs and environmental impacts of the implementation of these other regulatory requirements*.

(4) Externalized costs, particularly costs to California state and local government agencies.

(5) Association of the chemical of concern in the product with incidents of non-compliance with local, state, or Federal environmental laws and regulations

(b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize products, the Department shall give priority to products meeting one or more of the following criteria:

(1) The Chemical(s) of Concern in the product have a significant potential to cause adverse public health and environmental impacts;

(2) The product is widely distributed in commerce, and widely used by consumers;

(3) There is a significant potential for public and environmental exposures to the Chemical(s) of Concern in the product in quantities that can result in adverse public health or environmental impacts;

~~(4) For assembled products, the product contains one or more Chemical(s) of Concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts; and/or~~

~~(5) For formulated products, the product is intended to be:~~

~~(A) Applied directly to the body;~~

~~(B) Dispersed as an aerosol or a vapor: or~~

~~(C) Applied to hard surfaces with the likelihood of runoff or volatilization.~~

<u>Process for Consideration of the Prioritization Factors §69503.2 (c)</u> – I suggest that DTSC add consultation with other state agencies, including but not limited to other Cal-EPA agencies, DPH, Cal-Recycle, and Fish and Game.

<u>De Minimis Exemption §69503.4 (a)</u> – The proposed de minimis exemption approach is practical. The default levels provide appropriate guidance for manufacturers managing their supply chains. The ability to adjust the de minimis levels is necessary to address chemicals that are toxic at minute concentrations, like dioxins and PCBs and to provide for use of recycled materials in products at levels that are not environmentally harmful (e.g., higher levels of trace copper in recycled metals used to formulate brake pads).

<u>De Minimis Exemption - distinction between assembled and formulated products §69503.4 (b)</u> – Some products are a combination of "assembled" and "formulated" products. For example, vehicle brake pads are comprised of a formulated friction material that is assembled onto a backing plate. During use, the friction material wears off and is dispersed into the environment. Under the definitions in the code, brake pads would be "assembled products" and thus brake friction material pollutant concentrations would be numerically diluted by the weight of the backing plate. Similarly, children's toys can be coated with a pollutant-containing paint (e.g., the lead-containing paint on Thomas the Toy Train). Children's exposures are associated with the formulated paint, but the product would be classified as an "assembled product" and the paint's lead concentration would be averaged out with the materials inside the toy. Two possible options for DTSC to deal with the convergence of formulated and assembled products:

(1) Revise the definitions of assembled and formulated products to provide that when a formulated product is used in the creation of an assembled product and the formulated product's role in the assembled product creates the potential for human and/or environmental exposures to the formulated product, that portion of the assembled product is individually treated as a formulated product (e.g., paint on the toy, friction material on the brake pad).

(2) Revise the de minimis definition (and other places like chemical of concern identification and product prioritization where the distinction between formulated and assembled products is made) to indicate that the formulated product approach should be used when there is potential for human or environmental exposures to the formulated portion of an assembled product.

Article 5. Alternatives Assessments

Alternatives Assessment: First Stage §69505.3 – The design of this section will appropriately require assessments to include non-chemical alternatives like modifying product or using entirely different material type (e.g., wood instead of plastic).

Interim qualification requirements for assessors prior to January 1, 2015 (first set of AAs) §69505.1(d) – DTSC should establish minimum qualifications for alternatives assessors prior to the certification program. This could easily be accomplished by reference to the education and experience requirements listed in Article 8 (e.g., Section 69508 (a) (1) and (2) and "expertise in specific fields necessary to the performance of AAs."

First Stage AAs – Step 3 §69505.3 (a) (3) – DTSC should require the First Phase AA to identify the human and environmental exposure pathways throughout the life cycle of the product. This is particularly important for the product lifetime portion of the life cycle. This could be accomplished by requiring the AA to include simple conceptual models that check for the potential environmental importance of both large and small cross-media pollutant transfers. This approach can ensure identification of appropriate environmental endpoints for each AA. Please see the attached example of the types of conceptual models that U.S. EPA uses in its pesticide risk assessments, which provide a simple and clear means of communicating the exposure pathways that are expected to be environmentally relevant.

In my experience, most manufacturers do not correctly identify all exposure pathways to their products. I have seen particularly compelling examples of this in the brake pad and pesticides industries, where environmental managers did not identify the linkage between their product's use patterns and urban stormwater runoff and/or municipal wastewater treatment plants. Often, both manufacturers and traditional alternatives assessors commonly assume that their assessments

need only focus on environmental segments where "most" of a pollutant goes. These oversights are some of the primary reasons for regrettable substitutions. A key part of DTSC's review of the Preliminary AA will be to determine whether all potentially important exposure pathways are addressed in the AA. Capturing these oversights at the preliminary AA phase will help manufacturers and DTSC to ensure that the AA process achieves its desired outcome.

To support the screening process, the following information is necessary in the preliminary AA:

- Physiochemical properties and Environmental fate properties
- Product use pattern information, including reasonably anticipated misuse and common accidents
- Common methods of product disposal (whether or not these are theoretically legal)
- Chemical quantity information

This list includes but expands on DTSC's exposure pathways discussion in §69505.4(b) (3), which is procedurally too late in the process as proposed and which omits information that will be critical for preparation of the AA. (See related comments below)

The conceptual model identifying the exposure pathways selected for the AA and all of the above information should be required elements of an AA report and specifically listed in §69505.5.

<u>Second Stage AAs §69505.4</u> – This section has some elements that need to occur in the First stage:

- <u>In (a) (2) (A), items #4-Physiochemical properties and #5 – Environmental fate properties</u> do not fit on this list. These are data that may be used in modeling to examine environmental hazards and impacts. These data should be collected during the initial screening process (First Stage AAs) because these data are commonly used as indicators of the potential hazards of chemicals. Rather than deleting the reference to these two types of chemical properties, I recommend specifically referencing them in Step 3 of the First Stage AA - 69505.3 (b) (3) (see above).
- <u>(a) (3) Exposure pathways identification</u> should be moved to the First Phase AA and recast to be more scientifically robust. Exposure pathways must be initiated in the first phase of the AA to determine which hazard traits and environmental impacts to consider in the AA.
- <u>Exposure potential factors</u> – Instead of the smorgasbord approach here, I recommend use of a simple conceptual model as recommended above. The conceptual model should not only address the listed exposures, but also all other pathways and exposures that have potential adverse impacts.

<u>Peer Review of AAs</u> – Support the idea of establishing provisions that provide DTSC with the ability to obtain formal peer review of AAs. This could help DTSC during its

review of preliminary and final AAs as well as during subsequent audits. Reviews could be conducted via a U.C. peer review contract and/or by a set of advisors, perhaps a subcommittee of the GRSP. A peer review process would help to ensure scientific basis for DTSC decisions is credible.

Article 6. Regulatory Responses

In my professional experience, a process for public scoping comments on AAs and public input prior to DTSC's regulatory decisions will greatly improve the quality of AAs and the acceptance of DTSC's proposed regulatory decisions. Even though it might add a month or two, public input at these points will reduce the overall timeframe of the process by identifying scientific and public policy issues prior to the AA or decision instead of after all scientific work is done and DTSC at the point of a proposed decision.

A good example of the value of public input in a similar process is the U.S. EPA pesticide Re-Registration and Registration Review processes (see http://www.epa.gov/oppsrrd1/registration_review/public_involvement.htm). In this process, public involvement has identified gaps in EPA's scientific analyses at the work plan stage. The public has provided scientific information (like product use information) to help with assessments. It has also changed decisions because public input has given EPA has a better understanding of the external factors (particularly externalized costs) that EPA needs to weigh in its decisions.

- The initial comment period could be in parallel with the preliminary AA preparation; DTSC could consider these comments when reviewing preliminary AAs.
- DTSC should solicit input on regulatory responses upon receipt of final AAs and weigh these comments when developing its proposed decision on regulatory response.
- Based on my experience with government agencies reviewing and commenting on similar scientific documents (pesticide risk assessments and risk management decisions), comment periods should be a minimum of 45 days to ensure meaningful feedback.
- DTSC should include in its regulations a plan to post anticipated schedules for public comment opportunities and to update these schedules quarterly. These schedules allow stakeholders to plan for upcoming reviews. Without "crystal ball" schedules, stakeholder review periods need to be longer to provide time for commenters to adjust their work schedules such that they can provide meaningful input and useful (i.e., specific) scientific information.

No additional regulatory response §69506.2 (a) – "Mode of action" should be deleted from this section for reasons stated above. Where DTSC desires to address known cumulative effects, it should reference "cumulative adverse effects" instead.

This generic phrase accounts for the many biological mechanisms for chemicals to have joint adverse effects on organisms and ecosystems.

Product information for consumers §69506.3 (b)(2) – DTSC's requirements should include requirements for purchases that are not made in person, e.g., over the Internet or through a vendor. Possible wording:

> "(B) Posting the information in a prominent place at the point of retail display*, or on the webpage or catalog page where products are viewed and selected by consumers.* "

End of Life Management Requirements §69506.4 – Because product take-back programs without performance standards have generally been ineffective, DTSC needs to be able to set collection rates for product stewardship programs. DTSC should also be able to require that manufacturers establish the acceptability of their programs through metrics like convenience and public education success as measured through unbiased consumer surveys.

Other Regulatory Responses §69506.6 – DTSC should consider two additional regulatory options that have proven useful for pesticide regulators:

- Restricting use not only of a chemical of concern, but also of specific products (e.g., allow use by hospitals, but not by individuals).
- Providing for limitations on product types (e.g., concentrate vs. diluted products).

Article 7. Dispute Resolution Process

Processes like this have proven problematic in other regulatory programs (e.g., implementation of EPA's pesticides regulatory decisions can be delayed for years by a similar process. DTSC would likely have problems with this process for two reasons:

(1) Putting decisions on hold during disputes incentivizes disputing.
(2) The lack of transparency and the inequality of the process (manufacturers have rights but other affected parties do not) could negatively affect the public's confidence in the entire regulatory program.

Article 8. Accreditation Bodies and Certified Assessors

General – I support the proposed Assessor certification requirement. It will ensure reasonable quality AAs and will provide a framework for training a cadre of professionals and development of more robust methodologies

Structure of Accreditation program – I concur with comments made at the GRSP meeting that DTSC needs better control over accrediting bodies and the certification exam. I support the recommendation that there be an annual conference for continuing education and development of the profession of assessor.

Assessor consequences for poor AA report quality – Suggest that DTSC consider establishing some type of negative consequences for assessors that author particularly poor quality AA reports (e.g., a negative assessor list). Since DTSC will not be able to read every AA in detail, DTSC and the accreditation program should both have complaint follow-up processes that verify public or private complaints about AA quality.

Qualifications for Accreditation Bodies §69508.1 (a)(5) – This section should be expanded to include qualifications for environmental hazards, e.g. environmental toxicology, environmental chemistry, and environmental fate and transport modeling.

ATTACHMENT B: Product Examples

My professional work has touched on numerous products that have been associated with adverse effects on human health or the environment. In reviewing the regulations, I considered whether the process would be capable of prioritizing these problem products, most of which have been addressed by California state or local governments or by other U.S. state or Federal regulatory agencies in the last 15 years. Since most of my experience relates to water pollution, this list of examples may help DTSC with in evaluating the capacity of the regulation to address water pollution problems.

- Copper and lead in vehicle brake pads (copper may occur as the metal, as brass, or as a copper compound like copper sulfide), which is emitted to the air, falls on the ground, and becomes a source of water pollution in urban stormwater runoff
- Lead in vehicle wheel weights, which is a source of lead in urban stormwater runoff as well as a source of human exposure during vehicle maintenance
- Lead and arsenic in reflective beads in road paint, which are sources of lead and arsenic in urban stormwater runoff
- Lead in gasoline
- Lead in outdoor paints and roofing materials
- PCBs in paint (non-Aroclor PCBs [PCB-11] are formed during manufacturing of certain yellow and green pigments), which move into both air and stormwater runoff in urban areas
- PAHs in coal tar based pavement sealants, which slowly wear off and wash PAHs into urban stormwater runoff
- Groundwater polluting chemical toilet additives, which pollute groundwater when toilets are emptied at facilities served by septic systems (pollution can occur from the release of the chemical itself or because the chemical interferes with the normal operation of the septic system, causing untreated sewage to pollute groundwater)
- Mercury-containing products, particularly toys, thermostats, thermometers and other medical devices, and switches, which are water pollution problems when devices break as well as human health concerns
- Cadmium-containing jewelry
- Phosphates in dishwasher detergents
- Lead and cadmium in paint on the outside of products
- Lead, cadmium, and other metals in ink on packaging
- Lead in plastic items, such as window blinds, holiday trimmings, and electrical cords
- N-Hexane in brake cleaners
- Molybdenum in cooling water system additives, which are discharged with cooling water "blowdown" to municipal wastewater treatment plants, where they can cause municipal wastewater biosolids molybdenum concentrations

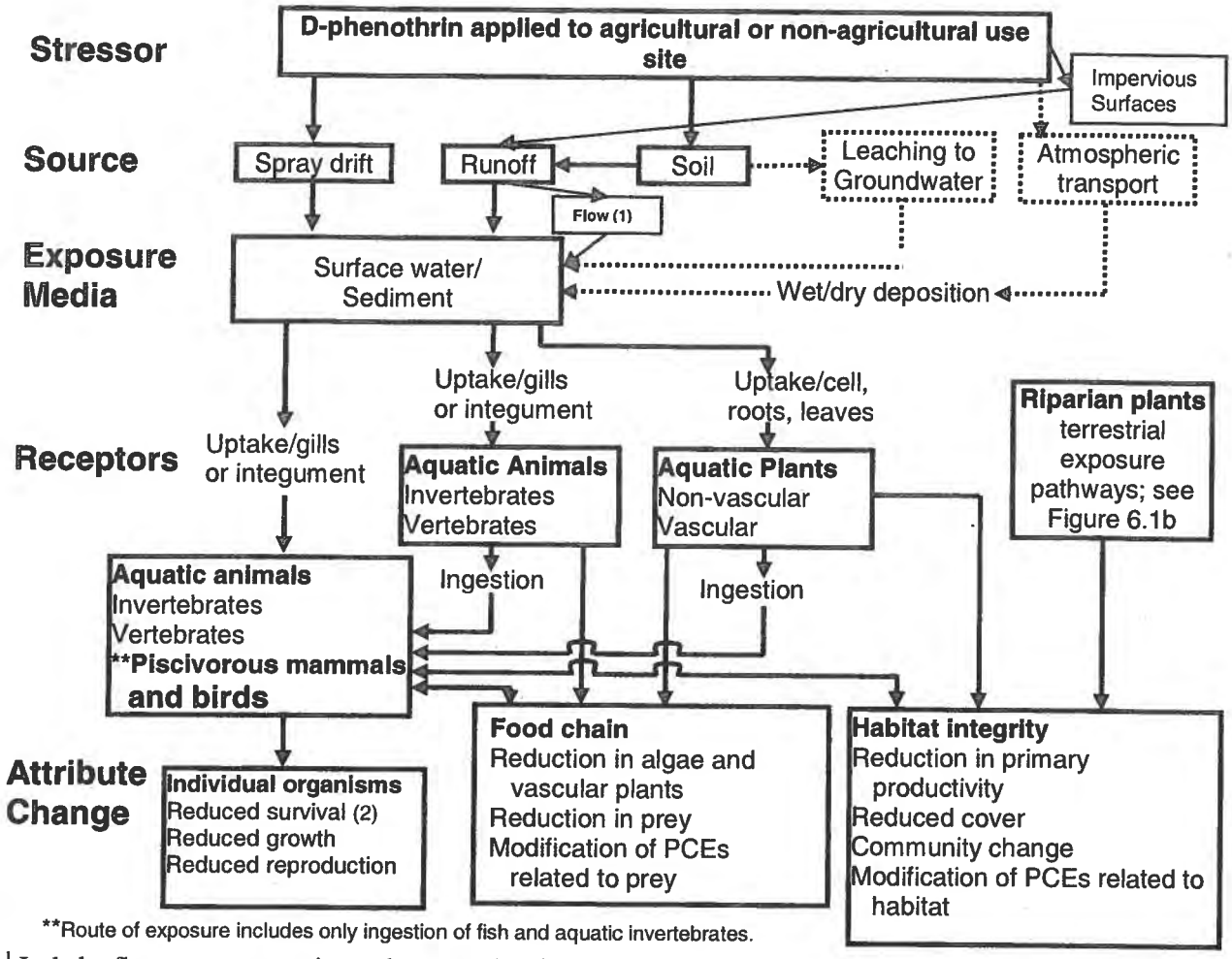
to exceed concentrations allowable for biosolids re-use as fertilizer for non-food crops

- Dioxins in vehicle tires, a source of dioxins in urban runoff—these were from the use of dioxins-contaminated chloranil used in tire manufacturing
- Nonylphenol ethoxylates in detergents—by the time the wastewater passes through a municipal wastewater treatment plant, these degrade to nonylphenol, a water pollutant
- Paradichlorobenzene in urinal "mints," which caused toxic air pollutant releases at municipal wastewater treatment plants
- Lindane in head lice and scabies treatments (these are not pesticide products), which is discharged to municipal wastewater treatment plants when the treatment is washed off
- Perfluorinated chemicals in stain repellent and non-stick coatings
- Brominated flame retardants (PBDEs and alternatives)
- Triclosan in soaps and other products discharged to municipal wastewater treatment plants (most of which are not registered pesticides)
- Lead shot, which has harmed endangered California condors (this is solely an example of a type of adverse effects on wildlife, since I understand that ammunition was exempted by AB 1879)
- Dioxins in cotton clothing (this appears to be from overseas use of dioxins-contaminated pentachlorophenol to treat raw cotton), which is discharged to municipal wastewater treatment plants when clothes are washed
- Silver in photographic film, which is extracted when film is developed, may be discharged to sewer systems, where some of it passes through municipal wastewater treatment plants and into aquatic ecosystems

ATTACHMENT C: Conceptual Model Examples

The attached conceptual models are typical of those used by U.S. EPA in its pesticide environmental risk assessments. These are from the work plan for the Registration Review environmental risk assessment for Sumithrin (d-Phenothrin) (U.S. EPA Environmental Fate and Effects Division (2011) "Registration Review: Preliminary Problem Formulation for Environmental Fate and Ecological Risk , Endangered Species, and Drinking Water Assessments for d-Phenothrin." U.S. EPA docket number EPA-HQ-OPP-2011_0539.)

spray drift.



[1] Includes flow across vegetation and vegetated drainage systems (*e.g.*, swales) and flow across

Figure 1. Conceptual model for d-phenothrin exposure to aquatic organisms. Dashed lines indicate route of exposure considered of lower importance for d-phenothrin.

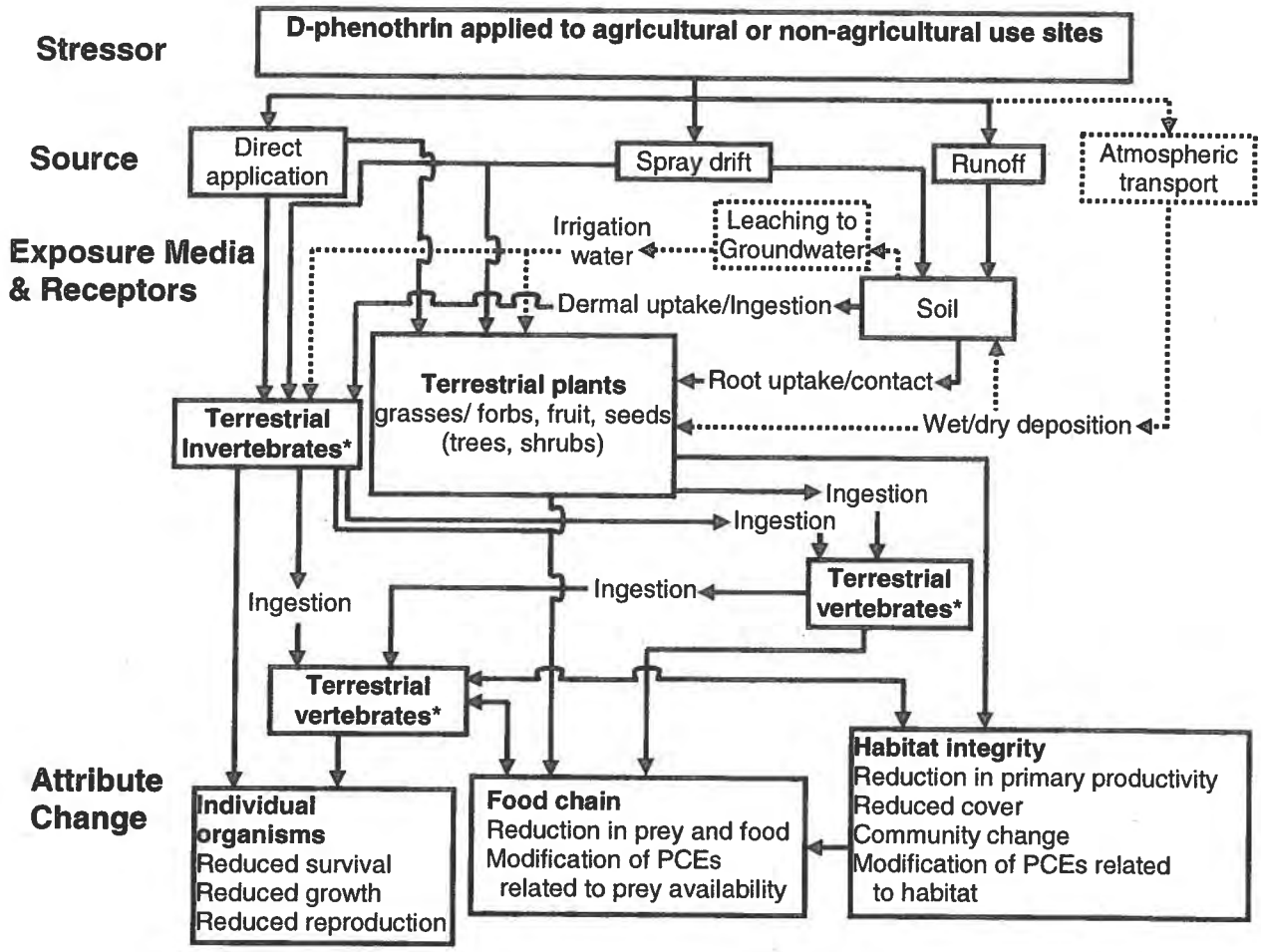
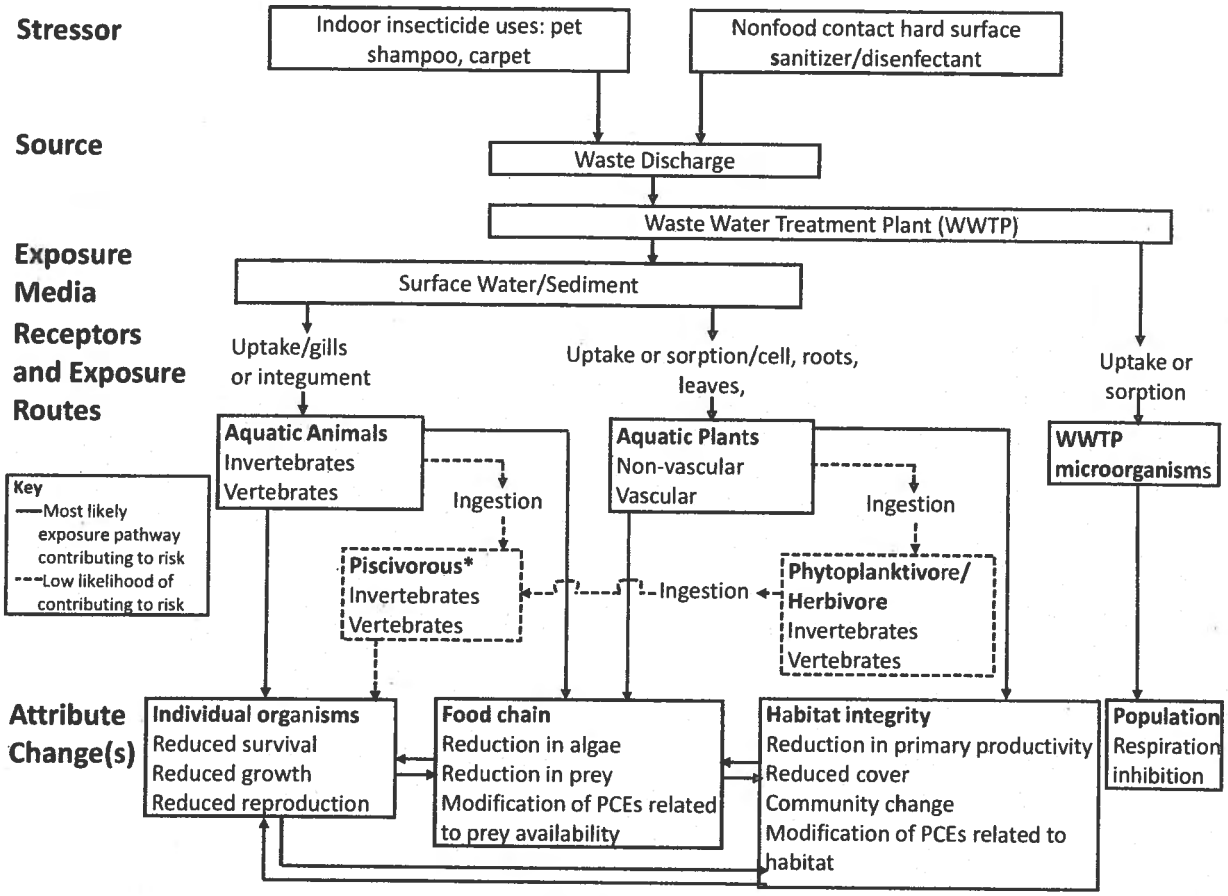


Figure 2. Conceptual model for d-phenothrin exposure to terrestrial organisms. Dashed lines indicate route of exposure considered of lower importance for d-phenothrin.

The conceptual model for potential risks of d-phenothrin to terrestrial and aquatic organisms as a result of treatments that could end up "down-the-drain" (e.g., carpet powder, pet shampoo and spot-on, human clothing/bedding/furniture) is depicted in **Figure 3**. The stressor is the chemical of concern, d-phenothrin, and potentially interactions caused by applications with the synergist PBO. The organisms that could be expected to be affected are terrestrial plants, aquatic plants and aquatic animals. It is noted that the potential transport pathway, the exposure media and the exposure point or route, receptor, and attribute changes for plant and aquatic organisms are similar to the conceptual model for agricultural applications **Fig. 6.1a**.



*As used here this term refers to animals (terrestrial or aquatic) that eat not just fish but any aquatic animal (*e.g.*, amphibians, mollusks, crustaceans, etc.)

Figure 3. Conceptual model for potential risks of d-phenothrin to aquatic organisms for various indoor uses of the chemical that could potentially end up in the "drain."

7. Analysis Plan

In order to address the risk hypothesis, the potential for adverse effects on the environment will be estimated. The use, environmental fate, and ecological effects of d-phenothrin will be characterized and integrated to assess the risks. This will be accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA 2004), the likelihood of effects to individual organisms from particular uses of d-phenothrin may be estimated using the probit dose-response slope and either the level of concern (discussed below) or the actual calculated risk quotient value. For down-the-drain risk estimates, an approach that estimates the number of days a concentration-of-concern (COC) is exceeded, also referred to as a probabilistic dilution model (PDM) approach may be used to assess risk to aquatic organisms.

(IC)55- Sierra Club California

December 29, 2011

Deborah O. Raphael
Director, Dept. of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Safer Consumer Products Draft Regulations

Dear Director Raphael:

Sierra Club California appreciates the time and consideration that DTSC has put into writing the Safer Consumer Products draft regulations. We support the innovation and the practical, meaningful and legally defensible approach of the new draft. We also believe the proposed draft can be made stronger and more effective and offer the following suggestions for improvements.

General Comments:

1. Sierra Club California supports including within the regulation a list of Chemicals of Concern (COC). This sends a strong message to the market that DTSC expects stewardship for hazardous chemicals. It also prevents regrettable substitutions if the substitute chemical is also on the list. However, for the list of COCs to be effective, it should be comprehensive enough to include chemicals hazardous to both humans and environment. The current list is not as comprehensive as possible or as needed for protection of California ecosystems.
2. By designing the regulation in a manner that guarantees substantial disincentives for submitting poor quality Alternative Assessments (AAs), including the possibility of fines and products being taken off the shelves, DTSC helps ensure the quality of information received from manufactures and other responsible parties. Implementation of the proposed Assessor accreditation programs to certify environmental professionals that perform AAs will enhance the likelihood of acceptable AAs being submitted. Qualifications for both Assessors and Accreditation Bodies should be expanded to include qualification related to wildlife and ecosystems.

3. All parts of the regulations should have equal focus on protection for humans and the environment. Current language of the draft regulations does not capture environmental endpoints such as wildlife, wetlands, and watersheds or larger ecosystems. To ensure these areas are equally addressed, DTSC should (1) bring into its regulatory team other agencies such as the Water Boards, Fish & Game, and the Air Resources Board and (2) substantially revise the sections for product prioritization, chemicals of concern list additions, and the definition of "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical."
4. Implementation of the regulations should be robust to gain public support, protect environmental and public health, and to meet expectations established with passage of the enabling legislation. The current plan to address only 2 to 5 priority products fails to meet any standard for meaningful implementation. We urge DTSC to revisit its plan for implementation to help avoid the need for additional legislative action.
5. With the current proposed timeframe, it will be years before safer products are on the market. DTSC has indicated that lack of funding and resources are an issue. Sierra Club California urges DTSC to include in its regulatory package information regarding agency funding required to ensure that the regulations' implementation follows the proposed timeframe and is not further delayed.
6. The implementation process should be transparent and there should be more opportunities for the public to provide comments before key decisions are made. We believe that public input would improve the quality and effectiveness of the regulatory program. We think that input can be included in the process without significantly extending implementation timelines. We think that the initial comment period could be in parallel with the preliminary AA preparation; DTSC could consider these comments when reviewing preliminary AAs. We don't think that the scoping comments can be obtained in parallel with the priority product selection public comment period, because DTSC might select different products than it initially proposes. DTSC should solicit input on regulatory responses upon receipt of final AAs and weigh these comments when developing its proposed decision on regulatory response. Comment periods should be 45 days minimum.

Specific Amendments to Articles in Draft Regulations:

We recommend the following amendments to improve the proposed regulation.

Article 1. General - Definitions
Definition of "Adverse environmental impacts" – Please add "Adverse waste and end-of-life impacts" §69501.2 (7).

Definition of chemical – Please include degradates, metabolites, and products of environmental reactions. Need to capture all forms of chemicals in families (e.g., all PCBs, metallic mercury and all mercury compounds).

Definition of Economic impacts – Please revise this definition to include both public and private externalized costs.

Definition of "Environment" – Please expand this definition to include all elements of the human and natural environment, including urban environments, pets, and ecological communities, populations and ecosystems.

Definition of "reliable information demonstrating the occurrence or potential occurrence of exposures to a chemical" – Please consider either removing this language or make significant revisions in consultation with the Green Ribbon Science Panel. It creates an unreasonable burden of proof for new chemicals that are often not well characterized, is too narrow to capture many types of impacts from chemicals, and is too limiting in the types of scientific data (particularly data related to non-residential human and environmental exposures) that would be allowable for DTSC to use to justify its decisions.

Article 2. Chemicals of Concern Identification
The list should include emerging pollutants like brominated flame retardants, endocrine disruptors, and nanoparticles.

Listing decisions should be based on chemical hazards. Exposure data should not be necessary.

Article 3. Prioritization Processes
The specificity in 69503.2 (a) (1) (B) "Potential Exposures" would effectively prioritize residential human exposures over any other human or all environmental exposures. We expect that this is not DTSC's intent. The best way to address this would be to remove the list of "considerations," i.e., to end subsection (B) after the words "…adverse impacts."

If DTSC elects to pursue revisions to this section, we urge that it work closely with the Department of Fish and Game, the Water Boards, and the Air Resources Board in developing an alternative proposal, which should be fully vetted by the Green Ribbon Science Panel.

The key prioritization criteria (subsection (b)) should not include proposed sections (4) and (5), which are confusing and unclear (is a lead-painted toy "assembled or formulated?) and which omit all non-human exposures and even exposure pathways that are critical for humans (e.g., mouthing toys, food consumption).

Article 5. Alternatives Assessments
For AAs prepared prior to January 1, 2015, DTSC should establish minimum qualifications for alternatives assessors prior to the certification program such as education and expertise.

Article 6. Regulatory Responses

DTSC's requirements for product information for consumers should include requirements for purchases that are not made in person, e.g., over the Internet or through a vendor.

When establishing End of Life Management Requirements, DTSC needs to be able to set collection rates to ensure product stewardship programs are effective.

Article 7. Dispute Resolution Process
Parties other than manufacturers should have the same dispute resolution rights and the process should be transparent. DTSC should not allow manufacturers to defer implementation of its regulatory decisions during disputes. This would create an incentive for every manufacturer to dispute DTSC's decisions, thereby delaying necessary human health and environmental protections.

Thank you for the opportunity to submit our comments.

Sincerely,

Annie Pham
Sierra Club California

COALITION FOR PRACTICAL REGULATION

"Cities Working on Practical Solutions"

(IC)56- Coalition For Practical Regulation VIA EMAIL

29 December 2011

Debbie Raphael, Director
Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
E-mail: gcregs@dtsc.ca.gov

ARCADIA
ARTESIA
BALDWIN PARK
BELL GARDENS
BELLFLOWER
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CERRITOS
COMMERCE
COVINA
DIAMOND BAR
DOWNEY
GARDENA
HAWAIIAN GARDENS
INDUSTRY
IRWINDALE
LA CAÑADA FLINTRIDGE
LA MIRADA
LAKEWOOD
LAWNDALE
LYNWOOD
MONTEREY PARK
NORWALK
PALOS VERDES ESTATES
PARAMOUNT
PICO RIVERA
POMONA
ROSEMEAD
SANTA FE SPRINGS
SAN GABRIEL
SIERRA MADRE
SIGNAL HILL
SOUTH EL MONTE
SOUTH GATE
SOUTH PASADENA
VERNON
WALNUT
WEST COVINA
WHITTIER

Subject: **Comments on Safer Consumer Products Informal Draft Regulations**

Dear Ms. Raphael and staff:

I am writing on behalf of the Coalition for Practical Regulation (CPR), an *ad hoc* group of small and medium-sized cities in Los Angeles County that have come together to address water quality. We appreciate the opportunity to review the Safer Consumer Products Informal Draft Regulations. Product safety and product stewardship are important to our member cities, since the vast number of consumer products on the market contain numerous chemicals – many of which can have adverse impacts to the health of our waters. Thank you for the opportunity to provide these comments.

CPR thanks the Department for considering the impact of harmful chemicals on the waterbodies and waterways of California. We note that numerous beneficial changes have been made to the draft regulations since the November 2010 draft. CPR's member cities face strict regulations dictating water quality – the federal Clean Water Act and the State Water Code. DTSC's Regulation for Safer Consumer Products could provide a vital tool to assist municipalities and others in their efforts to comply with water quality regulations.

Water quality can basically be improved in two ways: source control or treatment control. Treatment control involves treating water that has already been impacted by pollutants, including toxic substances. It is extremely costly – prohibitively so – and does not necessarily work well. Some chemicals of concern for water quality are present either in a dissolved form or as extremely small particles; so small, that even state-of-the art treatment technologies fail to remove them. Downstream efforts to filter pollutants such as copper, for example, would ultimately be futile, and the attempt would cost cities untold amounts of money. Cash-strapped municipalities do not have money to waste on infeasible treatment efforts. Therefore, we are strongly in favor of efforts that promote source control.

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Source control involves preventing a chemical of concern from entering the waters in the first place. It generally requires a significant shift in behavior – such as reformulation of product composition by manufacturers – but is the only way to truly prevent hazardous chemicals from impacting our waters. In the case of copper, the recent passage of SB 346, requiring the gradual phasing out of copper content in brake pads, will begin to address the deposition of copper that ends up in our waters and adversely impacts aquatic organisms. It is CPR's hope that the new DTSC regulations will similarly begin to affect change in toxic product chemicals. Controlling such product chemicals at the source is the best way to ensure they do not become pollutants.

CPR supports DTSC's work to create a regulatory method for keeping consumer product-originated chemicals out of our waters. However, the definitions related to water quality effects should be broadened to address the range of water quality impacts. We support the emphasis given to definitions in comment letters provided by the California Stormwater Quality Association (CASQA) and Bay Area Clean Water Agencies (BACWA).

CPR and its member cities urge DTSC to reach out to and consult with the State and Regional Water Boards and California Department of Fish & Game. DTSC could take advantage of the expertise of these other agencies to fully realize the water protection potential of its regulations. Further, gaining the support of the Water Boards, the California Department of Fish & Game, and other agencies could serve to build a strong framework within which the new DTSC regulations would be implemented. In addition, CPR strongly supports DTSC's use of a petition process to evaluate potential chemicals of concern. We also agree that "high priority shall be given to petitions by federal and other California state regulatory programs," as noted in the Informal Draft Regulations[1].

CPR appreciates DTSC's efforts to implement the Green Chemistry Initiative and control chemicals of concern. DTSC has worked diligently to move the process forward and has responsibly incorporated stakeholder input to improve the draft regulations. We appreciate the opportunity to provide these comments and look forward to the next iteration of DTSC's regulations.

Sincerely,

LARRY FORESTER
Mayor, City of Signal Hill
On Behalf of the Coalition for Practical Regulation

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[1] Safer Consumer Products Informal Draft Regulations, § 69504.1. Technical Review of Petitions

(IC)57- California healthy nail salon Collaborative

December 29, 2011

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Safer Consumer Products Regulations

Dear Director Debbie Raphael and Department of Toxic Substances Control,

The California Healthy Nail Salon Collaborative is writing to comment on DTSC's informal draft regulations to implement a Safer Consumer Products program in response to AB 1879.

The California Healthy Nail Salon Collaborative (Collaborative) was formed in 2005 out of a growing concern for the health, safety and rights of nail salon and cosmetology workers, owners, and students. As a statewide convener, the Collaborative provides critical leadership to raise the profile of this issue, to connect concerned groups across California, and to advocate for health-protective policies and greater regulatory protection for salon workers. The Collaborative has over 30 members, comprising environmental justice, reproductive justice, and public health organizations and advocates, researchers, government agency allies and others. Collaborative members collectively address the reproductive and environmental justice and health issues facing the salon sector through a multifaceted approach using policy advocacy, research, movement building, media and outreach, and education strategies.

The Nail Salon Industry.

In the US, the beauty industry is booming. In the last decade, the number of nail technicians has jumped 374% to more than 380,000 nationwide, with women making up to 96% of the industry's workforce. The majority of nail salon workers are women of color, an estimated 42% nation-wide are Asian immigrants, and most are of reproductive age. One in five manicurists work in California, where up to 80% are Vietnamese women. Many salon workers speak limited English and lack an understanding of and access to regulatory, legal and health care systems. Most tend to earn less than $18,200 a year, lack health insurance and work in conditions that can be hazardous to their health.

Salon products contain many harmful chemicals.

While demand for salon services has grown, little attention has been paid to health impacts associated with the occupational exposures experienced by this sector of low-wage workers. On a daily basis, for

up to 10 or 12 hours a day, salon workers handle solvents, glues, polishes, dyes and other beauty care products containing a multitude of chemicals known or suspected to cause cancer, allergies, respiratory, neurological and reproductive harm. Women working in salons are increasingly reporting acute health concerns such as headaches, dizziness, rashes and breathing difficulties in addition to more serious/chronic problems such as miscarriages, birth defects, cancers and respiratory illnesses. Published studies that have measured the level of air contaminants in beauty salons suggest that even when exposures are well below current occupational exposure standards, workers still experience related health problems.[1] [2]

While acute impacts in salons have been well-documented, little research has been conducted on the long-term, chronic health impacts resulting from occupational exposures. New studies provide reason for concern, correlating health problems with daily exposure to chemicals in salon products by this worker population. Several studies have shown that nail salon workers have higher - in fact 2-fold higher - levels of di-*n*-butyl phthalate (DBP), a reproductive and developmental toxicant, than the general population.[3] [4] Another study found that beauticians are likely to have significant exposure to solvents that are linked to birth defects.[5] Other studies have found cosmetologists are at a higher risk for having spontaneous abortions and low birth weight babies.[6] [7]

Three chemicals of particular concern in nail salon products are toluene, formaldehyde and DBP (the "toxic trio"). Toluene creates a smooth finish across the nail and keeps the pigment from separating in the bottle. It is a common volatile solvent that can impact the central nervous system, cause irritation of the eyes, throat and lungs, and is a possible reproductive toxin. Formaldehyde, a nail-hardening agent, is also a volatile chemical that evaporates into the air of salons and is known to cause cancer. Exposure to DBP, added to polishes to provide flexibility and a moisturizing sheen, can affect thyroid function. It has been linked to reproductive harm, including decreased sperm count in adult men. Products used in salons contain a myriad of other compounds that are harmful or fail have to any toxicological data at all.

Currently, there is little statutory or regulatory oversight of salon products and the chemicals they contain.

Despite documented occupational exposures, state and federal regulatory oversight of chemicals used in salons is limited and ineffective. While the Food and Drug Administration is authorized to regulate cosmetics, it has limited authority to actually do so. It is currently legal for cosmetics manufacturers to use virtually unlimited amounts of any chemical in beauty products, including chemicals linked to cancer, reproductive and developmental harm, and hormone disruption, with no premarket safety

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[1] Labrèche, F, et al., "Characterization of Chemical Exposures in Hairdressing Salons," Applied Occupational Health and Environment, 2003; 18: 1014-1021.

[2] Industrial Hygiene Assessment of Toluene and Formaldehyde Concentrations in California Nail and Full Service Salons, Clayton Project, project no. 800-97276.00, Clayton Environmental Consultants, Santa Ana, CA, March 16, 1999.

[3] Hines J, Cynthia et al. "Urinary Phthalate Metabolite Concentrations among Workers in Selected Industries: A Pilot Biomonitoring Study." The Annals of Occupational Hygiene. (2009); 53(1):1-17

[4] Kwapniewski, Rachel et al. Occupational Exposure to Dibutyl Phthalate Among Manicurists." Journal of Occupational and Environmental Medicine (2008); Vol. 50, No.6.

[5] Garlantezec, Monfort, Cordier. "Maternal occupational exposure to solvents and congenital malformations: a prospective study in the general population." Occup. Environ. Med. (2009); 66: 456-463

[6] John, EM, Savitz D, Shy C. "Spontaneous abortions among cosmetologists." Epidemiology. (1994) Mar; 5(2): 147-155

[7] Herdt-Losavio ML. "The risk of having a low birth weight or preterm infant among cosmetologists in New York State." Maternal Child Health Journal. (2009) Jan; 13(1):90-7.

assessment. Of the more than 10,000 chemicals used in beauty products, 89% have not been tested independently for their safety or impacts on human health.

This vacuum in regulatory protection creates a context where manufacturers have no incentive to reformulate their products or substitute harmful chemicals with safer ones. The burden created by industry's failure to take upstream responsibility for the safety of chemicals used in salon products falls unfairly upon salon workers and owners and often translates into occupational exposures that can lead to poor health outcomes.

The Safer Consumer Products program Informal Regulations should fully integrate consideration of worker health.

We believe that the AB 1879 statutory and regulatory scheme can fill the statutory and regulatory void referred to above. The regulations to implement a Safer Consumer Products program in response to AB 1879 are historic in many ways. Among others, this is the first time manufacturers of consumer products will be required to formally answer the question, "Is the use of this hazardous chemical necessary in my product?" This approach represents a long-overdue paradigm shift in how chemicals are managed. Successful implementation will result in safer products and better health for salon and other low-wage workers.

Additionally, the new leadership at CalEPA, and in particular at DTSC under new Director Debbie Raphael, has breathed new life into this reg-development process. The deeper involvement of the state's Green Ribbon Science Panel has been very welcome and the informal draft regs reflect this.

The Collaborative has reviewed the informal draft regulations with an eye toward their impact on its constituency, largely low-wage immigrant women workers. We applaud many aspects of the draft regs, including the intention to regulate chemicals and the products that contain them, by focusing first on intrinsic hazard traits of chemicals rather than relying only on risk assessment.

We also believe it is essential that consideration of occupational health be fully integrated into the regulations due to workers experiencing chemical exposures that are generally of higher levels and/or longer duration than experienced by the general public. Additionally, worker exposures at all stages of a product's life cycle should be considered, whether at the manufacture, transfer, use, disposal or other stage.

Unfortunately, the current informal regulations are inadequate in this regard; notably, there is only one reference to "workers" throughout the entire 68 pages of informal regulations. As this regulatory scheme is complex, there may be several ways to address these issues and achieve a fuller integration of worker exposures and health in the intent and the language of the regulation. However, we offer the following suggestions for your consideration:

- **Add the following definitions:**

1. "Consumer" A person as defined in 69501.2(a)(56) who uses or buys a product.

2. "Public" The term "public" includes workers in an occupational setting during any stage in the life cycle of a product.

3. "Public health" The term "public health" includes the health of workers in an occupational setting during any stage in the life cycle of a product. *(Note: The term "public health" appears at 69502.2(b)(1)(A), 69503.2(a)(1) and others. The clear inclusion of "worker health" is important either by referring to it within the definition of "public health" as suggested here, or referring to it separately and in addition to "public health.")*

- **Revise certain sections as follows:**

§ 69502.2 Chemicals of Concern Identification

69502.2(b)(1)(B)
(1) Children, *women of reproductive age,* pregnant women, and other sensitive subpopulations *in the general population and/or in the workforce;*
(3) Widespread adverse *or less common but extremely severe* public health and/or environmental impacts.

§ 69503.2 Priority Products Prioritization

69503.2(a)(1)(A)(2)
a. Children, *women of reproductive age,* pregnant women, and other sensitive subpopulations *in the general population and in the workforce;*
c. Widespread adverse *or less common but extremely severe* public health and/or environmental impacts.

69503.2(a)(1)(B)(4)
The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the *entire life cycle of the product*, considering:

_____

Again, we applaud the work of DTSC thus far, and look forward to continued improvement of the draft regulations. Thank you.

Sincerely,

Catherine A. Porter, JD
Policy Specialist
California Healthy Nail Salon Collaborative
(510) 985-1146

(IC)58- Unifrax

Comments of Unifrax I LLC
on
Informal Draft Proposed Rulemaking
Safer Consumer Product Alternatives

Department Reference Number: R-2011-02

December 30, 2011

Introduction

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF), offers the following comments on the October 2011 informal draft proposed regulations for Safer Consumer Product Alternatives, also known as the "green chemistry" regulations.

Unifrax commented extensively throughout the 2010 proceedings to consider these regulations.[1] As explained in those comments, RCF is a high temperature insulation material that produces energy savings up to 40% or more in industrial furnace and other applications. In these times, it is particularly important to encourage use of such materials where they can be used safely. For over 20 years, RCFC and its members repeatedly have been commended for their dedication to product stewardship and workplace health protection. Since the late 1980's, RCFC and its member companies have developed and implemented a comprehensive Product Stewardship Program (PSP) to control

[1] See Unifrax Comments of November 1, 2010 on Notice of Proposed Rulemaking and December 3, 2010 on Notice of Post-Hearing Changes.

potential workplace and other exposures to RCF. As discussed in our prior comments, the RCF PSP has been endorsed by OSHA, NIOSH and EPA at the federal level. The California Occupational Health Standards Board has commended the PSP as well.

Our prior comments focused on the following points: (1) restriction of the regulation to true consumer products and exposures; (2) effective exemptions for existing regulation and de minimis exposure pathways; (3) explicit credit for well-conducted product stewardship programs; and (4) a clear statement that alternatives must be economically and technologically feasible. Our comments on the new informal draft address similar issues. Specifically, Unifrax:

1. Supports the exemption for bulk chemical products not sold to consumers;

2. Opposes the changes to the exemption for products subject to other regulation;

3. Continues to urge explicit reliance on well-conducted voluntary product stewardship programs;

4. Supports the approach to consideration of feasibility; and

5. Urges inclusion of NIOSH in the list of agencies deemed to provide reliable information.

These points are discussed below.

Product Focus

DTSC received many comments in 2010 arguing that the scope of the proposal was overly broad and would ensnare many products, such as Unifrax industrial insulation products, that are not true "consumer" products. The agency replied that given the broad definition of "consumer product" in the California statutes, wide application is required. However, DTSC also proposed a number of changes designed to focus the program more clearly on traditional consumer

products that are not otherwise regulated. The rules discussed below with respect to existing regulation and exposure pathways are part of this approach. Beyond that, DTSC proposed to add definitions of "personal care" and "household cleaning" products, and to add provisions giving a high priority to such products. They also added new provisions giving a higher priority to products where the potentially exposed populations include general public consumers and sensitive groups such as children and the elderly. Unifrax supported all of these changes as consistent with the applicable legal requirements and the intent of the enabling legislation.

The new draft regulations include a provision exempting the following products from preparation of alternatives assessments:

> A bulk chemical that is placed into the stream of commerce in California and that meets the definition of a "consumer product", as defined in Health and Safety Code section 28 25251, but that is not packaged for sale to, or end use by, a retail consumer.

Unifrax supports this provisions as consistent with the applicable legal requirements and the intent of the enabling legislation. It appears that the exemption would only apply to the requirement that manufacturers of priority products must prepare an alternatives assessment. Accordingly, while it would not prevent a product from being listed as a priority product, if listing were to occur no alternatives assessment would be required. Unifrax supports this approach but urges DTSC to consider it at an earlier stage in the process where warranted. For example, if it is clear that a particular product is likely to be exempt from the alternatives analysis under this provision, it should not be listed as a priority product.

Adequacy of Existing Regulation

Our prior comments noted that for Unifrax products, which are industrial insulation materials subject only to workplace exposure limits, the existing regulation of a potential exposure pathway should be deemed adequate where additional regulation has been investigated and found to be unwarranted. The 2010 post-hearing proposal responds to this comment by proposing the following exemption for products otherwise regulated:

> The requirements of this chapter do not apply to a chemical or consumer product that the Department has determined is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination, address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern or the basis for the product being listed as a Priority Product. The Department may, at its discretion, re-evaluate a determination previously made pursuant to this paragraph and rescind that determination if the Department finds that the facts and/or assumptions upon which the determination was based were not, or are no longer, valid.

Unifrax supported the language exempting products "regulated by one or more federal and/or other California State regulatory program(s) . . . that, in combination, address the same public health and environmental threats and exposure pathways . . ." This provides maximum flexibility to exempt products adequately regulated through a combination of existing state and federal "programs," including product stewardship programs endorsed by regulatory authorities as discussed further below.

The new draft includes the exemption for insignificant exposures essentially as we supported it in the last proposal. The exemption for products regulated under other authorities also is retained in the new draft, but it has been

slightly changed. In the prior proposal, the exemption applied to products subject to other state or federal regulations that "in combination, address the same public health and environmental threats and exposure pathways that would otherwise be the basis for the chemical being listed as a Chemical of Concern." The new draft includes the same language, but adds a new requirement that the existing regulations must "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 was listed as a Priority Product."

This new requirement is problematic and should be removed. It appears that to qualify under this new language, a manufacturer would have to demonstrate that the various existing regulations are at least as effective as the outcome of an alternatives assessment for the product. However, it would be virtually impossible to know in advance what the results of such an assessment would be. Further, in some cases such as workplace regulation governed by state workplace standards, consideration of alternatives is not appropriate. Unifrax urges DTSC to remove this new requirement and return to the language that appeared in the 2010 post-hearing proposal on this issue.

Product Stewardship

The 2010 proposal included a definition of "product stewardship program," which presumably was intended to allow credit for such programs in the chemical and product listing proceedings. Our prior comments contained a detailed description of our industry product stewardship program, which has been endorsed by various federal regulatory authorities and the California Occupational Safety and Health Standards Board. As discussed above, we interpret the exemption for existing regulation to allow consideration of our

program. However, we urge DTSC to acknowledge this explicitly in the final regulations or Statement of Reasons.

Feasibility

The 2010 proposal included a statement of "Guiding Principles," which clearly stated (among other principles) the limitation to alternatives that are economically and technologically feasible. This provision was eliminated in the post-hearing proposal, thought the principle was retained in the substantive provisions. Our post-hearing comments stated that we believe that a clear statement at the outset would be useful and we urged DTSC to reinstate it.

The new draft continues to require assessment of the technological and economic feasibility of each potential alternative in an alternatives analysis. It further provides:

> 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.

This is similar to the language in the prior proposal and appears adequate to us for general purposes of determining feasible alternatives. However, we continue to urge a clear statement of the principle that alternatives must be demonstrated to be feasible pursuant to the language in the draft regulations.

Reliable Information

The new draft contains a long list of other state, federal and international agencies whose scientific studies are deemed to be "reliable information" for purposes of setting priorities under this rule. The National Institute of Occupational Safety and Health (NIOSH) is not among them. As discussed in our prior comments, NIOSH has issued a Criteria Document for RCF that endorses the industry PSP and details measures for control of RCF workplace exposures. The California Occupational Safety and Health Standards Board relied on the NIOSH document in recommending the state workplace standard for RCF. We urge DTSC to include NIOSH on the list of agencies whose scientific studies are deemed to provide reliable information for purposes of this rule.

Conclusion

For the reasons stated above, Unifrax:

1. Supports the exemption for bulk chemical products not sold to consumers;

2. Opposes the changes to the exemption for products subject to other regulation;

3. Continues to urge explicit reliance on well-conducted voluntary product stewardship programs;

4. Supports the approach to consideration of feasibility; and

5. Urges inclusion of NIOSH in the list of agencies deemed to provide reliable information.

Respectfully submitted,

UNIFRAX I LLC

Dean E. Venturin, Ph.D
Director, Health, Safety and Environmental

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December 23, 2011

Via email: drafael@dtsc.ca.gov & gcregs@dtsc.ca.gov

Debbie Rafael
Director
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulations- Draft Regulations, R-2011-02 Post-Hearing Changes (October 2011)

Dear Ms. Rafael,

The San Francisco Public Utilities Commission (SFPUC) is the water, sewer, and municipal power utility for the City and County of San Francisco, and is a regional agency supplying water to 2.5 million people. Protecting water quality is part of our core mission and the effectiveness of the draft Safer Consumer Products Regulations will impact that core mission for years to come. The purpose of this letter is twofold: (1) to commend California Department of Toxic Substances Control (DTSC) for listening to stakeholder concerns and for revising its previous draft regulations (November 2010), and (2) to express the SFPUC's concerns about some of the October 2011 revisions.

The SFPUC collects and treats more than 80 million gallons of wastewater and stormwater each day in order to remove harmful pollutants before the water is discharged into the San Francisco Bay and the Pacific Ocean. The SFPUC has a critical interest in ensuring that pollutants are kept out of consumer products in order to protect human, animal, and environmental health, comply with the federal Clean Water Act through our National Pollutant Discharge Elimination System (NPDES) permits, care for the biological processes used in our treatment operations, and to maximize the quality of our biosolids.

We commend DTSC for addressing many stakeholder concerns with the 2010 regulations through the revisions included in the 2011 draft regulations. The SFPUC particularly appreciates and supports the following revisions:

- DTSC changed the way in which products are placed on the list of Priority Products, by including an evaluation process of products with

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Mayor

Anson Moran
President

Art Torres
Vice President

Ann Moller Caen
Commissioner

Francesca Vietor
Commissioner

Vince Courtney
Commissioner

Ed Harrington
General Manager

consideration of factors such as potential chemical adverse impacts, hazardous traits, and other factors. (§69503.2)

- DTSC changed some of its criteria for the Priority Products Prioritization process to include not only specific impacts that can be difficult to document, but also key prioritization criteria such as worker safety and exposures and potential adverse public health and environmental impacts. (§69503.2)
- DTSC included manufacturers, U.S. importers, and the retailers as responsible entities that may be held accountable under this regulation. [§69501.2(a)(68)]

These revisions make the 2011 regulations a considerable improvement upon the 2010 regulations, and are a big step in the right direction for Green Chemistry. However, the SFPUC has some additional concerns that are outlined below.

De Minimus Level: The SFPUC acknowledges that DTSC is receiving significant opposition to the de minimus levels set in the 2011 regulations and that they are in fact a compromise between competing interests. The SFPUC strongly supports the changes in the 2011 regulations regarding the de minimus level, and we urge DTSC to not increase levels set forth in the current draft. In some cases, the SFPUC recommends that DTSC use its authority to specify even lower de minimus levels for particular chemicals, especially when hazards pose grave dangers to human, animal, or environmental health. [§69501.2(a)(25)]

Conflicts with the requirements of another state or federal agency: In the case of a conflict between another state or federal agency's requirements and the Safer Consumer Products Regulation, the SFPUC recommends that the strictest regulation in regard to toxicity should prevail. DTSC should revise §69506.7 to reflect this hierarchy of priority.

Nanomaterials: The SFPUC acknowledges that nanomaterials have many beneficial impacts on our society, but we also understand that this is an emerging technology with many unknowns, including the potential impacts on our wastewater streams and the natural environment. The U.S. Environmental Protection Agency recently started regulating the uses of nanosilver, but only because it is being marketed as a pesticide. Currently, the health and environmental impacts of nanosilver are unknown. The SFPUC recommends that nanosilver be included in the Chemicals of Concern list (§69502.3) so that it may be effectively evaluated.

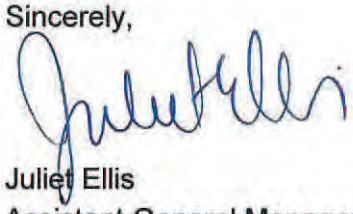
Section 25254 of the Health and Safety Code mandates that the Green Ribbon Science Panel include persons with specific expertise, including nanotechnology. The Legislature, in passing Section 25254 into law, expressed

an intent that nanomaterials are a concern that should be investigated. By striking nanomaterials from the definition of a "chemical" in the November 2010 regulation, it now could be argued that nanomaterials are not to be regulated by the Safer Consumer Products Regulation. Expressly stating that nanomaterials are chemicals subject to regulation will resolve any question as to their inclusion.

Third Party Assessors: The SFPUC acknowledges that Alternative Assessments can be completed by either certified outside parties or by companies' in-house scientists. However, the SFPUC recommends that all Alternative Assessments, particularly those cases where trade secrets are claimed, should be reviewed by certified third party assessors. Third party assessors will increase public confidence in the process by providing the opportunity for meaningful public review and will increase the accuracy and transparency of all Alternative Assessments.

The SFPUC's goal is that the Safer Consumer Products Regulation provides transparent and effective protection of human, animal, and environmental health by identifying the most toxic chemicals and then moving consumer product manufacturers toward the use of safer alternatives. We appreciate the opportunity to comment on the 2011 Safer Consumer Products Regulations, commend DTSC for addressing stakeholder concerns in the latest round of revisions, and urge your serious consideration of the concerns expressed above.

Sincerely,



Juliet Ellis
Assistant General Manager, External Affairs

cc: Regulations Coordinator, Department of Toxic Substances Control (gcregs@dtsc.ca.gov)
Melanie Nutter, Director, San Francisco Department of Environment

CALIFORNIA MANUFACTURERS & TECHNOLOGY ASSOCIATION

(IC)60- California Manufacturers & Technology Association

December 23, 2011

Via E-Mail to: GCregs@dtsc.ca.gov

Debbie Raphael
Director, Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Informal Draft - Safer Consumer Products Regulation

Dear Director Raphael,

I am writing on behalf of the California Manufacturers & Technology Association (CMTA) to express our concerns with the Safer Consumer Products informal draft regulations issued on October 31, 2011.

While we acknowledge that there are some positive changes from the previous draft, there were also changes that we view as a step backward in achieving a workable plan and they will absolutely have a chilling effect on the economy of the California and increase the cost of products to the State's residents.

The program as currently proposed will create a full blown bureaucracy to manage. AB 1879 and SB 509 do not require an undertaking of such scope. The goal was to have scientists deal with chemicals of concern rather than politicians discussing generally the same handful of chemicals year after year. Legislators felt uncomfortable ruling on chemicals that they couldn't even pronounce. The hope was to get politics out of it and science in. This program on the other hand would practically take on the world (or at least the universe of manufacturing) and put DTSC in charge of monitoring and approving everything made, sold or used in this State.

Moreover, little science is evidenced in these draft regulations. Virtually 20-30% of all consumer chemicals used in commerce have been included as chemicals of concern (3,000-5,000 out of 15,000) and virtually every hazard known to man is listed. There has been no explanation as to how these chemicals will be prioritized. A trust us approach is definitely not a scientific approach. Criteria need to be spelled out that can be justified and understood by manufacturers and the public. All we have now is a list of lists.

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Trade secrets must be protected or companies either will not sell in the state or will move operations out of the State. Please take the Green Chemistry Alliance's detailed recommendations into very serious consideration. A lack of protection in this regard will not only negatively affect the California economy, but also negatively impact innovation.

Reducing the de minimus to .01% and holding manufacturers responsible for unintentionally added chemicals, increases the cost and liability to manufacturers exponentially. Assuring that your products comply with a .1% de minimus is in itself an expensive and major undertaking. Combined with the cost of conducting an alternative analysis, it will be prohibitively costly for small or medium size manufacturers to comply and even many large manufacturers may balk.

For the above stated reasons, CMTA believes significant changes still need to be made in the structure of the informal Green Chemistry regulations and definitely more detail must be spelled out concerning the prioritization of chemicals products and alternatives. In addition to endorsing the Green Chemistry Alliance comments, we also agree with the comments that are being made by DuPont, the American Chemistry Council, the Grocery Manufacturers, the Auto Alliance and the Toy Industry Association. The informal draft regulations are simply not practical for manufacturers to accept.

Michael J. Rogge
Policy Director, Environmental Quality

CASQA
California Stormwater Quality Association
Dedicated to the Advancement of Stormwater Quality Management, Science and Regulation

December 23, 2011

Debbie Raphael, Director
California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
Attn: Heather Jones – Safer Consumer Products Regulations, MS 22A
P.O. Box 806
Sacramento, CA 95812-0806

Subject: Comments on Informal Draft Regulations for Safer Consumer Products (*released October 31, 2011*)

Dear Ms. Raphael:

The California Stormwater Quality Association (CASQA)[1] appreciates the opportunity to review the informal draft Regulations for Safer Product Alternatives. We submitted comments last year on earlier versions and we also testified at the workshop on December 5, 2011.

We are very encouraged by the changes that have been made to the proposed regulations since the final draft last year. The regulations in this proposal have the potential to significantly reduce the concentrations of harmful chemicals in waterways of California. Aquatic organisms will be better protected and human health should also be protected because of reduced biomagnification through the food chain.

We view the regulations as an essential component of our efforts to comply with the federal Clean Water Act and the State Water Code. Controlling problem chemicals at the original source means that local agencies as well as State agencies will not be forced to install, maintain, and operate expensive treatment facilities on stormwater systems, which can be an "end-source" for pollutants of concern.

Keeping problem pollutants from entering urban and roadway runoff will allow the agencies and also companies responsible for stormwater to comply with water quality standards. In fact, the feasibility of addressing many pollutant-impaired waterways is often dependent on the effectiveness of these regulations since effective treatment technology is not available for many of the chemicals of concern. And, even when treatment is feasible, the costs to the public agencies to control these pollutants will constitute a significant new financial burden in an era of decreasing revenues. We hope that you are able to consider these very substantial savings (or reduced demands) on public agencies during your deliberations and also during evaluation of individual chemicals and products.

[1] CASQA is comprised of stormwater quality management organizations and individuals, including cities, counties, special districts, industries, and consulting firms throughout California. Our membership provides stormwater quality management services to more than 22 million people in California. CASQA was originally formed in 1989 as the Stormwater Quality Task Force to recommend approaches for stormwater quality management to the California State Water Resources Control Board.

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We want to ensure that the final regulations provide a clear pathway to controlling product-originated pollutants that impair waterways in the State. Unfortunately, the informal draft is confusing with respect to the mechanism and priority with which the Department would address these problem products and their constituents and byproducts. We would appreciate clarification on how the regulations will address pollutants of concern in waterways (e.g., zinc and dioxins).

At the recent workshop, we also raised several programmatic or overview concerns. We believe the Department will require additional funding to implement the program as drafted. Otherwise our recourse may be to go to legislature as we did to help control problems caused by copper released from brake pads. We believe a DTSC program designed to address all product-related problem pollutants is a much better approach, however, the Department will need funding to support the necessary staff.

We also noted at the hearing that the definitions related to water quality effects need to be broadened to encompass the full range of impacts occurring in the waters of the State and we have included comments with suggested changes. Finally, we recommended the Department work closely with the State and Regional Water Boards, California Fish & Game, and possibly other agencies to utilize their expertise and experience in identifying and addressing water-related problems. In our comments, we have identified opportunities for increasing the involvement these agencies.

Our detailed comments are attached. The Green Chemistry Initiative presents a major step forward in protecting the environmental resources of California and we are excited to be involved. We appreciate that the Department has conscientiously and effectively involved stakeholders and we are encouraged by the significant improvements in the regulations over the past year. Thank you again for the opportunity to provide comments. Please contact me at (760) 603-6242 or Geoff Brosseau, our Executive Director, at (650) 365-8620 if you have any questions or need additional information.

Sincerely,

Scott Taylor, P.E. D. WRE
Chair, California Stormwater Quality Association

cc: Odette Madriago, Acting Chief Deputy Director, DTSC
Jeff Wong, Chief Scientist, DTSC
Kathy Barwick, Office of Pollution Prevention and Green Technology
Charles Hoppin, Chair, State Water Board
Tam Doduc, Member, State Water Board
Tom Howard, Executive Director, State Water Board
Jonathan Bishop, Chief Deputy Director, State Water Board
Vicky Whitney, Deputy Director, State Water Board
Darrin Polhemus, Deputy Director, State Water Board
Bruce Fujimoto, Section Chief-Stormwater, State Water Board
Alexis Strauss, Director, USEPA Region IX
CASQA Board of Directors and Executive Program Committee

Detailed Comments

Chapter 55. Safer Consumer Products
Informal Draft Regulations, R-2011-02
Department of Toxic Substances Control (10-31-2011)

1. ***General comment* – addressing chemicals of concern to public agencies responsible for protecting water quality**

   Our primary interest is that these regulations empower DTSC to address the chemicals (including residues and reaction products) that that cause or threaten to cause environmental or public health impacts via waterways in the State. Controlling these problem pollutants immediately prior to discharge—i.e., the "end sources" such as stormwater systems—is expensive and often infeasible.

   The regulations should target the following product categories when they are the original sources of the problem pollutants:

   - The product can be more efficiently and cost-effectively controlled at the original source rather than depending on downstream end-sources such as municipal separate storm sewer systems (MS4s), publicly owned treatment works (POTWs), and industrial stormwater dischargers. *Example:*
     - Zinc in tires and some galvanized products may contribute to exceedances of water quality standards by runoff and also may result in toxicity in waterways. Source control could potentially prevent zinc from being released to roadways and entering runoff. Control at the original source could be more efficient than requiring MS4s to build and operate multi-media filters, or other controls, on their stormwater outfalls that would be extraordinarily expensive.
   - The down-stream end-sources do not have available controls that can address the product or problem chemicals. *Examples*:
     - Copper brake pads contribute to exceedances and potentially also contribute to toxicity in waterways. Typically about 40% to 50% of this copper is dissolved. Filtration would not address the dissolved copper (or other dissolved pollutants of concern). Fortunately, recent legislation will address the original source and over time should greatly reduce this problem pollutant.[2]
     - Dioxins (TCDD equivalents) in urban and highway runoff typically exceed water quality standards by several orders of magnitude. Even high-level treatment (filtration) is unlikely to provide compliance. Identifying and addressing original sources may be effective, however.

In summary, for the stormwater agencies in the State, a key goal for the program should be to address products/chemicals of concern at the original source when that is less costly to society and more effective than addressing the problem chemicals at the end-sources such as MS4s.

[2] Recent legislation (SB 346) will reduce copper in brake pads to no more than 5 percent by 2021 and to no more than 0.5% by 2025. This is an example of source control at the original source that could be applied to other chemicals of concern.

2. ***General comment*** – ***Regulatory complexity*** - We are concerned about the complexity of these regulations. The extraordinary detail of these regulations (some possibly due to our previous comments) may end up hindering the Department from having the necessary discretion and flexibility to meet the intent of the law.

3. **Clarification of "Adverse environmental impacts"**. § 69501.2. Definitions (page 6 of 68), subsection (a)(4) [line 18]

   (4) "Adverse "Adverse environmental impacts" means any of the following:
   (A) Adverse air quality impacts;
   (B) Adverse ecological impacts;
   (C) Adverse soil quality impacts; or
   (D) Adverse water quality impacts
   (E) Adverse waste and end-of-life impacts
   (F) Adverse impacts as indicated by non-compliance with local, State, or Federal environmental laws and regulations.

Comment: Demonstration of adverse impact is sometimes very difficult due to the complexity of interactions with other factors. We suggest the addition of item (E) shown underlined above or a similar provision to address non-compliance.

4. **Unclear meaning of "Adverse waste and end-of-life impacts"**. § 69501.2. Definitions (page 6 of 68), subsection (a)(7)

   "Adverse waste and end-of-life impacts" means adverse impacts associated with any of the following:

   (A) The amount of waste and byproducts generated, and any special handling required for the waste and byproducts, during the life cycle of the Priority Product and each alternative being considered;

   (B) Disposal, treatment, or use of waste and byproducts, including solid waste, wastewater and storm water discharge streams; or

   (C) Disposal of the Priority Product in the trash, down the sewer, or down the storm drain that interferes with the proper operation of solid waste, wastewater, or storm water treatment facilities, ~~and that may result in the release of Chemicals of Concern to the environment~~.

   [proposed addition] *(D) Degradation and reaction products resulting from the interaction of the product or chemical of concern which create other chemicals exhibiting characteristics resulting in impairment to waterways. Synergistic effects should also be considered an adverse end-of-life impact when they result in waterway impairment*

We have several comments on this definition and clarification may be necessary:

Comment a: Although possibly addressed elsewhere, end-of-life impacts from some products include adverse impacts in waterways caused by degradation products, reaction products, and synergistic effects. It would be helpful to clarify where breakdown and reaction products fit into the regulatory scheme. Examples would be useful in these regulations or perhaps in separate

guidance issued concurrently and referenced in the regulations. Unless addressed by other definitions, it may be useful to add a fourth category (D) to the list as shown underlined above.

Comment b: Additionally, item (C) above, refers to disposal in *trash, down the sewer, or down the storm drain that interferes with the proper operation of solid waste, wastewater, or storm water treatment facilities, and that may result in the release of Chemicals of Concern to the environment.* Problem chemicals and their residues also enter waterways through other means such as direct deposition, release from physical structures in waterways, and aerial deposition. We presume that the wording above would not preclude addressing Chemicals of Concern (COCs) that enter waterways via these other routes.

Comment c: Interference with treatment facilities by itself is a significant problem. We suggest striking out the phrase in item (C) as shown above.

5. **Applicability or use of the term "Adverse water quality impacts"**. § 69501.2. Definitions (page 7 of 68), subsection (a)(8)(A) [line 8]

   (8) "Adverse water quality impacts" means any of the following adverse effects on the beneficial uses, as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan pursuant to article 3 of chapter 3 and/or article 3 of chapter 4 of division 7 of the Water Code, of the waters of the State, which include groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems:

   (A) Increase in biological oxygen demand;
   (B) Increase in chemical oxygen demand;
   (C) Increase in temperature;
   (D) Increase in total dissolved solids; or
   (E) Introduction of, or increase in, any of the following:

   Comment a: We understand that these adverse effects are considered during the alternatives assessment and are balanced with other effects and costs. However, the prominence given to these particular parameters is confusing.

   Probably most POTW and stormwater discharges increase biochemical oxygen demand (BOD), chemical oxygen demand (COD), total dissolved solids (TDS), and temperature although these increases are generally not significant. We question the emphasis given to these particular parameters as opposed to other parameters such as toxicity that are more likely to result from COCs and are more likely to have ecological and health impacts.

   1. Chemicals identified as priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act (i.e., California Toxics Rule); chemicals for which USEPA has developed criteria under Section 304(a)(1) of the Act, and chemicals for which the State Water Boards have established objectives in the Water Quality Plans (Basin Plans, Ocean Plan).

   Comment b: Those working in the water community are more likely to recognize these chemicals as those included in the *California Toxics Rule* (CTR). For clarification, a footnote or parentheses could indicate that this item refers to the CTR as published in the Federal Register on May 18, 2000, and any subsequent updates by USEPA. In addition, the

objectives established in Basin Plans should be considered similar to the CTR's priority pollutants, as well as USEPA's recommended criteria (see underlining above).

Comment c: As noted previously, it would be useful to indicate how this phrase will be used in the alternative analysis, otherwise the implication is that increases in the concentration of any of them would be judged as an adverse water quality impact and potentially targeted by the program.

Comment d: A catchall definition could also be added such as:

> *6. A pollutant identified by the California Water Boards as causing or contributing to violations of water quality standards, adverse effects to aquatic ecosystems, or degradation of any waters, including both surface or ground waters.*

6. **Different types of products**. § 69501.2. Definitions (pages 7 and 11 of 68),

   Pg 7 [line 7] - *(12) "Assembled product" means a heterogeneous product consisting of two or more components.*

   Pg 11 [line 19] - *(37) "Formulated product" means a homogeneous product, often, but not always intended to be consumed through use.*

Comment: Is this distinction necessary? Many products are both.

7. **A broader definition for "Chemical"**. § 69501.2. Definitions (page 8 of 68), subsection (a)(16), *line 22*.

   16) "Chemical" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element or uncombined

Comment: We suggest broadening this definition to ensure that "*chemical*" includes degradation products, reaction products, and chemicals acting synergistically with other constituents in the environment. Expanding the scope of the definition would reduce the need for clarification elsewhere in the regulations that these other materials are within the scope of the program.

For example, bromides and other chemicals can react with disinfection chemicals to produce disinfection by-products such as bromate, trihalomethanes, haloacetic acids, and chlorite. In other words, chemicals should be potential targets for this program if they are susceptible to reactions resulting in chemicals of concern. As MS4s are coming under increasing regulatory pressure to address bacteria, possibly by disinfection, these byproducts could become a significant issue.

Another example is dioxins, which can present a significant compliance problem for water system managers because they have been measured in stormwater runoff at concentrations orders of magnitude above water quality standards. Diesel combustion is considered a major source. Contaminants or intentional additives in diesel such as catalysts may apparently increase the production of dioxins but very little information is currently available regarding

the creation of dioxins. Expanding the definition of chemical (or possibly other changes to the regulations) could potentially help prevent the production of additional dioxins.

Some breakdown byproducts that occur after the chemical is released to the environment are even more toxic than the original chemical. For example, vinyl chloride is more toxic than trichloroethylene.

As we have noted previously, it is not clear how these draft regulations will address many of these problem pollutants in waterways.

8. Lower *de minimis* for some chemicals. § 69501.2. Definitions (page 9 of 68), subsection (a)(25)

> *(25) "De minimis level" means a concentration equal to whichever of the following is applicable:*
>
> > *(A) 0.01% by weight for chemicals exhibiting any of the following hazard traits or environmental or toxicological endpoints specified by OEHHA pursuant to title 22, California Code of Regulations, division 4.5, chapter 54: [etc.]*

Comment: This threshold may be appropriate for some chemicals but not all. It is very important that these regulations contain the provision in § 69503.4(C) that allows the Department to specify a lower *de minimis* amount. It may be appropriate to reference that section here in the definitions.

Several examples can illustrate the potential need for a lower *de minimis* value in some cases. The Ocean Plan standard for dioxins is 0.0039 picograms/Liter or 3.9×10^{-9} ug/L (Ocean Plan). The *de minimis* level of 0.01% equals 100,000 ug/L. Thus, a product or residue containing under the *de minimis* level of dioxins (TEQ) could potentially, via breakdown or other disposal, result in a discharge that could be orders of magnitude greater than the water quality standard and would have the potential to contaminate a significant portion of the receiving water.

Of course, many products will contain COCs that are bound and not likely to be released and typical disposal practices could prevent contamination of waterways. However, for some products or waste materials, releases to the environment of the product or wastes could result in waterway contamination above levels of concern. The risk, of course, is dependent not only on the concentration but also on the specific product and its life cycle including the life cycle of its degradation products.

Another example is PCBs. The criterion for PCBs in California waters is 0.17 nanograms per liter (0.00017 ug/L), also based on human health risk.[3] Thus, concentrations in products or product residues and byproducts at orders of magnitude less than 0.01% do present a substantial risk depending on how the material is handled and disposed of.

In looking at the Ocean Table B Standards for the protection of human health, we see that most constituents have the potential to cause adverse impacts to human health (via waterways) at concentrations well below the 0.01% *de minimis* threshold. We note that

[3] Criteria/objectives for both 2,3,7,8-TCDD and PCBs were promulgated in the California Toxics Rule for inland waters and in the Ocean Plan for ocean waters.

unless the product is released directly to the waterway, the standard will not be exceeded unless the diluted waste stream still contains concentrations that exceed the standard. However, for some cases a very high level of "dilution" must occur either within the product or in the waste stream for the pollutant to be reduced in concentration to levels lower than standards.

Ocean Plan Table B Category	**Number of constituents or groups**
	Standards are less than the *de minimis* threshold and thus product/COC may not be regulated even though risk is present from "undiluted" or inadequately diluted discharge
Non-Carcinogens	17 out of 20
Carcinogens	42 out of 42

Consequently, we strongly urge the Department to preserve the option of a COC-specific *de minimis* value.

9. Economic impacts. § 69501.2. Definitions (page 10 of 68), subsection (a)(27) [line 8]

(27) "Economic impacts" means an increase or decrease in any of the following:

(A) Capital investments;
(B) Cost of goods to consumers;
(C) Cost of marketing;
(D) Energy costs;
(E) Jobs or businesses;
(F) Operation and maintenance costs;
(G) Resource costs; or
(H) Waste disposal and/or treatment costs.

Comment: We strongly support item (H) since end-of-pipe treatment costs for these COCs can create a huge financial burden for municipalities.

10. More environmental fates. § 69501.2. Definitions (pages 10, 11 of 68), subsection (a)(32)

32) "Environmental fate properties" means all of the following:
(A) Aerobic and anaerobic soil and sediment half-lives;
(B) Aqueous hydrolysis half-life;
(C) Atmospheric oxidation rate;
(D) Bioaccumulation in organs and tissues;
(E) Biodegradation;
(F) Mobility among and between individual components of the environment;
(G) Persistence; and
(H) Photodegradation.
(I) Transformation or reaction and degradation products or metabolites
(J) Potential to cause synergistic effects

Comment: Even if addressed by other changes to the regulations, it would be useful to include (I) and (J) as indicated above.

11. Expansion of life cycle. § 69501.2. Definitions (page 12 of 68), subsection (a)(46)

(46) "Life cycle" means the sum of all activities in the course of a consumer product's entire life span, including raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

Comment: Unless addressed by changes elsewhere the regulations, the term *end-of-life disposal* may not fully encompass all after-use stages that need to be addressed. As we have noted previously, these additional stages include byproducts, degradation products, transformation products (as discussed previously), and impacts associated with synergistic actions with other materials in the environment. The next definition (#47) addresses life-cycle thinking" and all these additional stages need to be included in life-cycle thinking.

12. What is recycled material? § 69501.2. Definitions (page 14 of 68), subsection (a)(55)

(64) "Recycled material" means a material that has been separated from a waste stream for the purpose of recycling the material as feedstock.

Comment: This term appears too narrowly defined. Recycled material in some cases may not be reused as feedstock (but may be otherwise reused) and may also be diverted during manufacturing before it enters a waste stream.

13. Reliable information – Constraints § 69501.2. Definitions (page 15 of 68), subsection (a)(67)

(67) "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that are established by reliable information: …

Comment: It may be appropriate to have the Green Ribbon Science Panel (GRSP) review this section to ensure that it adequately encompasses the wide range of potential exposures and impacts associated with COCs in consumer products.

14. Reliable information – Monitoring Data § 69501.2. Definitions (page 15 of 68), subsection (a)(67)

(67) "Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following that are established by reliable information: …

…(H) Monitoring data indicating the presence of a chemical or its degradation products <u>or reaction products</u> in California solid waste, wastewater, or storm water streams <u>or in</u>

surface or groundwaters collected or managed by California State or local agencies in concentrations or volumes that:

1. Present potential adverse public health or environmental impacts;

2. May require the expenditure of public funds to mitigate potential adverse public health or environmental impacts;

3. Increase the costs of reusing or recycling materials containing the chemical; or

4. Interfere with the proper operation of solid waste, wastewater, or storm water treatment systems ~~and may result in the discharge of the chemical to the environment.~~

Comment a: We presume that this definition is intended to facilitate addressing pollutants that cause impairment based on monitoring and other related information, as appropriate. The additions shown underlined above could help clarify the intent. This is a complex definition and it may also be appropriate to request an in-depth review from the Green Ribbon Science Panel.

Comment b: In addition we suggest removing the phrase—"*and may result in the discharge of the chemical to the environment*"—as we noted in a previous definition, since the interference itself is a significant problem.

15. COC initial list – general concerns § 69502.2. Chemicals of Concern Identification (page 24 of 68), subsection (a) Initial Chemicals of Concern List.

§ 69502.2. Chemicals of Concern Identification.

(a) Initial Chemicals of Concern List. As of the effective date of these regulations, a chemical is identified as a Chemical of Concern, if it exhibits a hazard trait or an environmental or toxicological endpoint, and meets one or more of the following criteria: [etc.]

Comment a: We strongly urge the Department to include on this list the toxic chemicals currently impairing waterways in the State (CWA 303(d) list), especially those carried by stormwater that could be addressed by source control. It is not clear that this will occur as the regulations are structured.

Comment b: In addition, we also recommend inclusion of chemicals causing documented problems for freshwater or marine organisms but for which USEPA or the Water Boards have not yet promulgated water quality standards. For example, fire retardants (brominated compounds) are accumulating in sea mammals in San Francisco Bay as documented by the Water Board. (In addition, they are bioaccumulating in humans.) Would these brominated compounds be placed on the list? If not, these criteria should be modified to make the list more inclusive. We note that the route taken by these chemicals to enter waterways is not known but may include stormwater.

Comment c: It is also not clear that this list is structured so that it would include chemicals that break down into problem degradation products or are changed into other chemicals that adversely effect waterways. For example, nonylphenol ethoxylates, derived from detergents, may be degraded by bacteria in waterways into components that present an even greater estrogenic risk than the original nonylphenol isomers.

Comment d: In addition, we strongly support the petition process involving the Water Boards or California Fish and Game, and other State agencies as appropriate, but also recommend their direct participation in the creation of this initial list based on their experience in addressing water quality concerns.

16. **COC initial list - additional sources based on water quality** regulations § 69502.2. Chemicals of Concern Identification (page 25 of 68), subsection (a)(1)(M) [line 1].

    (M) Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act (i.e., California Toxics Rule); chemicals for which USEPA has developed criteria under Section 304(a)(1) of the Act, and chemicals for which the State Water Boards have established objectives in the Water Quality Plans (Basin Plans, Ocean Plan).

    Comment: Including section 303(c) pollutants is appropriate but will not necessarily address all chemicals causing adverse effects in waterways. We suggest the additional text underlined above, although this material could be included as a separate item.

17. **COC initial list – Safer Alternatives.** § 69502.2. Chemicals of Concern Identification (page 26 of 68), subsection (b) Additions to the Chemicals of Concern List. [line 9]

    (4) Safer Alternatives. The Department may adjust the prioritization prior to listing a chemical as a Chemical of Concern by considering whether there is a readily available safer alternative chemical that is functionally acceptable for one or more common uses of the chemical in consumer products.

    Comment: We are concerned that this provision will lessen the need to find safer alternatives. We are not sure how to reword this item, but we suggest it be structured so that a strong incentive remains to find alternatives.

18. **COC initial list – additional chemicals.** § 69502.2. Chemicals of Concern Identification (page 25 of 68), subsection (b) Additions to the Chemicals of Concern List. [line 20]

    (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 one or more hazard traits or environmental or toxicological endpoints, as Chemicals of Concern by considering the following factors for which information is available: [etc]

    Comment: Potentially add a new (5) at the end of this section following (4) Safer Exposures [page 26, line 9] or make other changes to prioritize the recommendations of other State agencies.

    (5) Recommendations by the California Water Boards, California Fish and Game and other State agencies. The Department will give high priority to chemicals recommended by these agencies for inclusion on the list.

19. Prioritization criteria – Environmental Considerations § 69503.2. Product Prioritization Criteria (pages 28, 29 of 68), subsection (a) Key Prioritization Criteria,

(page 28, line 28) *4. The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the useful life of the product and end-of-life disposal or management of the product, considering:*

…

(page 29, line 1) *e. Potential for release into, migration from, or distribution across environmental media, and potential for accumulation and persistence in biological and/or environmental components or systems of the Chemical(s) of Concern or its/their degradation products, considering the environmental fate properties of the Chemical(s) of Concern and its/their degradation products*

Comment: We are concerned that the wording in subsection 4., and e. does not provide for addressing direct or immediate adverse aquatic impacts in the prioritization process.

20. Prioritization criteria – Effect of other regulatory programs § 69503.2. Product Prioritization Criteria (page 29 of 68), subsection (a) Key Prioritization Criteria, (3) [line 7]

(3) Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs, and any applicable international trade agreements ratified by the United States Senate, under which the product ~~or the Chemical(s) of Concern in the product~~ is~~/are~~ regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a potential basis for the product being listed as a Priority Product.

Comment: Virtually all chemicals are addressed by some other regulatory program; however, these other regulations may be inadequate or may result in much higher costs to society. We propose the deletion of "Chemicals of Concern" from the item (3) above.

21. Prioritization criteria – Other costs § 69503.2. Product Prioritization Criteria (page 29 of 68), subsection (a) Key Prioritization Criteria, new subsection to follow (3) [line 7]

Comment: It is essential that a new criterion (a)(4) [beginning line 14, p. 29] be added that addresses the potentially major costs to public agencies and others of addressing these chemicals at the "end source," that is prior to discharge to waterways.

22. Prioritization criteria – Violations of laws § 69503.2. Priority Products Prioritization (page 29 of 68), subsection (b) Key Prioritization Criteria. [line 14]

(b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize products, the Department shall give priority to products meeting one or more of the following criteria:…

Comment: COCs contained in a product that result in a violation of the law (e.g., exceedance of water quality standards), should be a high priority. However, violating the law is not on the list – is it addressed elsewhere?

As we noted in an earlier comment, it may be appropriate to have the Green Ribbon Science Panel (GRSP) review the adequacy of these criteria in identifying products that should be addressed by this program, particularly those with known impacts or violations of permits, regulations, or laws.

23. Prioritization criteria – Significant potential for impacts § 69503.2. Priority Products Prioritization (page 29 of 68), subsection (b) Key Prioritization Criteria.(1) [line 17]

1) The Chemical(s) of Concern in the product, <u>or the degradation or reaction products of those chemicals</u>, have a significant potential to cause adverse public health and environmental impacts;

Comment: We suggest the addition of the underlined sentence above or an alternative that addresses the same purpose. Alternatively the definition of COC could be expanded. Our goal is to ensure that resulting chemicals are also addressed since these sometimes create water quality problems.

24. Prioritization criteria – Adequacy of Scope § 69503.2. Priority Products Prioritization (page 29 of 68), subsection (b) Key Prioritization Criteria. [line 23]

(4) For assembled products, the product contains one or more Chemical(s) of Concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts; and/or

(5) For formulated products, the product is intended to be:
(A) Applied directly to the body;
(B) Dispersed as an aerosol or a vapor; or
(C) Applied to hard surfaces with the likelihood of run

Comment: These two subsections do not provide for the prioritization of products impacting water quality other than those "*Applied to hard surfaces*". This is a major oversight. As currently drafted very few, if any, assembled or formulated products would ever be regulated by this program because of adverse impacts on water quality. Suggested language is included in the next comment, although addressing water quality may require a new subsection.

25. Prioritization criteria – formulated products § 69503.2. Priority Products Prioritization (page 29 of 68), subsection (b) Key Prioritization Criteria.(5) [line 26]

(5) For formulated products, the product is intended to be:
(A) Applied directly to the body;
(B) Dispersed as an aerosol or a vapor; or
(C) Applied to hard surfaces with the likelihood of runoff or volatilization.

(D) Applied or released by any other method resulting in its presence, or the presence of degradation or reaction products, at levels of concern in soils, air, or water

Comment: We suggest the addition of the underlined sentence above or an alternative that accomplishes the same purpose. It is not clear in the original material that formulated products using other routes of exposure will be addressed. The addition as shown above (and possibly other additions), may be necessary so that the list is not artificially constrained. (Our interest, of course, is that *all uses* of formulated products resulting in impacts to water quality be included.)

In fact, this item (5) may not be needed. Otherwise the regulations may need to describe every mode of travel or disbursement by which the products could result in harm. For example, we would want to add "*Used in a manner in which abrasion results in residual materials being deposited where they will likely be transported in stormwater runoff*" and similar items to address products creating water pollution.

26. Prioritization criteria – formulated products § 69503.2. Priority Products Prioritization (page 29 of 68), subsection (c) Process for consideration [line 30]

c) Process for Consideration of the Prioritization Factors.
(1) Potential Adverse Impacts and Exposures and Availability of Information. ..
(2) Other Regulatory Programs. …
(3) Priority Products...
(4) Safer Alternative...
(5) Key Prioritization Factors...

Comment: Our previous comments pertain. For example, the mere existence of other regulatory programs should not prevent the utilization of this program to address pollutants when this program is the more effective and results in fewer costs to society.

27. *De minimis* levels. § 69503.4. De Minimis Exemption (page 31 of 68)

Comment: As discussed in an earlier comment, it is important to preserve the Department's ability to set chemical or product-specific *de minimis* values. These values may vary with different products depending on the propensity for the COCs in the product to end up being discharged into waterways. A constituent of a product used to remove roots from sanitary sewers, for example, has a much higher risk than a product used in enclosed spaces that seldom comes in contact with runoff or wastewater.

28. Petitions from State Agencies. Article 4 Article 4. Petition for Inclusion of a Chemical or Product in the Identification and Prioritization Processes. (page 34 of 68) [line 10]

Comment: We strongly support the petition process and also believe in assigning a high priority to petitions from the Water Boards or California Fish and Game due to their experience in addressing water quality concerns.

29. Degradation products in AA, 2nd stage. § 69505.4. Alternatives Assessment: Second Stage. Page 40 [line 38]

> *7. Adverse waste and end-of-life impacts including degradation products or materials created by interactions in the environment*

Comment: Unless addressed by the definition of "chemical," we suggest the addition shown above.

30. Public Review of AA. § 69505.6. Department Review and Determinations for AA Reports. Page 46 [line 1]

Comment: We recommend that DTSC include a public review opportunity for the preliminary AA, and prior to proposing a regulatory decision. Similar comment opportunities during other regulatory processes (e.g., pesticides) have been very useful in identifying key issues for consideration by the reviewing agency.

(IC)62- OEHHA

OEHHA Comments on DTSC Draft Informal Regulation

Safer Consumer Products

Comments on Section 69501.2: Definitions

1. Section 69501.2 (a)(2) Adverse air quality impacts. Rather than separately listing nitrogen oxides, sulfur oxides, and particulate matter, we suggest you list "Criteria Air Pollutants and cite ARB's statute. This would also capture a few more of the pollutants, including H_2S and CO.

2. Section 69501.2(a)(8)(E)(5.) Adverse water quality impacts. This definition includes chemicals for which OEHHA has published public health goals for drinking water. This is a good addition. These chemicals should be added to the list of COCs. They were there in an earlier draft but were gone in the public draft.

3. Section 69501.2 (a)(14) Bioaccumulation. The definition in the Informal Regulation is different than the definition of the bioaccumulation hazard trait in the OEHHA regulation. In the informal regulation, bioaccumulation "means the accumulation of a chemical substance in an organism, or an individual component of the environment, which absorbs the chemical at a rate greater than that at which the chemical is lost."

The OEHHA definition of the bioaccumulation hazard trait is as follows: "The bioaccumulation hazard trait is defined as the accumulation of a chemical substance in the tissue of organisms through any route, including respiration, ingestion, or dermal, including direct contact with contaminated water, sediment, and pore water in the sediment, or through transfer up the food chain."

The informal regulation definition leaves out accumulation in tissues of an organism, so if you average out the concentrations in the entire organism it may not appear that the chemical is bioaccumulating as it may dilute the concentrations in the specific tissue (e.g., fat, liver, bone) where the substance is actually accumulating. Also, since bioaccumulation refers to accumulation in biota, we suggest adding the word "biological" in front of "component". We suggest that the definition be amended to read: "bioaccumulation means the accumulation of a chemical substance in an organism <u>or tissues of an organism</u>, or an individual <u>biological</u> component of the environment, which absorbs the chemical at a rate greater than that at which the chemical is lost."

4. Section 69501.2 (a)(16) The definition of "chemical " in the Informal Regulation is different than the definition in the OEHHA Hazard Trait regulation. References in these informal draft regulations to Chapter 54 and its sections (69401 through 69407.2) refer to regulations developed pursuant to Health and Safety Code section 25256.1entitled "Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse" (adopted January 19, 2012)."The informal regulation states "Chemical means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, and any element or uncombined radical."

The OEHHA definition of a "chemical substance" is a chemical, chemical compound, chemical mixture, elemental material, particulate matter, fiber, or radioactive agent, its metabolites or degradation by-products."

The main difference is that we included metabolites and degradation products. This is primarily because many proximate toxicants are a metabolite or sometimes a degradation product. DTSC should think about that a bit more in case the difference results in the inability to capture a chemical of concern (e.g., where the metabolite or environmental degradation product is the proximate toxicant, not the parent compound).

5. Section 69501.2 (a)(32) Environmental Fate Properties. Should there be more effort to coordinate DTSC's list of environmental fate properties with the physicochemical properties cited in OEHHA's regulation? More physicochemical properties related to environmental fate are listed in Article 7 of OEHHA's regulation than in DTSC's Informal Regulation. We are not sure whether there is a downside to that.

6. Section 69501.2 (33) and (40). Suggest deleting "by OEHHA".

7. Section 69501.2 (a)(54) Mode of action. We have two issues with how the term is defined and with how it is being applied in the regulation. The definition of mode of action in the Informal Regulation is incorrect. The definition is more appropriate for mechanism of action. Further, in other parts of the regulation talking about cumulative effects, it appears that having the same mode of action is required before DTSC would consider effects of COCs to be cumulative. This is not appropriate and we will provide more comment below in comment 25.

The 2007 NAS report Toxicity Testing in the 21st Century (page 38) provides a general definition for the term "mode of action":

> "Mode of action. A description of key events or processes by which an agent causes a disease state or other adverse effect."

8. Section 69501.2 (a)(58) Do you want to add more physico-chemical properties than are in our Article 7? Just checking…

Comments on Article 2, Section 69502 *et seq*: Chemicals of Concern Identification Process

9. Section 69502.2: Chemicals of Concern Identification
The text identifies chemicals on specific lists as Chemicals of Concern. OEHHA suggests adding the list of California Toxic Air Contaminants, Criteria Air Pollutants, chemicals for which OEHHA has developed a Public Health Goal for drinking water, chemicals that are tropospheric ozone forming agents or stratospheric ozone depleting agents, chemicals that are greenhouse gases, and chemicals that are on Biomonitoring California's designated chemicals list. This would make the list more coherent with the definitions of adverse air quality impacts and adverse water quality impacts, and include chemicals that California deems desirable for biomonitoring that are not on the federal Centers for Disease Control's biomonitoring list.

10. Section 69502.2(a)(3) indicates that a Chemical of Concern can be one identified by any of three specified "sources of reliable information". OEHHA suggests adding Reference Exposure Level documents here. We can give you the appropriate citation. OEHHA has developed RELs that have undergone public and peer review and then been adopted by the OEHHA Director for use in risk assessments under the Air Toxics Hot Spots program. These chemicals are not all captured by the previous lists and have a number of different hazard traits including respiratory or nervous system toxicity. The REL documentation should be considered "reliable information".

Also, the third source is listed as U.S.EPA Integrated Risk Information System (IRIS) identification of carcinogens. This should not be limited to carcinogens. Here again is another reliable source that will have information on chemicals with many non-cancer endpoints. Although we have not done the comparison, it is highly likely that almost all the carcinogens for which there are risk assessments in IRIS are captured by the IARC, NTP, and other lists of carcinogens. There may be a few that were old EPA Category C that are in IRIS. You may want to use IRIS as a way to identify neurotoxicants, immunotoxicants, and endocrine disruptors. This could be done by adding "US EPA Integrated Risk Information System Reference Concentrations and Reference Doses based on neurotoxicity, immunotoxicity, or endocrine toxicity." Or DTSC could consider broadening this by adding "US EPA Integrated Risk Information System Reference Concentrations and Reference Doses based on hazard traits specified in Chapter 54, Articles 2 and 3".

11. Section 69502.2(b)(1)(A)(3): Additions to the Chemicals of Concern List. In this section, the text indicates that DTSC may identify chemicals of concern based on the potential for adverse public health impacts including "the chemical's cumulative effects with other Chemicals of Concern with similar modes of action." We suggest deleting "similar modes of action". As explained below in comment 15 chemicals do not have to have similar modes of action to have additive or synergistic effects, an important component of "cumulative" effects. This language would prevent DTSC from evaluating multiple carcinogens because they do not have the same "mode of action". Likewise, the same would hold true for other health endpoints. In a risk assessment for multiple chemicals, cancer risks are added regardless of purported mode of action. In assessing cumulative effects of non-carcinogens in risk assessment, it is standard practice to add the Hazard Quotients of chemicals acting on the same target organ regardless of mode of action. Thus, this subsection of the regulation does not comport with standard and current risk assessment practices used in California and by the EPA Office of Research and Development. Finally, we do not know the mode of action of many chemicals where we have information on the toxicological endpoints or organs affected.

Comments on Article 3, Section 69503.2: Priority Products Prioritization.

12. Section 69503.2(a)(1)(A)1.a. This section describes product prioritization criteria. The text indicates that in prioritizing products, the department will consider the potential adverse impacts from chemicals of concern's hazard traits and environmental and toxicological endpoints and modes of action. In this context, it is not clear how the mode of action would be informative.

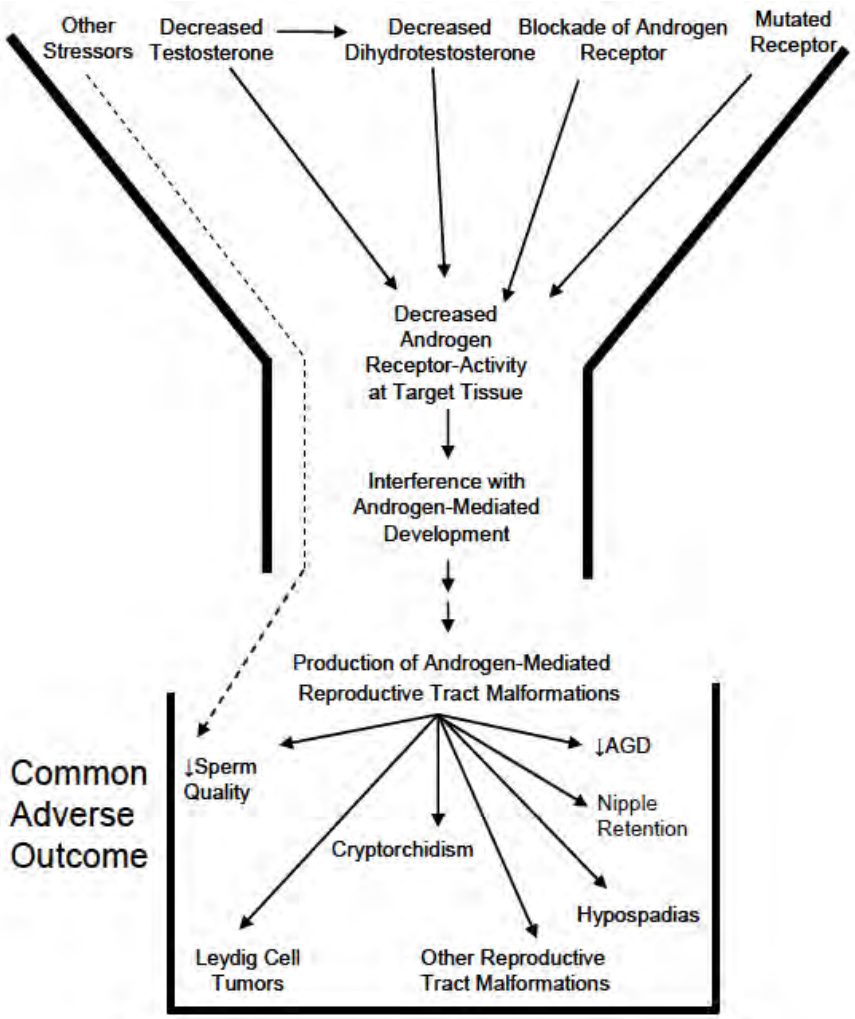
13. Section 69503.2(a)(1)(A)1.b. and c. The terms "aggregate effects" and "cumulative effects" need to be defined. It is not clear how DTSC intends to view this and whether it makes sense here. Again, the term "mode of action" is used and has the same issues raised earlier.

14. Section 69503.2(a)(1)(B)4.e. The term degradation product is introduced here for the first time in the regulation. It might be better to just have it in the definition of "chemical".

15. Section 69503.2(b): Key Prioritization Criteria. This section seems repetitive of criteria in Section 695302(a)(A)(1). It may be possible to combine these sections and use the term "key criteria" in the earlier section.

16. Section 69503.4 (b)(1) and (2): De Minimis Exemption. The text of the regulation indicates that in order for DTSC to consider chemicals of concern cumulative, the chemicals must have the same mode of action. This is problematic on a number of fronts. First, when assessing cancer risk from multiple carcinogens, a form of cumulative impacts assessment, the standard procedure is to add the risks posed by each carcinogen, regardless of the purported mode of action.

More importantly, chemicals do not have to have the same mode of action to induce similar effects. The figure below illustrates the adverse developmental effects, such as undescended testes, that can occur when the rat fetus is exposed to various chemicals that cause androgen insufficiency. This figure was taken from the NAS report "Phthalates and Cumulative Risk Assessment" (and is included in Final Statement of Reasons in the OEHHA Hazard Trait regulation).



As noted above in comment 6, mode of action refers to the processes or key events by which a chemical causes the effect. For phthalates a key early event is decreased testosterone. This decrease in testosterone precedes a series of effects in the fetal testis. (There are also a series of key steps that precede testosterone reduction by phthalates.) Other, non-phthalate chemicals can also cause androgen insufficiency and the resulting testicular effects seen with fetal exposure, but the early key events in the process can be different. For example, some chemicals can cause the same effects by blocking the androgen receptor. As noted by the NAS in the phthalate report:

> "The overall spectrum of induced malformations resulting from disturbances in androgen concentration is very similar to that resulting from disturbances in signaling. Although there might be quantitative differences in the individual malformations produced, depending on precise mechanisms or doses, the similarity in response of the androgen-dependent organs indicates that few independent pathways of response exist in relation to androgen disturbances. Thus, a developing prostate seems to respond in the same manner irrespective of the agent that lowers the concentration of a ligand, whether testosterone or DHT, or that blocks or alters signaling of the AR in the target tissue. Accordingly, the prostatic malformations induced by phthalates (which lower fetal testicular testosterone production), AR antagonists (such as flutamide and vinclozolin), mixed acting agents (such as prochloraz), and the 5α-reductase inhibitor finasteride are identical." (NAS, 2008, Phthalates and Cumulative Risk Assessment, page 55)

The major key event, decrease in androgen sufficiency, and subsequent male reproductive toxicity outcomes are similar across chemicals. Under the Informal Regulation requiring that DTSC assess cumulative impacts only of chemicals that have the same mode of action, chemicals that interfere with the androgen endocrine system and produce the same developmental toxicity in male offspring would not be considered together because early key events differ.

This problem could have a simple solution. If you use the word "or" instead of "and" in these two sentences, the problem disappears. So, we suggest that if you want to keep the mode of action concept in here, you reword the sentences as follows:
"(1) For a formulated product, the cumulative concentration in the product of all Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological endpoint ~~and~~ <u>or</u> mode of action shall not exceed the de minimis level."

"(2) For an assembled product….Priority Product listing and that exhibit the same hazard trait, or environmental or toxicological endpoint, ~~and~~ or mode of action shall not exceed the de minimis level."

17. Section 69503.4(c)(3)(A)d. The text indicates that a higher de minimis level may be specified if the chemical of concern is in the product because it is a processing intermediate, and the incidental residue is not intentional. This is counter to one of the principles of Green Chemistry, namely to use up all the reactants and avoid unnecessary intermediates. This allowance gets manufacturers to avoid improving their process and is not forward looking or technology forcing, as a green chemistry process should be.

Additional comment:

18. Section 69505.3 (b)(3)(A): Alternatives Assessment: First Stage. It may be useful to state explicitly that during the screening of alternatives, the responsible entity must collect and use available information on hazard traits, toxicological and environmental endpoints and any other relevant data to identify adverse public health and environmental impacts. If this is explicitly stated in the regulation, the responsible entity will not be able to simply look to see whether the alternative is on an authoritative bodies list or in IRIS. The responsible entity should do a thorough literature search on the alternatives and gather all available data.

(IC)63- American Chemistry Council

VIA ELECTRONIC MAIL

December 23, 2011

California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
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Sacramento, California 95812
E-mail: gcregs@dtsc.ca.gov

RE: Comments on informal draft Safer Consumer Product Regulation (R-2011-02)
October 31, 2011

Dear Mr. Woled:

The American Chemistry Council (ACC)[1] respectfully submits the attached comments relative to the Department of Toxics Substances Control's (DTSC) Safer Consumer Product Regulation, informal draft of October 31, 2011 (hereafter referred to as the "draft regulation"). ACC is a committed member of the Green Chemistry Alliance (GCA) and supports GCA's comments on the draft regulation.

We applaud Director Raphael's commitment to practical, meaningful and legally defensible regulation, and we are confident that DTSC will keep that commitment in mind as it reviews the comments received on the draft regulation. ACC has appreciated DTSC's willingness to meet with stakeholders and the substantive participation in the public process.

Our comments highlight our views and questions on issues that we believe require substantial consideration and clarification. ACC looks forward to further conversations with DTSC, and is

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy is designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $720 billion enterprise and a key element of the Nation's economy. It is one of the Nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the Nation's critical infrastructure.

willing to assist as DTSC advances with rulemaking. Please contact me if you have any questions or require clarification on any aspects of our comments.

Sincerely,

Emily V. Kolarik
Manager
Regulatory and Technical Affairs

CC: Ms. Debbie Raphael, Director, DTSC
Mr. Matthew Rodriguez, Secretary, CalEPA
Ms. Miriam Barcellona Ingenito, Undersecretary, CalEPA
The Honorable Bob Wieckowski, Member of the Assembly
The Honorable Jeff Miller, Member of the Assembly
Mr. Ken Alex, Senior Policy Advisor, Office of the Governor

Enclosures: ACC's Comments on the Proposed Informal Draft Safer Consumer Product Regulation October 31, 2011 (R-2011-02)
ACC's Prioritization Tool

ACC Prioritization Screening Approach

I. Introduction

This document provides background on ACC's approach to chemical prioritization screening. The approach is based on the following general principles:

- The purpose of this approach is to identify substances as priority to receive more detailed evaluation and assessment which, when conducted, could possibly lead to risk management measures.
- Apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Include criteria applicable to the range of chemicals being screened. Apply this principle through a two-step process rather than just those information elements available only for subsets of chemicals.
- Leverage available data and existing hazard classification frameworks already in use across industry and agreed by regulators.
- Incorporate relevant science advances where there is broad acceptance in the scientific community, e.g. improvements in how persistence and bioaccumulation considerations are addressed.
- Allow for the incorporation of significant new information to ensure prioritization decisions remain current.
- Adopt a simple, transparent screening method.
- Include opportunity for public review and comment to ensure the best available data and information is used in prioritization decisions.
- Allow professional judgment to be applied where appropriate, e.g. in hazard classification and second-tier ranking.

II. Applying Initial Screening Step in ACC's Prioritization Approach

The first step in applying ACC's prioritization approach is to apply criteria on human health and environmental toxicity potential to chemical substances.

A. Hazard Potential

The U.N. Globally Harmonized System of Classification and Labeling (GHS) was developed and internationally agreed to by many governments to provide criteria and a consistent approach for hazard classification of chemicals. It can also provide a recognized and generally accepted method for sorting chemicals in a prioritization process. The GHS framework has been used by international bodies, such as the OECD and WHO, and was endorsed by EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to support prioritization.

The GHS system applies to both human health and ecological endpoints. It includes criteria for both human and ecological health. For human health, criteria are available for both acute and chronic classifications, as well as CMR categorization. For ecological

endpoints, criteria are similarly available for both acute and chronic classification. The use of one common system allows for appropriate assessment of all substances. GHS classification information is readily available for all substances, as U.S. manufacturers have developed GHS classifications for their products to meet international requirements.

ACC's support of the GHS criteria for purposes of this prioritization tool is not a categorical endorsement of the GHS criteria for any other purpose. ACC has been an active participant in the development of GHS and supports the system in principle. The GHS has not been broadly implemented to date in the U.S., although the Occupational Safety and Health Administration (OSHA) has indicated an intent to publish a regulation applying GHS in the workplace. ACC's December 29, 2009, comments on OSHA's proposed rule to modify the existing Hazard Communication Standard (HCS) to reflect the GHS urged that implementation of the GHS adhere to certain principles (e.g., continued application of the "Building Block Approach" of the Purple Book). ACC made specific recommendations concerning details of the Hazard Classification definitions, cut-off values, among others. ACC stands behind those comments. In ACC's view, the use of GHS criteria in a screening-level prioritization of chemicals can materially assist in determining which chemicals receive additional evaluation by the Environmental Protection Agency, but does not necessarily preclude the use of other appropriate, applicable criteria developed under other systems.

To classify a chemical in a hazard based priority ranking where there is not direct data on the chemical, EPA can employ the full range of approaches, such as QSAR, SAR, read-across and other modeling tools in which EPA has confidence based on molecular structure. In those situations where there still remains insufficient information on either environmental or human health hazards, the chemical would be classified as "high" for its environmental or health ranking.

1. ***Environmental Ranking***

Table 1 provides a summary of how GHS criteria could be logically used for chemical management prioritization.

Table 1. Environmental Safety - Hazard Ranking

GHS Classification - Environmental	Ranking	Environmental Rank Score
Acute I or Chronic I or Insufficient Information to Classify	High	4
Acute II or Chronic II	Medium High	3
Acute III or Chronic III/IV or none	Medium	2
Not classified	Low	1

2. ***Human Health Ranking***

Table 2. Human Health - Hazard Ranking

GHS Classification - Human Health	Ranking	Health Rank Score
GHS CMR Cat 1a, 1b; OR Repeat Dose <= 10 mg/kg/day (oral); <= 20 mg/kg/day (dermal); <= 50 ppm/6hr/day (gas inhalation); <= 0.2 mg/l/6h/day (vapour inhalation); <= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	High	4
GHS CMR Cat 2; OR Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	Medium High	3
Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	Medium	2
Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	Low	1

It is important to note that specific concerns about children's health (specifically potential hazards and adverse effects on the nervous system) and those caused by endocrine disruption mechanisms are addressed in this prioritization process:

- The GHS CMR "R" classification includes specific evaluation of effects on development in utero and upon growth, maturation and reproduction. ("R" stands for reproductive toxicity and includes adverse effects on sexual function and fertility, as well as developmental toxicity in offspring).
- Endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a compound's ability to interact with components of the endocrine system. The prioritization process evaluates data and information on relevant apical tests, including tests for reproduction and developmental toxicity (potential

effects, which can be mediated by endocrine pathways). Thus, even if specific screening for potential endocrine activity has not yet been conducted on certain compounds, hazard identification based on observable outcomes from apical toxicity tests (e.g., outcomes such as pathologic states indicative of disease conditions) covers all modes of action, including endocrine pathways.

- The toxicity information evaluated (CMR and repeat dose toxicity) is directly relevant to evaluating potential hazards to all individuals, including children. Such data typically includes: 1) identification and definition of possible hazards upon all major organ systems from both acute and repeated exposures, including the nervous system; 2) detection of potential hazards arising from in utero exposures, including possible effects on the nervous system; 3) evaluation of potential of a substance to affect reproduction; and 4) evaluation of the potential of a substance to damage DNA.

Integration of Hazard Elements:
Each of the environmental and human health classifications is assigned a numeric value based upon its ranking, with 1 being the lowest value and 4 the highest. The greatest ranking (highest hazard potential score) of either Environmental or Human Health is used in a substance-specific priority ranking. The numeric value does not imply relative weighting, but rather a numerical order of priority.

B. Exposure Potential Ranking

The screening method allows for an initial indication of the extent of exposure potential by considering:

1. The chemical's uses and use pattern(s).
2. Production volume as a first pass indicator of relative emission/release potential since magnitude and route (i.e. air, water, soil) of emissions is not available for all substances.
3. Persistence and bioaccumulation characteristics of the substance.

Together the 3 elements are used to rank exposure potential.

1. Use Patterns

The proposed approach applies the most current 2006 TSCA Inventory Update Reporting rule (IUR, now called the Chemical Data Reporting rule (CDR) data. To keep the initial prioritization simple and transparent, the approach "bins" different use patterns to align with general exposure potential – intermediates, industrial use, commercial use and consumer use. These patterns are the same as those reported in the IUR and are consistent with REACH exposure categories (intermediates, worker, professional, consumer). Chemicals with consumer product use are likely to have widespread potential for general population exposures and are given high priority ranking within the approach. For the initial prioritization approach, child specific products are captured under general consumer products and all consumer products are weighted equally (see additional

discussion below under Second Tier Considerations). Intermediates will have low general population exposures, since these substances are consumed, by definition, within the workplace. Therefore, they are given the lowest priority ranking within the approach. In the context of the proposed approach, the intermediates category includes both intermediates and non-isolated intermediates. A chemical used in multiple use patterns is assigned the priority of the highest use, e.g., a chemical in both industrial and commercial uses would be assigned the commercial Medium-High rank.

Table 3. Use Patterns - Exposure Ranking

Use Pattern	Ranking	Use Pattern Score
Consumer	High	4
Commercial	Medium-High	3
Industrial	Medium	2
Intermediates	Low	1

The IUR Definitions of these terms are (40 CFR 710.3, 710.43):

- "consumer use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of article) when sold to or made available to consumers for their use.
- "commercial use" means the use of a chemical substance or a mixture containing a chemical substance (including as part of an article) in a commercial enterprise providing saleable goods or services.
- "industrial use" means use at a site at which one or more chemical substances or mixtures are manufactured (including imported).
- "intermediate" means any chemical substance:
    - which is intentionally removed from the equipment in which it is manufactured, and
    - which either is consumed in whole or in part in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or is intentionally present for the purpose of altering the rate of such chemical reaction(s)
- "non-isolated intermediate" means any intermediate that is not intentionally removed from the equipment in which is it manufactured, including the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

2. *Production Volume*

Recognizing that detailed exposure information will not be available for all substances to be screened, the proposed approach uses production volume as an indicator of exposure, which is widely used in many prioritization schemes. As production volume is just a rough surrogate of emissions, ACC suggests only very broad categories, covering about

two orders of magnitude each. It may be useful to consider how additional exposure estimates may be applied in the second tier assessment.

Table 4. Production Volume as Emission Surrogate - Exposure Ranking

Production Volume as Emission Surrogate	Ranking	Volume Score
>= 100,000,000 lbs national aggregate	High	4
1,000,000 lbs to < 100,000,000 lbs national aggregate	Medium – High	3
>= 25,000 lbs to < 1,000,000 lbs national aggregate	Medium	2
< 25,000 lbs (below IUR site reporting limit)	Low	1

3. Persistence and Bioaccumulation

Persistence and bioaccumulation are viewed as indicators of exposure, and therefore are considered under the exposure axis of the approach. A persistent substance that is emitted to the environment at the same rate as a non-persistent substance with similar partitioning properties will result in higher exposure to humans and the environment. In fact, multimedia modeling clearly indicates that environmental persistence in the compartment to which a substance partitions is a good indicator of human exposure potential (MacLeod & McKone et al. 2004). Similarly, substances that are not subject to biotransformation by higher organisms will exhibit a high bioaccumulation potential that results in higher exposures via the food chain (Arnot et al. 2010). Therefore, it is recommended to apply the proposed persistence and bioaccumulation criteria in assessment of exposure potential as described below.

The persistent and bioaccumulative (P&B) criteria of the proposed approach are targeted toward organic chemicals. Separate assessment criteria are likely needed for P&B evaluation for inorganics/metals, as in the approach taken by Canada's Chemical Management Program (CMP).

For assessing persistence, based upon recent expert consensus (Boethling et al., 2009) it is recommended to distinguish persistent from non-persistent chemicals using the following criteria:

- Volatile chemicals can be defined using a vapor pressure cut-off (i.e., > 1000 Pa)
    - For volatile chemicals, persistent versus non-persistent chemicals are differentiated using a half-life cut-off in air (e.g., a substance is not persistent if air half life is < 2 days).
    - For non-volatile chemicals, non-persistent substances can be defined as substances that are deemed:
        - readily or inherently biodegradable using standard biodegradation tests (OECD 301, 302, 306 test guidelines) or SAR or read across from measured data on a related substance,
        - show an equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111),

        - evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g. OECD 308/309) have half lives below 180 days, OR
        - if data are lacking, evaluation via BIOWIN model (EPIWEB 4)
    - Non-volatile substances that are not biodegradable or subject to abiotic losses based on the above criteria would be considered persistent.

For assessing bioaccumulation, the key question for screening is the potential for biomagnification based on recent expert consensus (Gobas et al. 2009). To determine if a substance has the potential to biomagnify the following metrics have been agreed:

- Trophic Magnification Factor (TMF)>1, fish Biomagnification Factor (BMF)>1, fish Bioaccumulation Factor (BAF)/Bioconcentration Factor (BCF) > 5000. These metrics can be derived using lab or field measurements (where available) or recently improved computational models that are included in EPA's EPIWEB model that can be freely downloaded at www.epa.gov/oppt/exposure/pubs/episuite.htm.

This approach allows all organics to be addressed and is a scientifically updated version of the approach used in Canada's CMP.

Based on the above recommendations, substances can be grouped with regard to persistence and bioaccumulation as follows:

Table 5. Persistence and Bioaccumulation - Exposure Ranking

Persistence and Bioaccumulation	**P&B Ranking**	**P&B Score**
Persistent and Bioaccumulative	High	5
Persistent and Not Bioaccumulative OR Not Persistent and Bioaccumulative	Medium	3
Not Persistent and Not Bioaccumulative	Low	1

Integration of Exposure Elements:

As demonstrated in the tables, each factor (use pattern, P&B, and production volume) would be assigned a numeric score based upon its ranking. All 3 factors are added to arrive at an overall value. These values are then separated into categories from low to high exposure potential. A proposed "banding" approach is illustrated in Table 6.

Table 6. Integration of Exposure Rankings

Combined Score – All 3 elements	Exposure Rank	Exposure Ranking Score
11 – 13	High	5
9 – 10	Medium High	4
7 – 8	Medium	3
5 – 6	Medium Low	2
3 – 4	Low	1

Overall Priority Grouping:
In the overall approach, both hazard and exposure elements are considered when placing a substance in a risk-based prioritization ranking. The overall prioritization score for priority grouping and risk evaluation is based on the combined consideration of the hazard and exposure rankings. Priority Groups 7, 8, and 9 are deemed High Priority; Priority Groups 4, 5, and 6 are Medium Priority; and Priority Groups 2 and 3 are Low Priority.

Review and Comment:
It is important that screening be done in an open and transparent way and that the best available information be used. When screening for thousands of chemicals, EPA may not have access to all available information. The process should provide an opportunity for review and comment on initial rankings and an opportunity to submit additional relevant data and information to update proposed rankings with improved information.

III. Second Tier Considerations:

After the initial screening, some substances within individual priority groupings may require further rank ordering, particularly where a large number of chemicals are in the same priority group. Listed below are the types of information that will be useful to consider in this Second Tier rank ordering:

Biomonitoring/Environmental Monitoring Data:
Mere detection of chemicals in humans or the environment, i.e.,"found in biomonitoring (CDC), found in water (NCOD), and found in air", while providing an indication of exposure, does not provide a useful criterion for exposure potential because almost any industrial or commercial chemical could be detected at trace levels, given increasingly sensitive analytical methods. Therefore, detection alone primarily reflects only the fact that a specific chemical was included in a measurement program. This criterion will also tend to bias the prioritization of chemicals for which well-established analytical methods are available. Consequently, this criterion is not used in the initial prioritization scheme. However, within a particular priority grouping, reliable monitoring information should be considered for Second Tier rank ordering within a quantitative process that assesses if the data is above a level of concern (i.e., places it in a risk context).

Use in Children's Products:
Protection of childrens' health is a top priority and, in the initial ranking, child-specific products are captured under general consumer products and all consumer products are weighted equally. The specific IUR reporting of information on chemical use in products intended for children would be considered further within a particular priority grouping for Second Tier rank ordering, noting the following points:

- the IUR definition is based upon use in a child specific product rather than child specific exposure potential[1] (see below). Without knowing a specific product type, it is difficult to understand if potential child exposure is greater than for a non-child specific product. For example, how does child exposure to a general use cleaner compare to exposure from use in a child's raincoat. In the VCCEP assessments, there are examples for inhalation exposures where estimates of passive child exposure during adult product use exceeded conservative estimates of child exposure during active use of a child-specific product (such as a hobby product) – differences were related to the amount of product used and substance concentration within the product (MEK VCCEP Submission).
- the IUR definition targets children age 14 and younger. Younger children may be exposed to a variety of non-child specific products that are in general household use. Older children may be exposed to a variety of additional products.
- the IUR information request is targeted to manufacturers, which may not have direct knowledge of all uses, particularly the presence in products for specific subpopulations, such as children. Therefore, it is not clear that the information requested for the IUR information would be consistently available across all substances being screened. Ideally, this information should be requested from formulators of child-specific products.

Therefore, for the initial prioritization approach, which represents a broad, unrefined categorization, child specific products are captured under general consumer products and all consumer products are weighted equally. The IUR information on child specific use would be utilized within a particular priority grouping for Second Tier rank ordering. If the IUR information is utilized, it is important that the limitations above be considered in its application.

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[1] IUR definition (Federal Register Volume 75, Number 156, Friday August 30, 2010, p. 49686): Intended for use by children means the chemical substance or mixture is used in or on a product that is specifically intended for use by children age 14 or younger. A chemical substance or mixture is intended for use by children when the submitter answers "yes" to at least on of the following questions for the product into which the submitter's chemical substance or mixture is incorporated:
(1) Is the product commonly recognized (i.e., by a reasonable person) as being intended for children age 14 or younger?
(2) Does the manufacturer of the product state through product labeling or other written materials that the product is intended for or will be used by children age 14 or younger?
(3) Is the advertising, promotion, or marketing of the product aimed at children age 14 or younger?

Emissions Data:
Production volume, which is readily available for substances, is used in this proposed approach, but only serves as a surrogate for environmental emissions. For further prioritization, data or estimates of environmental emissions can be used to refine prioritization. Estimates of environmental emissions will be available for some substances (e.g., TRI data). When TRI data are utilized it should be recognized that it addresses only emissions that result from industrial and not wide dispersive uses. In other cases, emissions estimates can be developed as a percentage of production volume based upon consideration of use categories. Within a particular priority grouping, available emissions information can be considered for Second Tier rank ordering, with the understanding that emissions information is not an indicator of actual exposure.

Similarly, non-isolated system intermediates, by definition, would have de minimis exposure potential. Therefore, this IUR information could be considered within a particular priority grouping for Second Tier rank ordering.

International Risk Management Actions:
An initial screening approach for chemical prioritization should be based upon consistent application of specific hazard and exposure science elements that define risk potential. The hazard and exposure elements should be applicable across all substances being evaluated. For initial screening, existence of international risk management action plans should not be a factor that determines priority grouping. Risk management plans may be based upon many factors, including political drivers. It is unclear how factors, their relative weighting, and the rigor of the evaluation may vary across agencies and substances. For initial screening purposes, the same science-based criteria should be used to rank all substances. Consideration of existing international risk management plans could be utilized to check the functioning of the approach and could be considered within a particular priority grouping for Second Tier rank ordering with the possible effect of moving a chemical up in a grouping if actions are being taken internationally.

IV. Summary

ACC's prioritization approach is an example of a risk-based screening prioritization process that implements the general principles outlined at the outset of this document. It is based upon widely available information that can be utilized to understand the relative priority of chemicals for further evaluation from a risk perspective, i.e., integrating both hazard and exposure elements. Implementation of the screening framework will be most effective when utilizing the best available information. When conducting screening for thousands of chemicals, EPA may not have access to all available information. An open and iterative process that includes an opportunity for review and comment on initial rankings, together with the information that led to the result, and an opportunity to update the ranking with improved information will create a transparent and scientifically sound process.

V. References

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van Wijk,D., R. Chénier, T. Henry, M. D Hernando, C. Schulte (2009). Integrated Approach to PBT and POP Prioritization and Risk Assessment, Integrated Environmental Assessment and Management, 5(4):697–711.

Proposed Prioritization Approach

DRAFT May 6, 2011

Exposure Elements				
Use Pattern	intermediate	Industrial - not intermediate	commercial	consumer
Use Score	1	2	3	4
Persistence / Bioaccumulation (PB)	not P, not B		P & not B OR B & not P	P&B
PB Score	1		3	5
Tonnage	<25,000 lbs (below IUR site reporting limit)	25,000 - <1MM lbs IUR aggregate	1MM- <100MM lbs IUR aggregate	≥ 100MM lbs IUR aggregate
Tonnage Score	1	2	3	4
SUM (Use + PB + Tonnage Scores)	range 3 -13			

PRIORITY GROUPING = Hazard + Exposure Rankings				Exposure Ranking = Based on Sum (Use + PB + Tonnage Scores)				
				3-4	5-6	7-8	9-10	11-13
				low	med-low	medium	med-high	high
Hazard Ranking = Higher Score from Environmental and Human Health Hazards				1	2	3	4	5
		Environmental Hazard	Human Health Hazard					
1	low	not classified	Not carcinogen/mutagen/repro/develop; OR Repeat Dose >1000 mg/kg/day (oral); > 2000 mg/kg/day (dermal); > 1000 ppm/6hr/day (gas inhalation); >5.0 mg/l/6h/day (vapour inhalation); > 1.0 mg/l/6h/day (dust mist fume inhal).	2	3	4	5	6
2	medium	Acute III OR Chronic III/IV ; [not acutely toxic and no chronic data]	Not carcinogen/mutagen/repro/develop;OR Repeat Dose 100 - 1000 mg/kg/day (oral); 200 - 2000 mg/kg/day (dermal); 250 - 1000 ppm/6hr/day (gas inhalation); 1.0 - 5.0 mg/l/6h/day (vapour inhalation); 0.2 - 1.0 mg/l/6h/day (dust mist fume inhal).	3	4	5	6	7
3	med-high	Acute II or Chronic II	GHS CMR Cat 2; OR GHS Repeat Dose Cat 2: Repeat Dose 10 - 100 mg/kg/day (oral); 20 - 200 mg/kg/day (dermal); 50 - 250 ppm/6hr/day (gas inhalation); 0.2 - 1.0 mg/l/6h/day (vapour inhalation); 0.02 - 0.2 mg/l/6h/day (dust mist fume inhal).	4	5	6	7	8
4	high	Acute I OR Chronic I OR insufficient information to classify	GHS CMR Cat 1a, 1b; OR GHS Repeat Dose Cat 1: Repeat Dose <= 10 mg/kg/day (oral); <= 20 mg/kg/day (dermal); <= 50 ppm/6hr/day (gas inhalation); <= 0.2 mg/l/6h/day (vapour inhalation); <= 0.02 mg/l/6h/day (dust mist fume inhal). OR insufficient information to classify	5	6	7	8	9

Hazard and Exposure Criteria for Prioritization Approach

HAZARD

Environment and Human Health Classifications based upon GHS

Environmental:

From GHS classification guidance document:

Table 4.1.2: Classification scheme for substances hazardous to the aquatic environment

Classification categories			
Acute hazard (*Note 1*)	**Long-term hazard** (*Note 2*)		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available** (*Note 1*)
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 (*Note 4*) Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 1 mg/l		

Human Health:

As above, based upon GHS

EXPOSURE

Use Elements - based upon IUR

intermediate — consumed during industrial processing
industrial (not intermediate) - used in an industrial setting
commercial — occupational use in nonindustrial setting
consumer — general population residential use

Persistence:

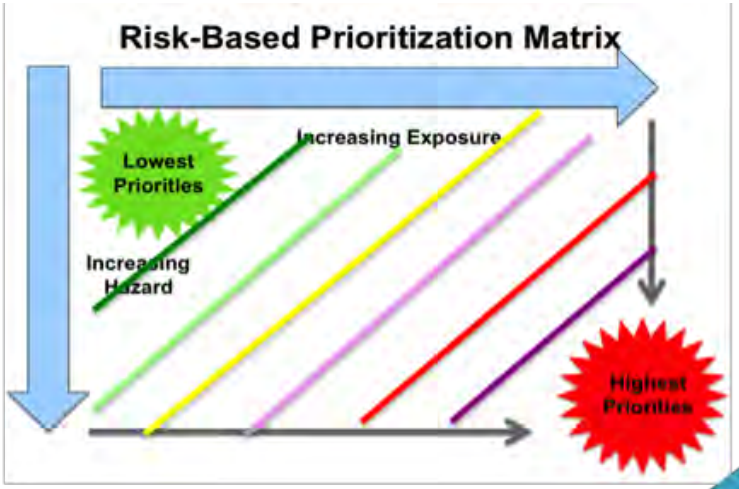
Volatile substance (VP > 1000 Pa): Not Persistent if air half life < 2 days
Nonvolatile (VP < 1000 Pa): Not Persistent if:
a) ready biodegradability (OECD 301)
b) inherent biodegradability (OECD 301, 302, 306)
c) read across from measured data on a related substance.
d) equivalent degree of degradation (i.e. >20% in 28 days) via an abiotic degradation mechanism such as photolysis (OECD 316) or hydrolysis (OECD 111)
OR, a substance is Not Persistent if:
e) evaluation of simulation data from transformation in soil, marine water/sediment, brackish water/sediment, surface water/sediment, oceanic water die away (e.g., OECD 308/309) have half lives below 180 days.
OR, if data are lacking:
f) evaluation via BIOWIN model (EPIWEB 4)

Bioaccumulation:

A substance is not bioaccumulative if:
a) measured TMF < 1 (field study)
b) measured fish BMF < 1 (lab study)
c) measured fish BCF < 5000 (lab study)
d) predicted BCF < 5000 using the BCFBAF model included in EPIWIN 4
The above order reflects the preference for use in decision-making
NOTE -- P&B CRITERIA ARE FOR ORGANICS

Tonnage - based upon IUR reporting ranges

< 25,000 lbs (below IUR site reporting limit)
25,000 - <1 MM lbs national aggregate
1MM - <100 MM lbs national aggregate
≥100 MM lbs national aggregate



Two-Step Prioritization Process

Second Tier

Rank Ordering within Priority Groups

- Biomonitoring / Environmental Monitoring
- Use in Children's Products
- Emissions (e.g. TRI)
- International Risk Management Actions

(IC)65- The American Chemistry Council

ACC COMMENTS ON THE PROPOSED INFORMAL DRAFT SAFER CONSUMER PRODUCT REGULATION October 31, 2011 (R-2011-02)

Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to comment on the California Department of Toxic Substances Control's (DTSC) informal draft of regulations to implement the statutory program to promote safer consumer products.

ACC appreciates DTSC's considerable efforts to develop an efficient and effective regulatory system and acknowledges that considerable process has been made on this informal draft as compared to the draft regulations released by DTSC in 2010.

Even in its essential elements, the draft regulation is breathtaking in its scope. By its terms, the draft applies to all manufacturers and all importers, whether or not they are located in California. The chemicals of concern list – likely to number thousands of chemicals – will be used to help identify a priority product list. Nearly all chemicals in commerce are potentially subject to identification as a chemical of concern, a status that relies solely on the hazard characteristics of the substance and not any actual risk of harm. The priority product list will contain products containing the identified chemicals of concern and from which DTSC believes there is a risk of exposures that have health, environmental, or ecological impacts. Priority products are subject to a two-stage assessment of alternative substances, designs, or manufacturing processes that might eliminate or reduce the presence of the chemical of concern. DTSC will have the authority to impose regulatory responses following the final alternatives assessment, including but not limited to a prohibition on sales. Manufacturers, importers, and retailers all have obligations under the regulation.

The current draft proposes to establish an all-encompassing program that appears to exceed the more modest intent of the underlying statute. Indeed, virtually all consumer products and their packaging will be subject to the regulation. 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, implementation of the draft will necessitate a large government program with a significant budget impact. We urge DTSC to assess the likely budget impact of the program for the State, and provide that assessment for public comment.

The intent of the underlying statute is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. ACC is concerned, however, that the proposed approach will create an unpredictable framework that will increase uncertainty in the business community. The proposal may actually endanger the vital intellectual property upon which innovation is built.

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 products or retailers to select inventory that could comply, since compliance

is an ever-shifting target in the current draft. It is critical that the draft regulation be practical, clear and concise, meaningful and legally defensible. At this stage, ACC believes the draft needs significantly more work to achieve those objectives.

ACC strongly recommends DTSC consider a more modest program designed to focus on the substances in consumer products that pose true risks for human health and the environment, based on hazard and exposure our comments outline one possible approach. We believe that a more modest approach in the regulation would address the practical problems raised by the scope and complexity of the draft. Indeed, ACC believes that DTSC should consider a pilot project in which the advantages and disadvantages of a more targeted approach could be tested and evaluated. In summary that approach would:

- Identify a relatively small, initial set of chemical substances that meet specific hazard criteria.
- Identify the consumer product uses of the substances in that set that are not otherwise regulated by federal or state law, or that have exposure and use patterns that may raise risks.
- Prioritize those substances for additional evaluation and review. ACC has developed a chemical prioritization tool that can be adapted to DTSC's use, with appropriate modifications addressing consumer product uses. A copy of the prioritization approach is attached to these comments.
- Substances not identified for further evaluation and review would be subject to no further evaluation unless additional data or information suggests the need in the future.
- Future "batches" of chemical substances could be identified and prioritized using the same approach.
- Manufacturers and importers of products would submit additional data and information on the chemical substance and its use in the identified consumer product.
- Alternative assessments would not be required by default, but only for those products (the priority products) where DTSC determines that an increased risk of harm is likely from the use of the substance in the product.

Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market. We look forward to working with DTSC in more fully articulating how such an approach might be developed and implemented.

The following areas are of particular concern to ACC and its members.

<u>Identification of Chemicals of Concern</u>
ACC commends DTSC for recognizing that chemicals are to be evaluated based on their individual use in specific products. Unfortunately, the draft does not adequately define the

objective criteria by which specific lists of chemicals might be identified and what chemicals would be listed as "chemicals of concern." It simply relies on lists compiled by a variety of governmental, intergovernmental, and academic interests to identify these substances. More problematic is that the substances on this very large list of chemicals of concern will apparently remain there for all time – even if they are used safely in consumer products. The draft thus stigmatizes chemical products on the list and is likely to result in unwarranted market impacts.

Priority Product Prioritization Process

As drafted, the regulation identifies a vague process by which DTSC will prioritize and establish a list of "Priority Products." ACC appreciates that the Priority Products list is apparently intended to be risk-based, as it requires some consideration of exposure and the potential for harm. It is unclear, however, how DTSC will objectively utilize the "Key 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 DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint.

Trade Secrets

New products and innovations in existing products can be promoted if the regulations assure the appropriate protection of trade secrets – particularly trade secrets. Given the likelihood that implementation of the program will have significant market impacts both in and out of California, DTSC should consider what modifications to the existing processes for handling and adjudicating claims of trade secrets are required.

Public Participation/Transparency

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

De Minimis Exemption Threshold

ACC supports a reasonable de minimis threshold of 0.1% (1,000 ppm). This is a threshold that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program. More importantly, it is a practical threshold that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. DTSC should limit the application of the regulation to intentionally added constituent chemicals.

Although ACC cannot support the proposed regulation as drafted, ACC looks forward to working with DTSC in the effort to develop a regulation that can be practically implemented and that is protective of health and the environment in the most effective and efficient manner possible.

I. General Comments

A. Practicality and efficient implementation should guide the development of the regulation.

The 68 pages of requirements detailed in the draft regulation constitute a complex approach to a problem that, in ACC's view, should be amenable to relatively simple solutions. In an apparent attempt to ensure that the regulation is comprehensive, DTSC has cast a wide net that implicates nearly every segment of the national economy. We believe a more modest approach is warranted given the practical challenges raised by the draft regulation.

ACC supports DTSC's primary objective to protect human health and the environment from dangerous exposures to chemical substances. Chemistry touches 96% of all manufactured goods, including the consumer products which are the target of the regulation. The federal Toxic Substances Control Act (TSCA) Inventory contains some 7,000 substances manufactured or imported in amounts greater than 25,000 pounds; and yet nearly every one of the substances is potentially subject to listing as a –chemical of concern" under this draft regulation. These chemical substances are used safely every day, in hundreds of applications. Because the draft regulation bases the listing as a chemical of concern solely on the extremely broad hazard characteristic framework developed by the Office of Environmental Health Hazard Assessment (OEHHA), DTSC may well be identifying hundreds if not thousands of chemicals that have little or no use in consumer products, or which pose no risk of harm in those uses.

Until DTSC makes an affirmative determination on the scope of this regulation and its relationship to regulations under other federal or State laws, the regulation applies to products regulated under other comprehensive systems, including the Federal Food, Drug and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Consumer Product Safety Act (CSPA), the Federal Hazardous Substances Act (FHSA), and TSCA. Even food contact packaging – otherwise regulated nationally by the Food and Drug Administration – is subject to the draft regulation.

The draft regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans to be made publicly available. While there is a public interest in information about the constituent substances in consumer products, it is also clear that there are legitimate commercial interests in such information that should be protected. ACC is particularly concerned that DTSC will not have adequate staff resources to properly process, adjudicate, and manage the volume of information that will be reported under the proposal. In addition, DTSC needs to be mindful about how the information is communicated to the public. The draft regulation will have little value if it simply creates unwarranted consumer anxiety about chemicals (e.g., suggesting a risk of harm where none exists), or imposes regulatory requirements that have marginal impact on health and environmental protection beyond that provided by existing labeling, warning, and use restrictions.

The broad scope and complexity of the regulation is exacerbated by an approach that suggests that any information, regardless of its quality or relevance, can be the basis for listing a chemical

of concern. It is a general principle of hazard assessment that all available data must be considered and the totality of relevant and reliable information integrated in order to arrive at a scientifically defensible decision regarding chemical hazard. Since, in many cases, dozens of toxicological studies will be available for review on any given chemical, the only valid scientific approach is to consider the weight of the scientific evidence. A scientifically sound weight of the evidence analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies.

Unfortunately, a weight of the evidence approach is missing from the draft regulation. Without it, the proposed regulation can be interpreted to suggest that a single study, regardless of its quality (and irrespective of other available relevant data), could be used to conclude that a chemical possesses "suggestive evidence" of a specific hazard.[1] The framework that DTSC and OEHHA should employ must provide for a transparent, scientifically-based evaluation of the overall weight of evidence that there is a *causal* relationship between an outcome of concern and exposure to a substance. We urge DTSC to articulate how weight of the evidence will be included in the various decision making opportunities described in the regulation, and particularly with regard to prioritizing chemicals of concern and prioritizing products.

DTSC proposes to consider aggregate and cumulative effects as part of the chemical identification and the priority product prioritization process. ACC is concerned that it is highly impractical to require such an analysis for all chemicals of concern or all priority products. Assessing aggregate effects and risks from the total exposure to a specific chemical from all different sources and routes requires considerable data and information that manufacturers of individual products do not have and cannot readily obtain. Aggregate assessments should only be required on a case-by-case basis for chemicals that meet certain criteria (e.g., cases that present a very narrow margin of exposure).

The assessment of cumulative effects or risks – the evaluation of a common toxic effect from a concurrent exposure to a group of chemical and non-chemical risks that act in the same way poses even greater challenges. Cumulative risk assessment is far from settled science. As with aggregate effects, scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. Cumulative risk assessment requires manufacturers to look at all the adverse effects caused by the chemical in question, and to evaluate all other chemicals that cause the same adverse effects (not just those in humans, but also in animal studies where doses are typically hundreds, thousands or even tens of thousands of times higher than humans ever experience). In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

The draft regulation does not mention small businesses or acknowledge the compliance challenges that small businesses would face as a result of the draft regulation. While ACC believes that all responsible parties should be held to the same standards, the Administrative Procedures Act requires DTSC to include within the Initial Statement of Reasons a "description of reasonable alternatives…that would lessen any adverse impact on small businesses"

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[1] OEHHA Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).

(Government Code §11346.2(b)(3)(B)). We look forward to a more adequate explanation of how DTSC proposes to adopt alternatives that will take into account impacts on small businesses.

The draft also raises an interesting question about DTSC's grant of authority to impose regulatory restrictions, which DTSC should address. Clearly, the underlying statute permits DTSC to adopt regulations to establish criteria for identifying and prioritizing chemicals of concern and to develop criteria to evaluate them and their alternatives in consumer products (Health and Safety Code §§25252-25253(a)(1)). Additionally, the statute authorizes DTSC to adopt regulations that ~~"s~~pecify the range of regulatory response that the department may take following the completion of the alternatives analysis" (HSC §25253(b)).

However, the legislative analysis of the final version of AB 1879 prepared by the Senate Committee on Environmental Quality, dated August 20, 2008, recognized that developing a range of regulatory responses DTSC ~~"m~~ay" take does not actually give DTSC a grant of authority. The Committee Analysis notes that while the language found in HSC §25253(b) ~~"a~~ppears to give the department the authority to take listed actions, this is not explicitly and clearly stated in the bill. Usually, an administrative agency is given authority by the Legislature to take some action and then the authority to adopt regulations to implement the authority."[2] Given that Article 6 of the draft regulation assumes express authority to subject regulated responsible entities to product information disclosure requirements, end-of-life management schemes, product bans, and a range of other potential regulatory responses, we recommend that DTSC obtain a clarification from the Attorney General's office on the scope of the grant of authority, and then provide stakeholders with an understanding of how the Agency will exercise its authority accordingly.

B. <u>The chemicals of concern list should be based on specific criteria.</u>

DTSC's approach to identifying chemicals of concern (CoC) is troubling in several respects. Notably, DTSC would develop a list of thousands of CoCs, but once listed, no chemical would apparently be taken off the list, even if it is not used in consumer products or is used safely in such products.

The draft indicates a welcome willingness to revise the CoC list in order to reflect the most current credible scientific evidence. DTSC staff has indicated in public venues that the intent is to allow for both additions and deletions to the list, but we do not read the ability to delete into the provisions related to the list or in the public petition process. To better reflect DTSC's intention, the draft should be amended to allow DTSC to periodically <u>revise</u> (not simply ~~"e~~xpand") the list of substances. This intention could be further advanced by DTSC's focus on small batches of chemicals meeting specific hazard criteria, as ACC has suggested.

The underlying statute explicitly mandates DTSC adopt regulations that ~~"e~~stablish an identification and prioritization process that includes, but is not limited to, all of the following considerations:

[2] http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080821_111017_sen_comm.html.

(1) The volume of the chemical in commerce in California.
(2) The potential for exposure to the chemical in a consumer product.
(3) Potential effects on sensitive subpopulations, including infants and children.[3]

These criteria apply both to ―chemicals or chemical ingredients in consumer products.” It is not clear how the approach described in the draft regulation fulfills these criteria.

Objective chemical selection criteria should be used in the regulation, rather than adoption of a ―list of lists” developed by other bodies. If DTSC nevertheless decides to adopt a list-based approach, it is critical that any such lists be developed by authoritative bodies. In ACC‘s view, authoritative bodies include government agencies and formal scientific organizations that:

- Characterize chemicals in an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- Are widely perceived to be objective, scientifically based, and do not engage in advocacy.
- Base chemical characterizations on a weight-of-the-evidence approach. To the extent available, authoritative bodies consider multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and give full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
- Publishes their characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

The confidence of the public and the regulated community in the regulation will be enhanced if DTSC can assure that appropriate processes and the best scientific data available inform the list.

A number of the lists in the draft regulation are not appropriate for use, as they are secondary sources of information. These include: the International Agency for Research on Cancer‘s (IARC) 2B list (―possibly carcinogenic chemicals” for which there is acknowledged to be inadequate evidence of carcinogenicity in humans); the California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity, a secondary source that does not provide additional information as it draws from Proposition 65 and IARC; the EU‘s Directive on Dangerous Substances (Directive 67/548/EEC), which has been superseded by the EU‘s EC 1272/2008 Annex VI; and the OSPAR List of Chemicals for Priority Action, which was compiled by a contracted party and without stakeholder input.

C. <u>DTSC should clarify its information collection process and solicit stakeholder input</u>

The draft regulation outlines the ways in which DTSC may collect information ―that it determines is necessary” on both chemicals and products. Although DTSC could use one or

[3] HSC §25252(a).

more of the proposed data collection methods, we believe a better approach is to ensure the process unfolds in a sequential, tiered manner. DTSC should begin its collection effort with information in the public domain that is readily available in a useable format, followed by information in the public domain that is available by subscription then followed by requesting data from chemical manufacturers or importers.

The final step should be used only as a last resort if the information obtained in earlier stages is insufficient to make a prioritization decision or to evaluate an alternative, particularly since the quality and availability of information on chemicals that is now available electronically has markedly increased. DTSC should clarify that the regulation is not intended to require new testing. DTSC should also better define the conditions under which information will be deemed necessary, and allow stakeholder input on them.

D. <u>The priority products determination process should be objective, and based on scientifically-valid criteria.</u>

The proposed "narrative standard" for the prioritization process (Article 3 of the draft) creates some significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the draft does not articulate a clear, step-by-step process, creating uncertainties about the scope of the prioritization list. The draft indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC might, in fact, use to reach a decision.

The proposal also expressly applies to products that "may" be placed on the California market, but that term raises considerable uncertainty about the scope of the program. ACC suggests DTSC limit the scope of the regulation to those products that are actually placed into the stream of commerce in California.

The draft regulation lays out multiple criteria to be used in prioritizing products for review, with products meeting "one or more" of the key criteria to be considered priorities. The regulation should be clarified to focus, at least in the first few years of the program, on products that meet all three criteria (as high priorities), an approach that is consistent with the statute.

From the draft, it appears that the key prioritization criteria are secondary to the longer list of other criteria that precedes the "Key Criteria" (§69503.2). DTSC should clarify the relationship between the key criteria and what is better characterized as supporting evidence.

The incorporation of "potential adverse impacts and exposures" as criteria for prioritization is an important addition to the proposal, and helps to ensure a risk-based approach in the implementation phase. Information on reasonable and foreseeable exposures during the manufacture, useful life, and end-of-life phases is routinely collected and analyzed by consumer product manufacturers.

Other information DTSC proposes to use, however, is too ambiguous and may not be appropriate as part of this exercise, or may be claimed as confidential information. The regulation states: "The Department shall consider the potential adverse public health and environmental impacts…" associated with a number of hazard and exposure scenarios. This information may be extremely diffuse, poorly defined or difficult to obtain, reliably, so the department can consider it.

For example, the proposal specifies that DTSC shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for children, pregnant women, and other sensitive subpopulations. ACC agrees that certain demographics, primarily children, should be given distinct consideration. However, the term "sensitive subpopulations" as defined by DTSC in the draft regulation is a vague and highly subjective term ("including but not limited to" §69501.2(a)(72)) that may include different demographics or conditions depending on the context.

In many cases it will be difficult to obtain product exposure information relating to "manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices." The draft regulation seems to expect consumer product manufacturers to have comprehensive manufacturing, use, distribution, and disposal data for every unit of its product. This is not a practical expectation. It becomes increasingly difficult to monitor the exact movement of products once they are sold to distributors and to primary and secondary retailers.

Similarly, with the exception of a few product categories, most consumer products find their way to a landfill or recycle stream at the end of their useful life, although it is often difficult to track the exact path of the product. As DTSC is surely aware, end of life management practices are commonly predisposed by municipalities in which the products reach the end of their useful lives, rather than by manufacturer or retailer plans. A manufacturer would clearly not know that location at the time of production or sale. The regulation should hold regulated entities accountable only for information that is reasonably obtained.

The inclusion of workers and worker exposure as part of the product prioritization process requires more consideration by DTSC. ACC believes it is appropriate to consider worker exposure in a retail setting, or perhaps worker exposure to products used in schools or hospitals. ACC questions whether DTSC has the authority to request information about workers a) in California – different from CalOSHA requirements; and b) regarding workers outside of the state.

The draft indicates DTSC will consider the availability of reliable information to substantiate potential adverse impacts and exposures in the prioritization process. ACC believes that DTSC should also consider reliable evidence that refutes potential adverse impacts or exposures.

E. <u>Appropriate recognition and protection of trade secrets is necessary to promote innovation</u>.

DTSC has been clear that one of its objectives in the regulation is to promote innovation in consumer products to reduce or replace the presence of substances, in those products, considered to pose a risk of harm. DTSC has taken important steps to protect sensitive commercial information from disclosure in the draft, but the sheer complexity of the process may undermine achievement of DTSC‘s stated goals. As drafted, the regulations could actually hinder innovation.

The proposal requires that entities submit information supporting any claims of trade secrecy protection. In many instances, however, DTSC should be able to make a trade secrecy determination using only the publicly available information provided in the initial submission and will not have to review and protect any portion of the initial submittal. ACC supports this streamlined approach, which could reduce costs and lead to more efficient trade secrecy determinations. We recommend that DTSC adopt this process. If DTSC cannot make a determination based on the initial disclosure, it will be able to obtain additional supporting information -- including information claimed as trade secret -- through a supplemental request. That section is discussed in greater detail below. ACC‘s specific recommendations for changes to the provisions on trade secrets and confidential information are included in Section II, below.

However, ACC is also concerned that DTSC may be unable to adequately protect sensitive commercial information, particularly supplemental information received by DTSC. The draft clearly states that trade secret supporting information ―shall not itself require further supporting documentation.” DTSC‘s ability to withhold information it receives is limited by the California Public Records Act,[4] which does not allow agencies to withhold information merely because they did not require the submitter to provide ―further supporting documentation” for that information. The risk is that, as drafted, the proposal will not actually permit the protection of supplemental supporting information actually submitted in support of a claim.

ACC also cautions against requirements to submit large quantities of potentially sensitive personal and business information to support alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program.

F. Transparency in DTSC‘s implementation process is critical.

The success of DTSC‘s regulation depends in large part on the degree to which the compliance and decision making processes are transparent. It is good practice to require DTSC to respond to any and all substantive public comments, but the draft lacks this basic process protection. For example, the CoC process allows DTSC the discretion to respond to ―some or all” public comments received on revisions to the list. Regulated entities materially affected by DTSC‘s decisions, and the public, should be able to understand the basis for the decisions, and DTSC‘s reasoning in accepting or rejecting particular recommendations, data, and/or information.
The proposed regulation includes a petition process to identify a chemical as a concern or to prioritize a consumer product. Unfortunately, the petition process does not appear to be open to public review and comment. Similarly, there is no process to petition for the removal of a

[4] Cal. Govt. Code §6250 *et seq*.

chemical or product, even when new information suggests that the substance or product should not in fact be listed. DTSC should provide for public review and comment on all petitions received by DTSC.

G. The de minimis exemption should be revised.

The proposed regulation appropriately recognizes that very small or trace quantities of chemicals in certain consumer products should not trigger full application of the alternative assessment or other regulatory restrictions. The proposed de minimis threshold level, however, is out of sync with that used by other federal and international agencies. ACC strongly recommends that the de minimis concentrations be harmonized with those applied by other federal and international agencies.

The de minimis threshold proposed by DTSC applies a ten-fold safety factor to the levels applied under other programs. For example, the federal Occupational Safety and Health Administration (OSHA), the Globally Harmonized System for Classification and Labeling (GHS), and the European Union‘s REACH standard apply a de minimis threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens and reproductive toxins. The proposed DTSC regulation in contrast adopts a de minimis threshold of 0.1% for hazardous chemicals and 0.01% for CMRs and PBTs. Satisfying these de minimis exemption requirements will be a significant challenge for product manufacturers. At a minimum it suggests that considerable product testing will be necessary to make the demonstration required to claim the exemption. The degree to which small and medium sized businesses, much less importers and retailers, would have access to and resources to put toward the degree of materials analysis DTSC requires is questionable and impractical. In addition, ACC strongly recommends limiting the scope of the regulation to intentionally-added constituents to better focus the regulated community and DTSC‘s oversight on CoC intentionally added to priority products.

ACC agrees with the proposed approach that would give DTSC discretion to establish a higher de minimis threshold. The process should recognize potential for contaminants in recycled materials without inhibiting the use of recycled content, the necessity for using processing agents, and that in some cases the CoC cannot reasonably be removed from the product (and that its presence does not cause potential for adverse impacts DTSC should clearly identify the criteria by which it will determine that a new threshold level is required, and the information or data required justifying that level.

II. Comments on Specific Provisions

Article 1. General

ACC agrees that the purpose for identifying chemicals as CoCs, and identifying Priority Products that contain CoCs for alternatives assessment, is to determine how best to limit exposures or the level of adverse impacts posed by the CoC in a Priority Product. In the Purpose and Applicability section, as well as throughout the draft regulation, an approach is proposed that

explicitly refers to ―potential exposures" and ―potential adverse impacts" (§69501). ―Potentiality" is a nebulous concept that will prove to be difficult to objectify in terms of regulatory compliance. A more objective, practical approach would be ―reasonable and foreseeable exposure pathways" or ―foreseeable adverse impacts," which limit the scope to the intended use of the product and to uses that might reasonably be anticipated by manufacturers and factors that are reasonably within their control. We believe that ―reasonable and foreseeable" should be incorporated throughout the draft regulation.

ACC agrees with the proposed exemptions noted in §69501.1(b)(2), (3), and (4). However, it is unclear how §69501.1(b)(4)(A)(2) will function in practice. How can responsible entities know, prior to regulation under the Safer Consumer Product regulation, whether their product, already regulated by one or more federal and/or other California State regulatory program(s), provides a level of public health and environmental protection that is equivalent to or greater than the protection that would be provided if the product was listed as a Priority Product? Moreover, the language in the draft regulation is much narrower than what is provided for in the authorizing statute. HSC §25257.1(c) states that ―t[]he 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." Thus, if a product category is regulated by a federal or state agency for the same reason(s) that caused it to become a Priority Product (i.e., potential human health or environmental impact) under the draft regulation, the Priority Product should be automatically exempt from regulation. The statute does not authorize DTSC to adopt and enforce the ―equivalent to or greater than" standard in §69501.1(b)(4)(A)(2), and as such the language should be removed.

§ 69501.2. Definitions

Adverse Ecological Impacts (§69501.2(a)(3)). It is unclear what DTSC would consider an indirect ―a[]dverse ecological impact." If the intent of distinguishing between direct and indirect effects stems from the ecological literature on direct and indirect interactions among members of ecological communities, DTSC should be clear in that regard and define the concept of ―indirect" more thoroughly. Such clarity is needed for the regulated community to understand what DTSC will consider an ―indirect" adverse ecological impact.

Alternative (§69501.2(a)(9)). ACC 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 public health and/or environmental exposures as part of the definition of ―alternative." 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. Product improvement is not an all-or-nothing game.

Assembled Product (§69501.2(a)(12)). The proposed definition of ―assembled product" requires further clarification. It is unclear, for example, whether ―heterogeneous product consisting of two or more components" includes packaging or the top of a bottle. DTSC should clarify what is meant in this and similar regards.

Persistence and Bioaccumulation (§§69501.2(a)(55) and 69501.2(a)(14), respectively). In the spirit of drafting regulation that is practical, meaningful and legally defensible, DTSC should make an effort to utilize definitions that are widely accepted at the federal and/or international level and that employ specific criteria. ACC is concerned that the definition for ―Persistence" and ―Bioaccumulation" are novel California definitions and depart even from the proposed definitions in OEHHA‘s Green Chemistry Hazard Traits. The conflict 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. We suggest that DTSC adopt the definition outlined by U.S. EPA as part of an EPA policy statement titled, ―Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances," or the more recent definitions of ―persistence" and ―bioaccumulation" developed by the SETAC Pellston Workshop in 2009.[5]

Functionally Acceptable (§69501.2(a)(38)). ACC agrees with the proposed definition of ―functionally 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.

Reliable Information (§69501.2(a)(66)). The proposed definition of ―reliable information" correctly includes the OECD‘s and the U.S. Food and Drug Administration‘s Good Laboratory Practices, TSCA Testing Guidelines, and OECD Guidelines for Testing Chemicals. Industry has repeatedly called for an information quality standard based on reliability, relevancy, and adequacy of data and other information. However, the definition also misses necessary quality concerns. Three proposed ―reliable" sources do not share the same scientific standing as the others: §69501.2(a)(66)(C), i.e., ―published in scientifically peer reviewed reports or other literature;" §69501.2(a)(66)(E), ―published in reports by…state and local agencies that implement laws and programs governing chemicals;" and, §69501.2(a)(66)(F) ―developed by a state agency, or local agency for compliance or other regulatory purposes." Single reports in even the peer-reviewed literature do not constitute a weight-of-evidence evaluation of hazard or exposure. More often than not, state and local agencies adopt chemical legislation and regulation that may not be based on scientific principles and characteristics, such as risk and exposure; rather, they adopt a list of unknown provenance. State and local agency decisions are often made without scientific peer review or in accordance with internationally accepted scientific frameworks, methods, or standard. Therefore, they should not be afforded the same level of deference as federal and international chemical management regimes without DTSC‘s consideration of the underlying technical basis and quality of the work.

In addition, while ACC considers the proposed inclusion of biomonitoring data to be appropriate, it is imperative that the data come from an authoritative source, such as the Centers for Disease Control and Prevention‘s National Health and Nutrition Examination Survey, rather than arbitrary ―other biomonitoring data" as stated in §69501.2(a)(67)(D). The inclusion of ―other

[5] http://epa.gov/oppt/newchems/pubs/pbtpolcy.htm; and Boethling et. al., Environmental Persistence of Organic Pollutants: Guidance for Development and Review of POP Risk Profiles, 2009; and Gobas, et. al. Revisiting Bioaccumulation Criteria for POPs and PBT Assessments, 2009, respectively.

biomonitoring data" means that any individual study, regardless of appropriate methodology, interpretation, or representativeness, that can claim to show a chemical to be present in human organs, tissues, or fluids will be given the same level of consideration as the federal and California State data. ACC recommends that the language "or other biomonitoring data, that show the chemical to be present in human organs, tissues or fluids" be struck from the draft regulation.

Finally, "reliable information demonstrating the occurrence, or potential occurrence of exposures" should not include merely being "present in...products used in…the home," as this condition will always be satisfied for purposes of a statute that governs consumer products. Further "presence" in a product is in the absence of other factors, not an indication of potential exposure, a reality acknowledged by U.S. CPSC in its consideration of whether components are accessible or subject to extraction, among other factors. ACC recommends that DTSC strike §69501.2(a)(67)(b), as it is at odds with the risk-based statute.

Responsible Entity (§69501.2(a)(68)). Regarding "Responsible Entity," ACC suggests that DTSC adopt a definition of "manufacturer" that is consistent with the 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 "manufactured for" or "distributed by." It is practical for DTSC 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.

Safer Alternative (§69501.2(a)(70)). ACC agrees with the proposed definition of "safer alternative," which requires the comparison of the existing Priority Product to the alternative and in so doing, allow for a reduction, avoidance, or elimination of the use of, and/or exposure to, one or more CoC. We agree with the recognition of a risk-based approach to the definition of "safer alternative."

Sensitive Subpopulations (§69501.2(a)(72)). The definition of "sensitive 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 "including, but not limited to…" inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of "sensitive subpopulations" in ways that the regulated community cannot anticipate. Has the Department identified what proportion of the population -- at least a range -- might be considered sensitive? If the entire population is sensitive, none of it is. DTSC should carefully review the draft regulation for such instances of open-ended language in this and other sections, giving careful 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.

Technologically and economically feasible alternative (§69501.2(a)(74)). ACC agrees with two of the three proposed criteria for defining a ―technologically 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;" and, ―(C) The alternative does not increase aggregate externalized costs to consumers, public health and the environment." The remaining criterion, §69501.2(a)(74)(B), appears to require DTSC 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 ―reasonable 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 DTSC. In practical terms, if the manufacturer chooses an alternative it is because he or she has made the determination that the return is adequate. This should be dropped as a criterion.

§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, DTSC should use the provisions of the federal FPLA, which mandates there be a single responsible entity in lieu of the current ―responsible 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.

ACC 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 DTSC that demonstrates that the product-chemical combination is no longer placed into the stream of commerce in California. However, DTSC is proposing to require that the notice include ―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). DTSC should grant some flexibility in this area to reflect the complex nature of today‘s global marketplace.

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

§69501.4. Information Submission and Retention Requirements

ACC is troubled by the proposed requirement to have all information submitted to DTSC 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)). ACC agrees that this is likely to draw the attention of upper management, but it is unreasonable and unnecessary, as DTSC itself 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 certify something that is by definition out of his or her control.

ACC suggests DTSC edit §69501.4(c), striking "person," and replacing it with ―responsible 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.

§69501.5. Chemical and Product Information

Section 69501.5 of the draft regulation outlines the ways in which DTSC may collect information ―that determines is necessary" on both chemicals and products, and ACC largely agrees with the proposal. The proposal for information collection is outlined in four steps, which ACC believes should be a sequential, tiered process. ACC agrees that DTSC 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, ACC finds use of the term ―necessary" 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 DTSC‘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 ―necessary to fill a blank in the Toxics Information Clearinghouse?" DTSC 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 DTSC‘s ―satisfaction that it does not have and is unable to produce the requested information" or, DTSC 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? DTSC should provide further clarity.

§69501.6. Availability of Information on the Department’s Website

It is apparent that DTSC is proposing to provide an unprecedented level of information about products, chemicals, and manufacturer‘s business plans to the public, public interest groups, competitors, and retailers. Overall, ACC is concerned that DTSC will not have adequate staff resources to properly process, adjudicate, and manage the volume of information that will be reported under the existing draft. DTSC should also be mindful how the various forms of information are communicated to the public, notably ACC recommends that DTSC 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

In §69502.2(b)(4) DTSC appears to be attempting to streamline the availability of ―safer alternative chemical[s]” and product prioritization. First of all, it is not obvious to ACC how DTSC will determine that a chemical is a ―readily available safer alternative chemical that is functionally acceptable” for any application. Presumably, this refers to some hazard trait DTSC 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.

Nor does the ―safer alternative” provision account for the possibility that an ―alternative” may include ―reformulation 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, ―redesign 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 DTSC could adjust prioritization merely by ―considering” 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 ―safer alternative” or struck.

Article 5. Alternatives Assessments

§69505. General Provisions

ACC 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 DTSC 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 proposed requirements for the Preliminary and Final AA Reports are straightforward, but the determination of due dates for these reports is unclear. The responsible entity must submit the Preliminary AA Report within 180 days of listing the product on the final Priority Product List, *unless* DTSC specifies a different due date (§69505.1(a)(3)(A)). Not only will this have the unintended consequence of adding a layer of uncertainty, but DTSC‘s potential reasoning for

altering the Preliminary AA Report due date is not explicit. DTSC should list potential foreseeable conditions that could cause it to shorten or extend the due dates in order to add clarity to the compliance process.

The draft regulation outlines where alternatives assessments are unnecessary and not required (§69505.1(b)(1) – (3)). ACC agrees with and supports all of these exemptions as being consistent with the intent of the authorizing statute. ACC recommends that DTSC incorporate the following as two additional instances where alternatives assessments are unnecessary:

> a) An alternatives assessment is not required if the responsible entity determines that the Chemical of Concern is not necessary for the product to continue to meet function, performance, technical feasibility, and legal requirements and certifies within 60 days of notifying the Department of its determination, its intent to stop using the Chemical of Concern in the Priority Product and will not use a substitute chemical in place of the Chemical(s) of Concern that is the basis for the priority product designation. The manufacturer must confirm that it has begun the process of removing the Chemical(s) of Concern that is the basis for the priority product determination no later than 120 days after the date the manufacturer notified the Department of its intent; and
>
> b) An alternatives analysis is not required if the responsible entity replaces the Chemical of Concern that is the basis for the Priority Product determination with a substitute chemical that has been determined by a deliberative scientific process conducted by a state, federal or international agency or organization to be safe, or, in lieu of a safety determination, has been determined by a deliberative scientific process run by a state, federal or international agency to not exhibit the toxicity trait(s) that caused the Chemical of Concern to be on the Chemical of Concern List.

Thus, elimination of the CoC without replacement, or replacement with a non-CoC, given appropriate notification of the action to DTSC, should not require an alternatives assessment.

The timing of the alternatives assessment process is crucial, for both the responsible parties and DTSC. Section 69505.1(c)(3), and §69505.1(g) propose that although responsible parties must comply within a specified number of days, failure by DTSC or by the Director, respectively, to issue a decision or respond to an appeal, does not constitute an approval of the extension request nor does it cause a Preliminary or Final AA Report to be deemed compliant. In effect, it is possible that DTSC could simply never provide a response and proceed to seek out companies with a now ~~"v~~iolating" product on the shelves, because the request was not answered within the 30 day statutory response period. It is not appropriate for responsible entities to be held liable if DTSC fails to provide a response within the statutory timeframe. Doing so is unfair to any responsible entity acting in good faith whose further work is contingent upon a determination by DTSC.

§69505.3. AA First Stage: Steps 1, 2, 3, and 4

ACC agrees with the proposed staged process that identifies the necessary functional, performance, and technical qualities that must be present in the alternative(s), funneling down to a subset of processes and chemical options. Additionally, ACC agrees with the draft regulation's use of separate Preliminary and Final AA Reports, the final report focusing on a comparative assessment at the product level, integrating all relevant factors of the alternatives assessment.

Clarity is requested for §69505.3(b)(3)(C)(2). It is unclear what is meant by "greater and lesser individual adverse impacts," in both instances in the following subpart:

> "Subparagraph 1. does not apply to a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern. However, a responsible entity is not required to retain, for further consideration in the AA, a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern."

We simply do not understand what that means or how a responsible entity would comply with it in the context of step 3, and would appreciate DTSC's clarification.

§69505.4. Alternatives Assessment: Second Stage

The Second Stage of the alternatives assessment proposes a step to identify factors relevant for comparison of alternatives. This reference to "relevance" is somewhat arbitrary. It is unclear what is meant by a "demonstrable contribution," and "demonstrable difference," in §§69505.4(a)(1)(A) – (B). The language of the underlying statute, AB 1879, outlines the goal of significantly reducing adverse impacts,[6] and therefore we recommend that "demonstrable" be replaced with "significant." Also, having to bring forward to the Phase 2 process any factor with *any* variation or deviation from the Priority Product is inconsistent with a practical approach.

Furthermore, the draft regulation proposes that "[t]he responsible entity shall collect and use available quantitative information, supplemented by available qualitative information and analysis, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives…," referring to the multimedia life cycle impacts and chemical hazards (§69505.4(a)(2)). We would like to ensure that quantitative analysis (e.g., QSARs) is not precluded. Therefore, we suggest the following edits, "[t]he responsible entity shall collect and use available quantitative information **and analysis tools**, supplemented by available qualitative information and analysis…"

Section 69505.4(a)(2)(A) proposes to require responsible entities to collect data on multimedia life cycle impacts and chemical hazards, for *chemical ingredients known to be in the Priority Product and the alternatives being considered…*"[7] This language expands the boundaries of the alternatives assessment beyond the CoC/Priority Product combination and its potential alternatives to include all chemical ingredients known to be in the Priority Product and its

[6] HSC §25255(a).
[7] Emphasis added.

alternatives. This kind of "scope creep" is inconsistent with the purpose of the statute. The focus of the alternatives assessments should be the CoC/Priority Product pair and its alternatives. This section should be revised to be consistent with the rest of the alternatives assessment process.

ACC disagrees with the extremely low threshold set in the definition of "economic interests" (§69501.2(a)(28)). DTSC 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. DTSC only needs to assure that an accrediting body does not have a material economic interest in certifying alternatives assessment assessors. ACC recommends §69501.2(a)(28) be revised 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…[8]

Also, regarding the assessment of externalized costs (§69505.4(a)(2)(C)), "externalized costs" is not defined, which may cause confusion for responsible entities. Consumer product manufacturers utilize different methods for calculating cost-benefit analyses and thus have different considerations and frames of reference. We believe it is in DTSC's and responsible parties' best interests to explicitly define what is required for a calculation of externalized costs, what methodologies should be consulted, and what these costs include. Without such direction, in the regulation, DTSC determinations on the adequacy of consideration of "externalized costs" will be vulnerable to challenge.

§69505.5. Alternatives Assessment Reports

ACC cautions DTSC 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.

Article 6. Regulatory Responses

§69506.1. AA Report Supplemental Information Requirements.

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

ACC understands the potential need for further information in order to accurately determine an appropriate regulatory response. Subparts (a) and (b) of §69506.1 are almost identical. We suggest that DTSC strike §69506.1(b) from the draft regulation and that DTSC provide further clarity regarding the time period during which the responsible entity shall respond. Subpart (a) proposes to allow DTSC full discretion regarding the time a responsible entity has to respond, without any indication of how this determination would be made. We request that DTSC provide objective criteria for this determination.

§69506.4. End-of-Life Management Requirements.

―Total tonnage," or ―tonnage" is an unrealistic metric conveying little meaning in this instance (§69506.4(a)(2)). The draft proposes that every two years after an end-of-life program is initiated the responsible entity will provide DTSC with the ―total tonnage" of product placed into the stream of commerce in California over that period. This is unrealistic for two reasons. First, not all product deliveries will be easily measurable in ―tonnage" – this is especially true for assembled products - or ―tonnage" may be meaningless considering the potential routes of exposure. Second, very often consumer product manufacturers may not have sufficient clarity of the movement of their products after the product is sold to the next level of the supply chain and thereby will only be able to estimate the amount of product in the stream of commerce in California.

ACC agrees with the provision proposed in §69506.4(d) that there will be times when an end-of-life management program cannot feasibly be implemented for the product. DTSC should define what is considered ―feasible" in this case. Without better articulation of the term it will be left to interpretation on a case-by-case basis at each point in time.

§69506.5. Product Sales Prohibition.

The draft regulation proposes a specific timeframe during which responsible entities must comply with DTSC's notice of a product sales prohibition. The draft regulation, also affords DTSC an unstructured ability to specify shorter periods of time during which responsible entities must cease to sell the product within California. There is no specification as to when, why, or under what circumstances a shorter period may be required, and there is no limit to the amount of a change that can be allowed. In essence, according to the draft regulation, DTSC could, if the regulation were in place, require that product sales be prohibited immediately and the entire product line removed from the shelves. At a minimum, a specific list of circumstances, with proof from DTSC, and a limit on the speed at which the prohibition can be initiated must be incorporated into the regulation.

Additionally, it is important to note that typically inventory take-back programs are conducted on a voluntary basis, as a result of a product falling short of federal safety standards. ACC is troubled that DTSC may require a product sales prohibition when the product is deemed safe by federal consumer product standards but DTSC refuses to recognize those standards as ―otherwise regula[tion]" for the priority product.[9] DTSC's take-back program may have the unintended

[9] §69501(b)(4)(A).

consequence of confusing consumers about the safety of products when the federal government has deemed them to be safe for their intended uses.[10] We emphasize that the authorizing statute explicitly states that the regulation "shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."[11]

§69506.6. Other Regulatory Responses.

Unlike all of the aforementioned potential regulatory responses the "Other Regulatory Responses" do not appear to include any conditions or criteria that would invoke them. If this is the case and the "Other Regulatory Responses" do not require the underlying criteria mentioned in §69506.1, and §§69506.3 - 69506.5, then ACC requests clarification from DTSC as to when each of the potential "other regulatory responses" would be triggered.

§69506.7. Exemption from Regulatory Response Requirements.

ACC is concerned that the decision process for granting regulatory response exemptions is overly subjective (§69506.7). Exemption requests must include a comprehensive submission of information that must:

> "demonstrate to the Department's *satisfaction* that either or both of the following apply:
>
> (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 benefits."[12]

Metrics regarding the standard of information required to satisfy DTSC should be defined in this section.

§69506.8. Regulatory Response Determination Process.

DTSC should be required to respond to any and all substantive comments from the public on the proposed regulatory response determination (§69506.8(b)).

Article 7. Dispute Resolution Processes

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[10] In addition, the recently enacted federal H.R. 2715 provides a good example of recognizing that inventory recalls do not serve the greater good. The Consumer Product Safety Improvement Act was amended to no longer require the new lower lead limit for children's products to cover store inventories. Any product prohibitions should be put in place as a "manufactured after" requirement.

[11] HSC §25257.1(c).

[12] Emphasis added.

§69507.1. Informal Dispute Resolution Procedures.

ACC believes that 15 days to request an informal dispute resolution to DTSC, after the notice or web posting of the decision appears, is too short. The proposal also would provide DTSC with the opportunity to resolve the dispute within 30 days of receipt of the request (§69507.1(a)). However, there is no notation as to how this is calculated. For example, it is possible that a responsible entity has office hours from 8:30 AM – 5:00 PM EST, and could be impacted by a decision by DTSC due to the timing. If DTSC were to "inform" the business (either by posting, fax or email) at 3:00 PM PST (6:00 PM EST) on a Friday, there would be no one there to "inform" until the following business day. If the 15 day clock begins based on the time that DTSC sent the notice or posted it to their website, a business conceivably could lose three of the 15 days they have to request dispute resolution. This situation is further complicated if the timing fell around a holiday. The response time should be extended to 30 days to ensure sufficient time for responsible entities to receive, process, and respond to DTSC determinations without unnecessarily waving dispute rights based on a too narrow response time requirement.

§ 69507.2. Appeal to the Director.

If the dispute escalates to the level of appealing to the Director of DTSC, resulting in a denial of the dispute in whole or in part, the DTSC decision will also specify the date by which compliance is required for the portions of the dispute that have been denied. As with other, previously noted date specifications, there is no explanation as to how to calculate a reasonable compliance date, nor is there any minimum grace period provided in the draft regulation. We request that DTSC clarify how to calculate the compliance date.

To complete the review process, DTSC should incorporate a Statement of Denial, if DTSC denies the Request for Review (§69507.6(a)). As drafted, "within 60 days following the filing of a Request for Review under §69507.4, the Department shall issue an order either granting or denying the Request for Review." DTSC should be required to substantiate its reasoning. Furthermore, subsection (b) suffers from the same potential problem as noted in §69507.2, there is no indication as to how this date will be calculated.

Article 8. Accreditation Bodies and Certified Assessors

§69508. Qualification and Certification of Assessors.

ACC 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, and Alternative Analysis" symposium, on September 15, 2011, experience in product development should be a significant credential leading to assessor certification. Specific product development experience should play a significant role in the time and effort necessary for certification. Additionally, DTSC staff members who review alternatives assessments should also be certified assessors.

§69508.1. Qualifications for Accreditation Bodies.

DTSC should add "Exposure assessment" to the fourteen subjects listed in §69508.1(a)(5). 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 "safer alternative."

Additionally, we request further clarity as to how DTSC defines an "indirect investment" versus a "direct 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 (e.g., point of view/ "mission," and publication and public statements or advocacy positions). If the goal is to eliminate conflict, the rules must be substantially rethought.

Article 9. Audits

Given the fact that DTSC will approve each stage and step of the alternatives assessment process, ACC does not understand the necessity of the audit provision. Both DTSC and the responsible entity should have ample opportunity to discuss the choices made regarding the particular alternatives assessments. We request clarity from DTSC on the necessity for this provision, given that, as the draft is currently written, responsible entities cannot move through the AA process without multiple approvals from DTSC.

Article 10. Trade Secret Protection

By limiting the initial submission of supporting information to publicly disclosable information, DTSC will reduce the cost of implementing the program and will increase transparency without compromising its ability to make trade secrecy determinations. DTSC should therefore revise §69510 as follows:

> (a) A person who asserts a claim of trade secret protection with respect to documents or information submitted to the Department under this chapter will receive a written request from the Department to furnish the Department with all of the following supporting information, **which shall be immediately available for disclosure to the public and shall not contain trade secret or confidential business information:**
>
> (10) Copies of, or references to, any pertinent trade secret or other confidentiality determinations previously made by the Department or other public agencies, **to the extent that the copies do not themselves contain any trade secret or confidential business information;**

. . .

> ~~(e) If the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation shall be separately supplied in both complete and redacted form as required by subsection (c), and marked as required by subsection (d), but shall not itself require further supporting documentation. Such documentation shall be separate from documentation used to comply with other provisions of this chapter.~~

Often, in determining the validity of an alleged trade secret, DTSC may decide that it needs more information than was initially provided by the submitter. Foreseeing this likelihood, DTSC included a provision at §69510.1(b) that would allow it to obtain additional information. ACC supports the purpose of this provision. But ACC believes that the provision, which states that additional information will be requested only if the initial disclosure is "deficient," inaccurately implies that the submitter failed to adhere to the requirements of §69510(a) when submitting the initial supporting information.

Trade secrecy review is a fact-specific, iterative process. Requests for additional information are therefore likely to be routine parts of the Department's review, especially if DTSC tailors the scope of the initial submission as suggested above. Section 69510.1(b) should be rephrased to recognize the routine nature of the request and to avoid characterizing it as a punishment for an inadequate initial submission. The provision should also be rephrased to give submitters some minimum amount of time—ACC suggests no less than 30 days—to assemble and submit the supplemental information, as follows:

> (b) If the Department determines that information provided in support of a request for trade secret protection is incomplete or **requires supplementation in order for the Department to make a trade secrecy determination,** ~~insufficiently responsive~~, the Department shall **request additional information, shall provide written notice at least 30 days before the date on which the information must be submitted, and shall provide an explanation of why the additional information is needed.** ~~notify the submitter of the Department's finding of deficiency, the specific area(s) of deficiency, an explanation as to why the Department has determined the information to be deficient, and the date by which the submitter must cure the deficiency~~. . . . If the submitter fails to **provide the additional information** cure the deficiency within the timeframe specified, the Department shall notify the submitter by certified mail that the claimant is out of compliance with this article . . .

The only way for DTSC to withhold claimed trade secret information on the basis of its trade secret status under Govt. Code §6245(k) (incorporating Evid. Code §1060) is to actually determine whether the claim is valid or to be ordered by a court to protect the trade secret information. But to do so, DTSC would need to obtain further supporting documentation to review the claim that the supporting information is trade secret. To further complicate matters, it is likely that the supporting documentation would itself contain trade secret information, thereby forcing the submitter to continually produce additional supporting information, and forcing DTSC to conduct repeated trade secrecy reviews, *ad infinitum*.

Fortunately, there are two ways that DTSC may withhold the supporting information from disclosure under the Public Records Act without having to make a trade secrecy determination. First, DTSC has the discretion to withhold the information from disclosure under §6255 of the Public Records Act by declaring that the public interest served by not disclosing the records—that it will allow DTSC to review the original trade secrecy determination in a thorough and efficient manner—outweighs the public interest served by disclosure of the record. Second, DTSC may withhold the information from disclosure under §6254(k) of the Public Records Act if it claims that the supporting information is privileged ~~"~~official information" under §1040 of the California Evidence Code.[13]

To protect additional supporting information claimed as trade secret efficiently and in a manner consistent with the requirements of the Public Records Act, DTSC should add the following language to §69510.1(b):

> **(b) . . . <u>The Department shall withhold from disclosure any supplemental information marked by the submitter as confidential or trade secret information. Information so marked shall be withheld from disclosure under Govt. Code § 6255(a) and shall be classified as privileged "official information" that is exempt from disclosure under Govt. Code § 6254(k).</u>**

And if DTSC chooses not to follow the recommendations above, that it should only require submission of supporting information that may be disclosed to the public under §69510(a), it should also revise §69510(e) as follows:

> (e) If the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection **or a claim that the information is confidential business information**, such supporting documentation shall be separately supplied in both complete and redacted form as required by subsection (c), and marked as required by subsection (d). ~~, but shall not itself require further supporting documentation. Such documentation shall be separate from documentation used to comply with other provisions of this chapter.~~ **Information so submitted shall be withheld from disclosure under Govt. Code § 6255(a) and shall be classified as privileged "official information" that is exempt from disclosure under Govt. Code § 6254(k).**

Under proposed §§69510.1(b)-(c), DTSC establishes a precise timeline for disclosing claimed trade secret information to the public once it rejects the submitter's claim. The submitter has 30 days from when DTSC mails the rejection to seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief, after which time DTSC will disclose the information unless ordered not to do so by a court of law. There are several problems with this proposed timeline.

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[13] Cal. Evid. Code §1040 (stating that a public entity may refuse to disclose ~~"~~information acquired in confidence by a public employee in the course of his or her duties [if] disclosure of the information is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice.")

First, it is not fair to start the 30-day clock when the notice is mailed, since the submitter will only become aware that its claim was rejected once the notice is received. It is for precisely this reason that California courts assume that litigants do not receive mailed documents until several days after they are sent.[14] The simplest solution is to start the 30-day clock from the date the submitter receives the certified notice.

Second, the regulations should not allow the submitter to file an action for a ~~"~~writ of mandate, injunction, protective order, or other appropriate relief." HSC §25257(d)(3) clearly states that submitters may only file an action for ~~"a~~ declaratory judgment . . . or for a preliminary injunction . . ." and must notify DTSC. To be consistent with the implementing statute, the regulations should only allow the submitter to file an action for declaratory judgment or for a preliminary injunction, and should require that the submitter promptly notify DTSC upon doing so.

Finally, but most importantly, by requiring the submitter to obtain a court ruling within 30 days, the regulations will subject both DTSC and the submitter to substantial, unnecessary costs. The only judicial relief that a litigant can receive within 30 days is a temporary restraining order. The cost associated with seeking (or, for DTSC, opposing) a temporary restraining order is significant. And the only purpose of a temporary restraining order is to give the submitter enough time to file a motion for a preliminary injunction. To reduce costs and increase efficiency, §§69510.1(b) and (c) should be revised to eliminate the need for a temporary restraining order and to ensure that the ability to meet all timelines is within the submitter's control.

Initially, the submitter should have 30 days from the date the rejection notice is received to file an action for declaratory judgment or injunctive relief. This 30-day period is the minimum amount of time needed to file a detailed, accurate complaint. From the date of filing, the submitter should then have 60 days to file a motion for a preliminary injunction. As discussed above, a trade secrecy determination is fact-intensive. Often, the submitter is required to obtain declarations from multiple employees and to consult with technical experts. A 60-day deadline for the filing of all the briefs in support of a preliminary injunction is, therefore, reasonable.

Requiring that the submitter meet these two deadlines has two purposes. First, the deadlines guarantee that the submitter is serious about defending the claim. Second, by requiring that the submitter file both a complaint and, subsequently, a motion for a preliminary injunction, the deadlines put the litigation on track for the fastest possible resolution. By contrast the process described in the draft regulation will take far longer, because the submitter, now committed to litigation, will have invested a considerable amount of resources to dispute the trade secret claim and will be less likely to negotiate an agreement with DTSC. Thus, this leaves the decision to the courts. The deadlines ACC proposes are objectively fair because the actions they require (i.e., filing papers) are all within the submitter's control. It would be unjust, for example, for

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[14] *See, e.g.,* Cal. Code Civ. Proc. §1005(b) (~~"if~~ the notice is served by mail, the required 16-day period of notice before the hearing shall be increased by five calendar days if the place of mailing and the place of address are within the State of California, 10 calendar days if either the place of mailing or the place of address is outside the State of California but within the United States, and 20 calendar days if either the place of mailing or the place of address is outside the United States . . .")

DTSC to require that submitter obtain the preliminary injunction within a prescribed number of days, because the submitter cannot control how fast the court schedules hearings or rules on motions. For that reason, so long as the submitter meets these two deadlines, DTSC should be barred from publicly releasing the information until authorized to do so by a court.

Sections 69510.1(b) and (c) should therefore be revised as follows:

> (b) . . . the Department shall notify the submitter by certified mail that the claimant is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is ~~mailed~~ **received**. During this 30-day period, the submitter may seek judicial review by filing an action for a **declaratory judgment or** ~~writ of mandate~~, injunct**ive** ~~ion, protective order, or other appropriate~~ relief, **and shall notify the Department upon filing. From the date of filing, the submitter shall have 60 days to file a motion for a preliminary injunction to prevent the Department from publicly releasing or disclosing the claimed trade secret information. If the submitter files the motion for a preliminary injunction within that 60-day period,** ~~During this 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 **until authorized to do so by a court of law.**
>
> (c) If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is ~~mailed~~ **received**. During this 30-day period, the submitter may seek judicial review by filing an action for a **declaratory judgment or** ~~writ of mandate~~, injunct**ive** ~~ion, protective order, or other appropriate~~ relief, **and shall notify the Department upon filing. From the date of filing, the submitter shall have 60 days to file a motion for a preliminary injunction to prevent the Department from publicly releasing or disclosing the claimed trade secret information. If the submitter files the motion for a preliminary injunction within that 60-day period,** ~~During this 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 **until authorized to do so by a court of law.**

GlobalAutomakers

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McLaren ◦ Mitsubishi ◦ Nissan ◦ Peugeot ◦ Subaru ◦ Suzuki ◦ Toyota

December 23, 2011

Deborah O. Raphael, Director
1001 "I" Street
P.O. Box 806
Sacramento, California 95812-0806

RE: Department of Toxic Substance Control Informal Draft Regulation of Safer Consumer Products (released 10/30/2011)

(Delivered via Email)

Dear Ms. Raphael:

The Association of Global Automakers, Inc.[1] (Global Automakers) appreciates the opportunity to provide comments to the California Department of Toxic Substance Control (DTSC) on the Informal Draft Regulation of Safer Consumer Products, released October 30, 2011. We previously submitted comments on December 3, 2010 on the Post Hearing changes to the regulatory text of the Safer Consumer Product Alternatives proposed regulations.

Global Automakers and its members are committed to supporting the development and use of safe chemicals and products available for use in the automotive industry. Through the application of green chemistry principles and sound scientific methods, Global Automakers believes that the design and development of new chemistries and technologies will continue to provide innovative solutions to current and emerging environmental challenges. Our goal is to ensure that our members have the opportunity to provide high quality, environmentally sound, and safe products and services. With these goals in mind, we look for ways to provide tools to our members to facilitate continuous improvement and to ensure that wherever possible we assist them to not only meet but exceed safety and environmental standards.

Global Automakers has been actively engaged in the development of the Safer Consumer Products (SCP) regulations from the outset of this effort. We recognize that DTSC has been working hard to balance the requirements of AB 1879 and SB 509 as well as the input from a wide array of interested and important stakeholders. We would like to recognize the considerable progress that has been made in a number of areas but also believe, as currently drafted, the regulations may create an unworkable system that will

[1]The Association of Global Automakers, formerly known as the Association of International Automobile Manufacturers (AIAM), represents international motor vehicle manufacturers, original equipment suppliers, and other automotive-related trade associations. Our members' market share of both U.S. sales and production is 40 percent and growing. We work with industry leaders, legislators, regulators, and other stakeholders in the United States to create public policy that improves motor vehicle safety, encourages technological innovation and protects our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. For more information, visit www.globalautomakers.org.

result in unintended chemical and/or product substitutions and misdirected resource investments in low rather than high priority areas.

Wherever possible we have commented on the provisions and tried to offer alternative strategies that we believe will make these regulations more workable not only for the regulated community but also for DTSC and the public as well. We recognize the enormity of the task at hand and would like to make clear that we support the overarching goals of the law and regulations. It is with that same goal in mind that we offer the enclosed comments and recommendations. We would be pleased to discuss any of these suggestions.

Thank you for the consideration of our comments. If you have any questions, please contact John Cabaniss, our Director, Environment & Energy, at jcabaniss@globalautomakers.org or (202) 650-5562.

Sincerely,

Michael J. Stanton
President & CEO

Enclosure

GlobalAutomakers

Comments submitted by

The Association of Global Automakers

On

Informal Draft Regulations: October 31, 2011.

Division 4.5, Title 22, California Code of Regulations

Chapter 55 Safer Consumer Products

DTSC Reference Number R-2011-02

Global Automakers would like to recognize the considerable effort that the Department of Toxic Substances Control (DSTC) has put into balancing the various views and perspectives of all stakeholders. We believe that a number of modifications that are reflected in this informal draft contribute to making these regulations more workable, such as:

- The movement from multiple chemical and product lists to one list each has added precision to the process and removed some of the uncertainty created by multiple lists.
- DTSC has also added clarity to the definition of responsible party and has made clear that all parties along the supply chain have a duty to comply.
- The most recent draft also refers to the need to provide guidance for the Alternative Assessment process beyond the regulations – this will be essential for meaningful compliance.
- We believe that DTSC's decision to have an initial focus on a short group of chemical/product combinations is a sound policy step that will allow both DTSC and the regulated community to "learn by doing" without being overwhelmed by a lengthy list.
- Similarly, DTSC's focus on components of complex products instead of the entire product will provide for a more targeted approach to assessments.
- We also support DTSC's decision to defer the development of new data to fill data gaps. This will allow the process to move forward rather than be delayed waiting for data.
- The flexibility now provided for the AA process will allow for more tailored and relevant assessments, and the removal of the third party verification requirement returns ultimate responsibility to the company or group preparing the assessment.

At the November 2011 Green Ribbon Science Panel (GRSP) meeting, DTSC reiterated that these regulations need to be meaningful, practical and legally defensible**,** as they will set the precedent for the rest of the country and maybe the world. We cannot agree more and in that spirit, offer these comments and recommendations.

1. Setting Priorities: Identifying the most significant hazard and exposure combinations

Recommendation to DTSC: Reduce the initial chemical source lists to focus on PBTs and CMRs; move from qualitative priority setting criteria to quantitative criteria wherever possible; and focus the initial list of chemical/product combinations on a limited (2-5) number of products.

Global Automakers supports the goal of identifying and addressing risks associated with chemical/product combinations that present real and demonstrable human health or environmental impacts and using this goal as a factor in determining priorities. DTSC has stated its commitment to setting priorities based not only on the hazard associated with a chemical of concern but also on the potential for exposure when used in a particular product. When balanced together, the use of replicable, peer-reviewed hazard and exposure data will allow DTSC to set sound priorities and identify chemical/product combinations that warrant further evaluation and assessment.

Global Automakers is concerned that the proposed process for setting these critical priorities has a number of weaknesses that will compromise DTSC's ability to select the highest priorities in a way that is replicable and predictable – both key elements of sound chemical regulation programs. We are also concerned that starting with over 3000 chemicals will overwhelm DTSC's ability to focus on the highest priority concerns. We recommend reducing the list by using a screening process focused on high hazard candidates. We are not suggesting that other lists be exempted – just deferred until later in the process.

In the area of setting priorities, Global Automakers has identified four major concerns: (a) the use of multiple source lists for initial chemical identification; (b) the availability of reliable exposure data; and (c) qualitative versus quantitative prioritization criteria; and (d) size of the initial chemical/product list.

a. **Multiple Source Lists for Chemical Identification**: As stated by DTSC at the November 14-15, 2011 Green Ribbon Science Panel (GRSP) meeting, "the decision was made to start with a rather large list of chemicals of concern that incorporates 22 lists of chemicals developed by a range of other authoritative bodies." DTSC went on to state, "This approach was chosen to (i) send signals to manufacturers and consumers; (ii) enable DTSC to immediately begin work on developing the list of Priority Products….; and (iii) reduce the motivation for manufacturers to implement early (potentially regrettable) substitutes." While Global Automakers understands DTSC's goals in this area, there are a number of potential outcomes from this approach that may be in themselves regrettable. By relying on multiple lists that are inconsistent in terms of scope, focus and rigor, DTSC is building a process on a shaky foundation. If it is DTSC's intent to add chemicals from other lists without further review, Global Automakers has serious concerns. Every chemical list is developed for a specific purpose not all of which are regulatory in nature. The scientific rigor applied to each list is different and the accuracy of the hazard and exposure data may be more or less sound. A wholesale incorporation of "lists of lists" is inconsistent with the priority process articulated by DTSC and would result in a flawed foundation step for the program. Global Automakers recommends that DTSC start with a shorter, more focused list of chemicals. For example, starting with a list of known CMRs and PBTs would provide DTSC with a sound foundation and a list of manageable length to begin the process.

b. **Availability of Reliable Exposure Data:** None of the lists identified during the GRSP process are reliable sources of chemical or product specific exposure data. It is not clear how DTSC will determine the potential for exposure for any particular chemical/product combination. At best it will be a rough estimation process that would not meet scientifically sound exposure assessment standards. Our concern is that the outcome will be the identification of chemical/product combinations where exposure potential is low or none, and responsible parties will be forced to invest resources to demonstrate that finding for DTSC. As DTSC has recognized on a number of occasions, the presence of a chemical in a product by itself does not equate to exposure.

c. **Qualitative versus Quantitative Prioritization Criteria:** DTSC's choice to rely on qualitative versus quantitative criteria for priority setting appears to be an outgrowth of the issues we have already identified. Lack of consistency for the lists cited and lack of reliable and quantitative exposure data sources leave DTSC with few alternatives in terms of developing and using quantitative criteria.

DTSC has recognized that the use of a qualitative approach leaves the regulated community at a loss in terms of predictability and replicability of the decision process.

d. **Size of the Initial Chemical/Product List:** DTSC has frequently stressed the need to work on the most important chemical and product combinations first. In order to accomplish that goal, we recommend that DTSC focus on a small number of chemical and product combinations that have well-characterized and significant hazards, demonstrated exposure and existing alternatives. Similar to the selection of the chemical lists, selecting combinations of chemical/product priorities based on both hazard and exposure criteria will help to focus the initial product lists. By making strategic policy choices at the beginning, DTSC can assure that both they and the regulated community can learn by doing and ensure a greater possibility of success. History has shown us that by overloading such a new regulatory system, it can crumble under its own weight. While we strongly support limiting the initial chemical/product combinations to a small subset of products (2-5), Global Automakers also believes that it will be beneficial for DTSC to adopt in the following iterations of product lists, a multi-year plan for application to products. Especially once the program begins to address more complex products, a multi-year plan for products will be a key method for providing much needed lead-time to products and may encourage manufacturers to begin the alternative assessment process earlier than required.

Recommendation: Global Automakers recommends that at a minimum DTSC use established criteria for Persistence and Bioaccumulation as well as scientifically sound and accepted levels for carcinogenicity, mutagenicity, and reproductive toxicants. To further refine the list, we recommend removing chemicals that are regulated or under review by other agencies. The U.S. Environmental Protection Agency's (EPA) Design for the Environment (DfE) program has established a robust set of quantitative hazard criteria, and we recommend that DTSC consider adopting these criteria for their prioritization process. While this approach will not remedy the lack of quantitative exposure data, it will provide clarity and predictability to identifying levels of concern. We also recommend that DTSC narrow the focus of the first chemical/product combinations to no more than 2-5 products in the initial year(s) of the program and should provide a multi-year plan for products in future iterations of the list.

2. Exemptions:

A. De Minimis Exemption

Recommendation to DTSC: Adopt a *de minimis* level that is consistent with current federal, state and international regulatory systems.

In DTSC's September, 2010 proposal of the SCPA regulations, DTSC proposed a *de minimis* level of (1) 0.1% by weight or (2) the lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination. Global Automakers urges DTSC to reconsider its rejection of that approach and to adopt the same or similar regulatory language as in the 2010 proposal.

Ideally, a *de minimis* risk level will distinguish between small or insignificant risks that belong in a low priority assessment category and significant risks that pose a threat to human health and the environment and belong in a high priority assessment category. The costs of assessing *de minimis* levels of chemicals and chemical/product combinations are unreasonably high for all involved in the process – DTSC, the regulated community and the public. For a regulatory program designed to set priorities and focus on high priority hazard/exposure combinations, a practical and predictable *de minimis* exemption is essential, especially one that is already being used as an industry standard.

The issue of *de minimis* has been addressed by many regulatory authorities. The Occupational Health and Safety Administration (OSHA), the Department of Transportation (DOT) and the European Union's (EU) REACH articles have all established a fixed *de minimis* level at 0.1%. The U.S. EPA has established *de minimis* levels for the Toxics Release Inventory (TRI) program with the base *de minimis* level set at 0.1% for any non-PBT chemical and OSHA-defined carcinogens. PBTs and a small number of specific chemicals have lower *de minimis* thresholds. Other regulatory programs have developed similar chemical specific *de minimis* levels – RoHS, the EU regulation governing electronics, has set a *de minimis* level for five hazardous chemicals at 0.1% and one at 0.01%. The EU Classification and Labeling System has identified *de minimis* levels for over 3000 chemicals – approximately 85% of those at 0.1%.

Based on the findings and experience of and precedent set by these regulatory programs, it is clear that a 0.1% *de minimis* level should be the base or default level to incorporate lower, or higher levels, identified for specific chemicals that warrant a different approach. In particular when a lower *de minimis* level may be identified as necessary, it will be important to provide industry, especially those with multi-tiered supply chains, with adequate lead-time to adjust to a lower *de minimis* level. We recommend a minimum of five years lead-time for lower *de minimis* levels to allow for changes in reporting (i.e. method of reporting or software changes) and testing methods throughout the supply chain.

The level that DTSC adopts for *de minimis* will have a significant impact on the availability of reliable chemical tracking data for the automotive sector. The automotive sector began the development of a robust chemical tracking system in 1998. That system has evolved and now serves as a critical tool that allows automotive manufacturers to work closely with their suppliers to ensure that identified chemicals are not present in automotive components above the *de minimis* levels. The list is based on regulations, *de minimis* levels and other data developed by federal, state and local agencies worldwide. Today, there are over 2,700 substances on the list. Selecting a *de minimis* level that is inconsistent with other federal, state and international regulatory agencies will create a major gap in available data and will create the need for expensive and extensive testing and/or creation of new data at lower thresholds throughout the supply chain for components. The resources that will be needed to generate that data will be resources that could be better used for chemical/product combinations where both hazards and exposures may present greater concerns.

Global Automakers urges DTSC to reevaluate the current proposed approach to setting *de minimis* levels and to adopt *de minimis* levels that are consistent with existing state and federal and international levels. This consistency will allow for predictability and harmonization across programs. We can continue to support raising the *de minimis* level, if necessary. However, any action to lower the *de minimis* level would result in regulatory uncertainty for the regulated parties and could only be supported if, *and only if* [emphasis added], DTSC could guarantee adequate lead-times for industry to change reporting and tracking methodologies, as well as revise testing methods for quantifying chemical levels in products.

Recommended Language:

De minimis level means a concentration less than or equal to the lower of:

(1) 0.1% by weight; or

(2) the lowest federal or California State public health or environmental regulatory threshold that applies to the chemical or the chemical/product combination.

This recommended language mirrors that included in the 2010 proposed regulations. We also support that DTSC can also raise the *de minimis* level to greater than 0.1% if deemed appropriate.

B. Unintentionally Present Chemicals and Chemicals with No Exposure Pathway

Recommendation to DTSC: Global Automakers urges DTSC to reconsider the removal of these two common sense exemptions from the draft regulations. Both of these earlier provisions provided a filtering system [a funneling system] to assist DTSC in further refining the list of chemical/product combinations that would form the basis of the priority listing.

a) Unintentionally Present: If a chemical is unintentionally present, it is likely that (1) the manufacturer is unaware of its presence; (2) it is likely present in very low or *de minimis* concentrations and (3) DTSC will not have any exposure data by which to prioritize the chemical/product category.

b) Exposure Pathway: If a chemical is present in a product in such a way that there is no potential for exposure, there would be no sound basis for including that chemical/product combination on a priority list.

Recommendation: Global Automakers urges DTSC to include these previous exemptions and the associated regulatory provisions in the final SCP regulations.

As an alternative to including explicit exemptions for unintentionally present chemicals and no exposure pathways, DTSC could instead codify these concepts as considerations in the prioritization process when selecting chemical/product combinations.

3. Legacy or Replacement Parts:

Recommendation to DTSC: Exclude from the scope replacement parts that have been manufactured prior to inclusion on any Priority Product listing.

Global Automakers is concerned about the lack of clarity regarding automotive replacement parts that are manufactured for vehicle maintenance prior to inclusion on any priority product list. Automobile manufacturers are responsible for manufacturing and stocking replacement or legacy parts for the automobiles that they supply to the public. In many cases vehicle warranties address availability of parts as a specific and binding issue. Consumers purchase cars with the expectation that they will be able to repair or replace any necessary components over the lifetime of the vehicle.

Replacement parts are often manufactured at the same time or shortly after individual vehicle models are manufactured. These replacement parts are compliant with all relevant state, local and federal regulations in place at the time of production. It is often efficient and effective to produce a lifetime supply of replacement parts in parallel with the vehicle model because assembly plants and equipment have been tooled for that specific model. As a result, large inventories of replacement parts are often in commerce and available for consumers as the need arises over the course of a vehicle's life. It is not uncommon for suppliers that manufacture these parts to stop manufacturing parts over the life of the vehicle, resulting in no means to gather information about the chemicals in these products or a means to obtain new parts with safer alternatives. The reasons for stopping manufacturing vary. Sometimes the supplier has gone out of business or faces low demand for the part, unavailable tooling, lack of resources, or high costs associated with re-engineering legacy parts.

Replacement parts for newer vehicles often cannot be used interchangeably with parts needed for older models. If pre-existing (prior to SCP listing effective date) replacement parts for older models are subject to new DTSC regulation, a series of significant and cost prohibitive consequences could follow:

(1) Many automobiles will not be able to be repaired and a major consumer investment will be lost;
(2) Automotive safety will be jeopardized as "work arounds" are developed to extend the life of the vehicle;

(3) Repair shops and companies that manufacture and use these parts will be significantly disadvantaged by the loss in revenue and stock value.

In order to avoid these unintended consequences, and to implement a forward facing regulation, we urge DTSC to add language to the regulations that limits the scope of coverage for spare parts to those manufactured after the effective date of the SCP regulations, or more specifically after the date in which the part in question is included on the priority product list. This type of approach is consistent with both international and domestic approaches to product and component regulation. For example, the RoHS Directive (Article 2(3)) makes it clear that the directive does not apply to spare parts for the repair of electrical and electronic equipment put on the market before 1 July 2006 in order to ensure the availability of spare parts for equipment placed on the market before the entry into force of the substance restrictions. Washington State's 2010, Better Brake Law recognized the need to allow for a phase-out of copper and other materials covered by the regulation. Specifically, for spare parts, the implementing regulations state: "Brake friction material manufactured prior to 2015 is exempt from subsection (1) of this section for the purposes of clearing inventory. This exemption expires January 1, 2025." The law also exempts service parts manufactured as part of an original service agreement: "Brake friction material manufactured as part of an original equipment service contract for vehicles manufactured prior to January 1, 2015, is exempt from subsection (1) of this section."

Additionally, there may be limited cases where it is also appropriate to exempt replacement parts that were manufactured after the effective date of the product listing. As noted above, replacement parts are generated for the purpose to repair as produced assembled products. When no drop-in replacement part is available [See replacement parts issues identified in Global Automakers' (then AIAM) July 2010 comments], it may be appropriate for the product listing to note that specific replacement parts are not included, even if manufactured after the effective date of listing, assuming such replacement parts are intended for use only on previously manufactured assembled products already in the market.

Recommended language: To be inserted in §69501.2 - Definitions (a) (20) (A) or (B).

> Replacement or legacy parts that form a part of a component or constitute the component itself, and have been manufactured prior to the effective date of listing on a priority product list, are outside the scope of these regulations and/or are exempt from these regulations.

4. Harmonization with Federal and State Performance and Safety Standards

Recommendation to DTSC: Global Automakers recommends that DTSC work collaboratively with the automotive sector regarding the regulation of product/chemical combinations that would apply to the auto industry, to develop a series of case studies and guidance documents to design a workable, effective program that addresses all Federal and State requirements.

As DTSC is aware, the design and development of automobiles is governed by adherence to strict safety standards, as well as numerous other regulations. Automobile manufacturers must meet standards established by U.S. EPA, DOT, and multiple state requirements. Individual automotive components often contain materials that are specifically stipulated by these standards. Decisions made by DTSC must take into consideration all the performance and safety requirements that need to be met by the automotive sector.

5. Lead-Time Requirements for Implementing Changes in the Automotive Sector

Recommendation to DTSC: Global Automakers recommends that DTSC adopt a multi-year product list approach (after experience with the development and implementation of the initial list) and establish timeframes for the AA process based on the complexity of individual sectors and product development times.

The development of an automobile and its component parts from the concept to the engineering phase takes several years. Engine development and much of the R&D associated with the powertrain components and fuel systems, mobility and safety systems, and materials and manufacturing processes can take significantly longer. If major changes need to be made to any component, the automotive sector needs a minimum of a 3-5 year timeframe to redesign and test any new component or product to assure it meets federal and state performance and safety standards. Also, most changes are only made at the time of a major model change which is typically every 5 years [See specific timeframe issues identified in Global Automakers' (then AIAM) July 2010 comments]. We request that DTSC address the issue of timing for complex products in their next draft so that there are clear expectations and understanding of this issue. This could be accomplished in a number of ways.

a) Multi-Year Product Lists – A multi-year chemical/product list would provide the lead-time necessary to redesign, test and obtain all the necessary performance and safety approvals for alternative components. A multi-year list would also provide early notification to manufacturers and provide an opportunity to start the regulatory process early. The "multi-year" timeframe would need to span a minimum of 5 years.
b) Sector or Product Specific AA Timeframes – DTSC, working with the regulated sector, would set timeframes for the AA process based on the complexity of the redesign or reformulation process. Longer timeframes would be established for products that required extensive performance and safety testing.

6. Financial Guarantee for End of life

Recommendation: Global Automakers recommends that DTSC rework §69506.4 to include language that places responsibility on intermediate suppliers and state and local governments for creating the needed public infrastructure, and consumers for following safe and sustainable disposal practices. We recommend that DTSC remove the financial guarantee language for sectors that have demonstrated effective programs in this area. Additionally, DTSC should consider ways to promote and incentivize more effective collection, segregation and recycling of consumer wastes.

§69506.4 describes the end of life management requirements for priority products. As proposed, the manufacturer of the final product bears a disproportionate share of the responsibility for developing end of life programs, state and local infrastructure programs and all related costs. If the final manufacturer is responsible for all aspects of end of life management, there is no incentive for all players along the supply chain to invest in green design and development. Product Stewardship should assign responsibility all along the supply chain including all intermediate suppliers as well as the consumer. Products are designed to meet the needs of consumer demands. If consumers are not assigned some responsibility in DTSC's regulatory approach then all the upfront work will be negated. End of Life management is not a responsibility that should rest solely with the final manufacturers. The financial impacts of an up-front financial guarantee will impose significant and disproportionate hardships on the manufacturing sector. The automotive sector has already demonstrated a commitment to end of life management of wastes and believes the financial guarantee provisions are inappropriate.

Conclusion:

Global Automakers appreciates the enormity of the task that DTSC has ahead of it as well as the complexity of meeting multiple stakeholder expectations. DTSC has made considerable progress in crafting and refining a set of regulations that will move the design and development of consumer products towards a green chemistry approach by identifying and utilizing the most appropriate performance and safety-based chemical alternatives. We urge DTSC to continue to use sound science approaches and to structure a program that is built on clear priority setting criteria, common sense exemptions and practical risk management solutions.

Global Automakers strongly recommends that DTSC reduce the initial chemical source lists to focus on PBTs and CMRs; move from qualitative priority setting criteria to quantitative criteria wherever possible; and focus the initial list of chemical/product combinations on a small (2-5) number of products. This will allow DTSC and the regulated community to learn by doing and refine the process as needed. We also recommend that DTSC reinstate the exemptions for *de minimis* levels, no exposure pathway and unintentional presence as defined in the September 2010 version of the draft regulations. These exemptions contribute significantly to the practicality of the regulations and the harmonization with other federal and state chemical regulations. We also request that DTSC include a specific exemption for replacement parts. As we have identified in these and all our previous comments, replacement or legacy parts manufactured prior to inclusion on a priority list, must be available for repair and maintenance of automotive vehicles in commerce. We have provided specific regulatory language that will ensure these essential automotive components are available when needed. We also ask DTSC to reconsider the current approach to end of life, most notably the financial guarantee requirements. We recommend that DTSC remove the financial guarantee language for sectors that have demonstrated effective programs in this area.

We thank you for considering these recommended changes and would be happy to discuss the alternatives we have proposed.

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21 December 2011

Debbie Raphael, Director
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Dear Director Raphael,

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Thank you for the opportunity to review and comment on the October 31, 2011 informal draft of the Safer Consumer Products (SCP) regulations.

The draft regulations provide a strong framework, approach, and processes for identifying chemicals of concern, prioritizing products, evaluating potential alternatives, and proposing appropriate regulatory actions. HP strongly supports the goals of Assembly Bill 1879 and believes that the selection of good alternatives is an essential step in reducing potential risks to public health and adverse impacts on the environment.

We think the general approach outlined in this draft can be achieved. Our comments and suggestions that follow are offered in the spirit of helping refine the key concepts and elements to improve clarity and implementability while still retaining the flexibility needed to cover a wide range of chemicals and products.

We look forward to the continued discussions on these requirements during the rulemaking process in 2012.

Best regards,

Marjorie MartzEmerson

Review Comments from Hewlett-Packard
Informal Draft Regulations, R-2011-02 (10-31-2011)
Safer Consumer Product Regulations

HP is pleased to offer the following comments on the informal draft regulations:

General Comments:

- HP supports the process for identifying and listing chemicals of concern
- HP supports the concept of a phased approach, namely notification and two stages of alternative assessment (preliminary screening AA and the final AA)
- HP supports the concept of a flexible de minimis threshold when determining whether an AA is needed to protect public health and the environment from a specific combination of chemicals of concern and priority products
- HP supports good quality AAs but we are not convinced that an assessor certification process is the most efficient or effective methods of achieving this objective. A multi-stakeholder review process could be developed to ensure the transparency and technical adequacy of each AA.

The more specific comments, provided in a section-by- section format, suggest areas where the concepts can be refined to clarify uncertainty and improve implementability.

Chapter 55. Safer Consumer Products
Article 1. General

- **§69501. Purpose and Applicability**—This chapter also specifies the regulatory responses that will be imposed… Suggest changing this language to "This chapter also specifies the types of regulatory responses that the department may consider in imposing a regulatory response…

- **§69501.2. Definitions.**
- (a)(9)"**alternative**" (A)--recommend adding "an existing or" to make it read as below "Removal of Chemical(s) of Concern in a Priority Product, with or without adding or increasing the concentration of a**n existing or** substitute chemical;
- (a)(14) "**bioaccumulation**"—recommend using one of the standard definitions of bioaccumulation or the definition of bioaccumulation hazard trait from OEHHA to clarify that while bioaccumulation may be influenced by the accumulation in an individual component of the environment, it is actually tied to the accumulation in living systems. Examples of definitions:
  - "The bioaccumulation hazard trait is defined as the accumulation of a chemical substance in the tissue of organisms through any route, including respiration, ingestion, or dermal, including or direct contact with contaminated water, sediment, and pore water in the sediment, or through biomagnification transfer up the food chain." OEHHA, 22 CCR §69405.2
  - "Progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organism's ability to remove the

substance from the body." International Union of Pure And Applied Chemistry, 1993) http://sis.nlm.nih.gov/enviro/iupacglossary/glossaryb.html

- (a)(25) "**de minimis level**"—We support the new approach for a using a default de minimis level based on hazard trait but which can be adjusted for a specific chemical of concern depending on the potential for exposure and adverse impacts.
  - Recommend moving away from the term "de minimis" to more precise terminology to clarify the intent and help all parties better articulate their concerns and ideas regarding these concepts. An example of how three specific terms—[alternative] assessment threshold, practical quantitation limit, and maximum concentration value—might be used to clarify the differences between the important concepts that could be used within this rule may be found in addendum 1.
  - Recommend moving the criteria for adjusting the "de minimis" from 69503.4 into the definition of "de minimis" in (69501.2 (a) (25)).
  - Clarify in 69506.6 (a) (2) (B) that a maximum concentration value in a regulatory response may be different from the initial "de minimis" (assessment threshold) level set as per 69503.3 based on the application, potential exposure, hazard, existing restrictions in other jurisdictions, and/or findings in the alternative assessment.
- (a)(40+) "**homogenous material**" means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes. Adding the concept of "homogenous material" is a possible option for defining thresholds for substances in components in assembled products without diluting the concentration by the entire weight of the product, component, assembly, or subassembly. Please see addendum 2 for further discussion.

Article 2. Chemicals of Concern Identification Process

- **§69502.2. Chemicals of Concern Identification**—support using a list of lists approach to generate the Chemicals of Concern list because this approach relies on authoritative bodies to make determinations on substances and will be more harmonized with other jurisdictions. It may be helpful to define authoritative bodies and lists, as in Proposition 65. Please see addendum 3 for a more detailed discussion.
  - Recommend adding EPCRA Section 302 to list
  - (a)(1)(C)—recommend substituting CEPA Schedule 1 for the PBiT list
- **§69502.3. Chemicals of Concern List**— recommend more frequent review and update of the Chemical of Concern list to remain current because the source lists change over time.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

- **§69503.3. Priority Products List--r**ecommend that when "de minimis" levels are set for particular priority products as per 69503.3 (a) (2) (B) the announcement also define the preferred test method(s) and practical quantitation limits.
  - Recommend that information in 69503.3 (a) (2) (C) also include the level of product specificity required for notifications (e.g. general application type, representative product, products by model, each product SKU). New definitions for each of these levels may be required.

- **§69503.5 and §69503.6 Notifications**—recommend formalizing the working plan into an "Intent to List" process for priority products, with long lead times, in order to allow the regulated community to prepare for compliance prior to the formal announcement of priority products and targeted substances.

Article 5. Alternatives Assessments

- **§69505.1. Alternatives Assessments: General Provisions**—(g) recommend clarifying that failure of the Department to make a compliance determination does not place the responsible entity in a position of noncompliance.
- **§69505.3. Alternatives Assessment: First Stage**—(b)(3)(C)(1) support the first stage alternatives assessment requirement to screen out alternatives that may pose greater adverse public health and/or environmental impacts than the original chemical of concern as a key concept in achieving the objectives of AB 1879. Clear criteria should be included here or in the guidance documents on what is considered unacceptable as a replacement for a Chemical of Concern.
- **§69505.4. Alternatives Assessment: Second Stage**—(c) recommend the selection of suitable alternatives be clarified to say "shall select alternatives" rather than "**the** alternative" because it is not necessary to choose a single replacement for the chemical of concern as long as all selected options have lower impact to human health and the environment.
  - The phrase "priority product and potential alternatives" is often used when the intent is to compare the chemical(s) of concern within a priority product and its chemical and non-chemical alternatives in that product. Suggest clarifying that the alternatives are to the chemical(s) of concern, not alternatives to the products.
- **§69505.5. Alternatives Assessment Reports**—(n) recommend removing the proposed regulatory responses from the alternatives assessment report prepared by the responsible entity. Regulatory response recommendations should be made by the Department.

Article 8. Accreditation Bodies and Certified Assessors

- Recommend replacing the accreditation and certification program with a balanced multi-stakeholder review process to ensure the quality and transparency of the AAs. High quality alternative assessments are critical to meeting the goals of AB1879. While we understand that the certification program is intended to provide quality assurance for the AAs, our experience leads us to believe that certification programs do not alone significantly improve the quality of assessments. We have found that the single biggest contributor to better assessments has been a thorough review process. Good peer review is standard practice in technical publications, multi-stakeholder perspectives is imperative to ensure that the AA (even in redacted form) provides a thorough analysis of the impacts of each alternative and presents a clear justification for selection of the recommended alternative.

Article 10. Trade Secret Protection

- **§69510. Assertion of a Claim of Trade Secret Protection**
  - Suggest only including (a)(1),(2),(3),(6), (10), (11), and (12) because some types of information requested may not be available and the absence thereof should not significantly impact the ability of theDepartment to make a ruling.

Addendum 1 – Concepts and language around "de minimis"

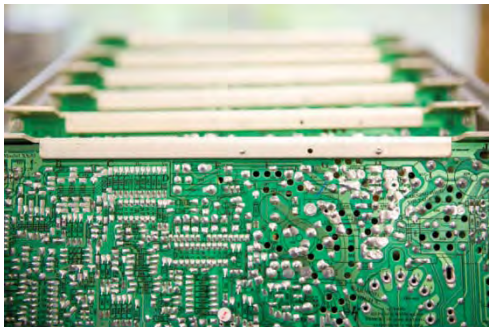
In reviewing the use of the term "de minimis" in SCP, we have found that what is being called a "de minimis" is not actually a true *de minimis*, in the sense of being too small to be of concern. We recommend moving away from the term "de minimis" to more precise language to help clarify the department's intent, and help all parties better articulate their concerns and ideas regarding these concepts. This addendum is intended to help better define the important thresholds and limits that are referenced in SCP.

We recommend introducing and defining the following three terms and using them appropriately throughout the document:

1. [Alternative] Assessment Threshold (AT) – The amount of a chemical(s) of concern in an assembled or formulated product above which an alternatives assessment must be completed, and below which an exemption for the use/presence of a chemical of concern may be requested.
2. Maximum Practical Quantitation Limit (MPQL) – The maximum allowable detection limit for any analytical test methods that may be used to show compliance with the necessary notifications for the particular chemical of concern in the listed component or formulated product. MPQL should be lower than the assessment threshold (AT) to be meaningful and to allow the summation of the concentrations of like hazard trait. The MPQL may be used by the Department to establish the accepted test methods for showing compliance with 69503.5(a)(6)(B) and 69503.5(a)(7). A result of "not detected" by an accepted analytical test method for the chemicals of concern for the listed priority product would result in an exemption for that product from the alternatives assessment process.
3. Maximum Concentration Value (or equivalent) (MCV) – The maximum allowable level of a chemical of concern in a component or formulated product that is set as part of a regulatory response after an alternatives assessments has been completed. The MCVs would be based at least partially on the environmental and health determination by the department.

These values are different and do different things within the regulations. We have found in our own discussions that much of the disagreement on "de minimis" between various stakeholders has been linked to confusing these terms and associated numbers, and it would probably help everyone to split out the concepts and define them clearly.

Here is how the three more precise terms would come into play in an example.



If SCP were to have been applied to lead (Pb) in electronic solders prior to RoHS:

- The assessment threshold (AT) might have been set at 500ppm in homogeneous solder material to determine if Pb was being used in solder.

- The MPQL might have been set at 50ppm to ensure that we were accurately measuring down to the 500ppm assessment threshold (AT), but no lower so that a range of analytical methods could be used to generate data.

- The final MCV (restriction) might have been set at 1000ppm in solder based on the alternatives assessment that found:
    - Tin-based (Sn) solders have lower impact to human health and the environment than Pb-based solders and can be an acceptable alternative
    - Pb serves no purpose in solder below 1000ppm
    - Pb is a natural contaminant in tin (the replacement for Pb-bearing solders) and might be present up to 1000ppm
    - The human health and environmental impacts of solder containing up to 1000ppm Pb is significantly less than Pb-bearing solder
    - Several inexpensive analytical methods were available to reliably detect Pb to 50ppm (XRF)

- A final MPQL of 50ppm might have been set for compliance verification because a 50ppm MPQL will enable a type of testing that can accurately prove compliance to a 1000ppm MCV. [Alternatively, the MPQL could have been used to help determine the standard analytical test methods that would be accepted as proof of compliance, which is actually what occurred in the case of ROHS, through the work of the IEC technical working group TC111.]

By separating out the terms and defining them clearly, it would allow the regulated community to better comply with the requirements and also provide more transparency to other stakeholders on the intent of the different thresholds for Chemicals of Concern in Priority Products.

Addendum 2 – Homogenous materials option for components

Using “components” as a way of targeting materials within assembled products is an important way to focus on substances of interest. However, the current definition could lead to the “dilution” of chemicals of concern by including an assembly or subassembly weight in concentration calculations rather than phasing out the chemical’s use.

One way to further refine the targeting of substances and reduce the risk of continued use of chemicals of concern in assembled products would be to allow a “homogenous material”-based maximum concentration value as an <u>option</u> for setting de minimis by extending the definition of “component.”

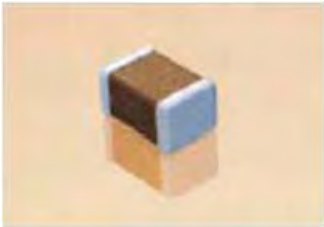
The concept of “homogeneous materials” was introduced as a way of restricting substances within electronics through the EU Restrictions on the Use of Certain Hazardous Substances (RoHS). According to their definition, homogeneous material means “one material of uniform composition throughout or a material, consisting of a combination of materials that cannot be disjointed or

separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes." This definition was incorporated into California's version of RoHS (Health and Safety Code sections 25214.9-25214.10.2) http://www.dtsc.ca.gov/hazardouswaste/rohs.cfm.

The EU adopted maximum concentration values in homogeneous materials because of a concern that setting a product level de minimis would result in the continued use of substances of concern if the entire product weight was allowed to be used in the concentration calculations. Allowing homogeneous materials to be used as one possible way to set a de minimis concentration within assembled products could be very useful, especially for complex products like electronics.

The concept and definition of homogeneous materials is familiar and widely accepted within the electronics industry as a way of designating substance restrictions. It is replicated in many jurisdictions around the world, and there is a relatively robust infrastructure of analytical testing and material data disclosure available for demonstrating compliance.

Chip Capacitor Example



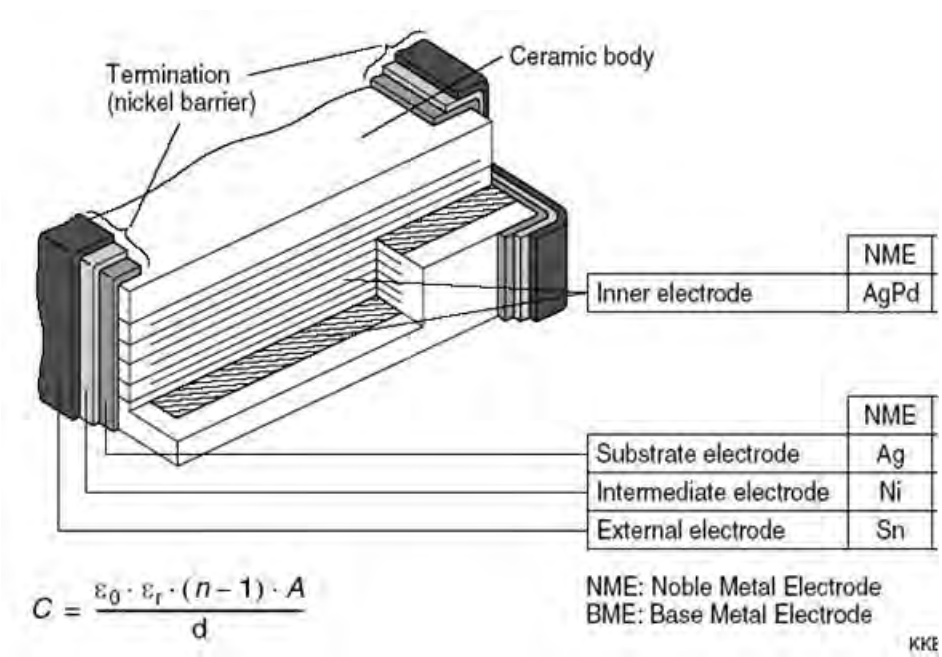


Figure 1: Cut-away illustration of homogeneous materials in a chip capacitor

It's important to note that maximum concentration levels in homogeneous materials are not the best way to restrict substances in all cases. Within electronics, very small components and coatings have proven to be poor fits for this type of restriction definition.

However, the overall utility of the "homogeneous material" approach in driving the intended phase-out of undesirable substances, as proven by the successful implementation of the ROHS Directive, make the addition of this option to the definition of "component" appealing.

Addendum 3 – Authoritative Bodies and Lists

Since there is no standard definition of what constitutes authoritative bodies and authoritative lists, it might be helpful to define them based on the way that Prop 65 Section 12306(l) defines them.

As a possible approach, we have adapted the Prop 65 definitions of authoritative bodies and lists, which are specific to cancer, to apply to a broader range of topics.

> A "body considered to be authoritative" is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (a), and which DTSC has identified as having expertise in the identification of chemicals with the potential to cause adverse public health and/or environmental impacts on specific topics defined within 69505.2 (a)(4) and 69505.2 (a)(5).
>
> For purposes of this section, "authoritative body" means a "body considered to be authoritative" in the identification of chemicals that cause a particular adverse public health and/or environmental impact on one or more topics defined within 69505.2 (a)(4) and 69505.2 (a)(5).
>
> DTSC shall have the authority to revoke or rescind any determination that a body is authoritative on the grounds that the department no longer considers the body to have expertise in the identification of chemicals on the relevant public health and/or environmental impacts topics defined within 69505.2 (a)(4) and 69505.2 (a)(5), in which case chemicals listed pursuant to this section prior to the effective date of the revocation shall remain on the list. Nothing in this section shall be construed to limit or otherwise interfere with such authority.
>
> …
>
> (a) For purposes of this section a chemical is "formally identified" by an authoritative body when the lead agency determines that:
>
>> (1) the chemical has been included on a list issued by the authoritative body stating that it causes an adverse public health and/or environmental impact on a specific topic defined within 69505.2 (a)(4) and 69505.2 (a)(5); or is the subject of a report which is published by the authoritative body and which concludes that the chemical causes an adverse public health and/or environmental impact on a specific topic defined within 69505.2 (a)(4) and 69505.2 (a)(5); or has otherwise been identified as causing an adverse public health and/or environmental impact on a specific topic defined within 69505.2 (a)(4) and 69505.2 (a)(5) by the authoritative body in a document that indicates that such identification is a final action; and
>>
>> (2) the list, report, or document specifically and accurately identifies the chemical, and has been:
>>
>>> (A) Reviewed by an advisory committee in a public meeting, if a public meeting is required, or
>>>
>>> (B) Made subject to public review and comment prior to its issuance, or
>>>
>>> (C) Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or
>>>
>>> (D) Signed, where required, by the chief administrative officer of the authoritative body or a designee, or
>>>
>>> (E) Adopted as a final rule by the authoritative body, or
>>>
>>> (F) Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

Klaus Berend *Brussels, 22 December 2011*
European Commission
Head of Unit Chemicals - Classification & Labelling, Specific Products, Competitiveness
Directorate-General Enterprise and Industry
Rue de la Loi 200, BREY - 11/254
B-1049 Bruxelles

Disclaimer: *the opinions expressed in this submission are personal and do not necessarily represent an official position of the European Commission*

Submission during the public comment period for DTSC's proposed Informal Draft Regulations for Safer Consumer Products R-2011-02

I would like to thank the Californian authorities for the possibility to submit comments on the Informal Draft Regulations for Safer Consumer Products.

Given that the draft Regulation will affect a potentially very broad range of consumer products and chemical substances contained in them and sets a number of technical requirements for their placing on the market in California, **the draft Regulation** – when being formally proposed for comments, which is expected early in 2012 - **should be notified to the WTO in the framework of the TBT agreement** to allow third countries to submit official comments in accordance with the TBT agreement. This is all the more important as many consumer products placed into the stream of commerce in California are manufactured outside the United States. Not all members of the WTO might be aware of the public commenting period in California, whilst notifications to the WTO are circulated to all members, giving all the possibility to examine draft regulations and provide comments as appropriate.

EU policy with regard to chemicals pursues very similar objectives as the informal draft Regulation, namely to achieve a high level of protection of human health and the environment by informing the users of products containing chemicals adequately about the risks and by substituting the most hazardous chemicals with safer alternatives. To this effect, the EU has put into place, among others, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (known as "REACH" and "CLP" Regulations). Both Regulations were developed in a transparent way with extensive consultation of all stakeholders (including from countries outside the EU) and on the basis of comprehensive feasibility studies and ex-ante impact assessments.

Unfortunately, in the accompanying documents for this public commenting period, DTSC has not provided information on possible costs or other impacts on companies, nor on any feasibility studies or considerations on whether and how the proposed Regulation would actually work in practice, nor quantitative or semi-quantitative estimates of any expected benefits. There is a suggestion that the initial list of chemicals of concern would comprise around 3.000 substances and the initial list of priority products 2-5 products. However, there is no analysis on how many companies would be affected by these initial lists, nor how they will develop in the future. Furthermore, alternative assessments have to be conducted by certified assessors (who can only be certified by accreditation bodies still to be recognised by DTSC), but it is unclear whether DTSC has estimated how many AA's will be required

following the publication of each list of priority products and whether a sufficient number of certified assessors will be available to deal with the expected number of AA's.

In particular, no examination has been made how the draft Regulation will affect companies in 3rd countries. This would be all the more important as the scope of the notified Regulation is very broad and covers all products that are placed on the market in California. The requirement to have the alternative analysis conducted by 'certified assessors', who can only be certified by accreditation bodies recognised by DTSC could be particularly difficult for companies in third countries. How can third country operators participate in the system which is set up by the draft Regulation, i.e. is there a possibility for third country operators to become 'certified assessors'? Who would be able to certify them? If this can only be done by accreditation bodies in California, operators from third countries would be at a significant disadvantage compared to those based in California or the US

In addition, the requirements concerning the alternative assessments and certain 'regulatory responses' seem very burdensome and difficult to comply with, in particular for small and medium size enterprises.

In the following, I will comment on the various sections of the draft Regulation in their order of appearance in the draft text.

Article 1:

Pages 4-5, list of acronyms: it might be useful to add also the following acronym for later reference in the text:

CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council on the classification, labelling and packaging of substances and mixtures

Page 8, lines 28-33: it is unclear why points (C) 'Physicochemical properties' and (D) 'Environmental fate properties' are considered to be part of a chemical identification. This is rather unusual as according to normal conventions Points (A) and (B) are sufficient for chemical identification purposes.

Page 9, line 23: a general *de minimis* level of 0.01% seems to be very low. The REACH Regulation in the EU uses 0.1 % as the standard *de minimis* concentration to decide whether certain obligations do apply or not. Likewise, the CLP Regulation (which follows the internationally recognised standard of the UN GHS system) uses 0.1% as the lowest concentration for a substance in a mixture to be taken into account for classification of the mixture. Furthermore, it would be interesting to know whether DTSC has ascertained that it will actually be possible to determine with analytical certainty for all potential substances of concern whether a *de minimis* level of 0.01% is complied with or not.

Page 13, lines 17-18: the definition of 'persistence' is not sufficiently clear as there is no indication about how long a substance is to exist in the environment in an unchanged form to be considered persistent. Criteria should be added as for example contained in Annex XIII of the REACH Regulation, or in the Stockholm Convention on Persistent Organic Polutants (POPs).

Page 14, lines 17-18: it is unclear why there is no reference to the EPA's rules on Good Laboratory Practice alongside the reference to Test Guidelines. The list of 'reliable

information' sources could also usefully be completed by a reference to the EU's REACH and ECHA guidance on information requirements and Chemical Safety Assessment, and a reference to the EU's test method Regulation (Commission Regulation (EC) No 440/2008). DTSC might also consider to explicitly recognize data from the registration dossiers submitted under REACH and published on the website of the ECHA as being 'reliable information'. This would avoid the repetition of tests on chemicals registered under REACH, which will avoid unnecessary animal testing and save costs for companies and authorities.

Page 18, line 39 and following: It is unclear how DTSC will be able to identify products that should be listed in the 'failure to comply list', if certain products have never been notified to DTSC as foreseen in section § 69503.6 (page 33). In fact, the entire system relies on 'self-identification' of priority products by manufacturers / importers / retailers, who might not all be willing to cooperate. How will DTSC ensure enforcement across all products?

Page 20, lines 6-7: when will DTSC determine the electronic format to be used and where will this information be available?

Page 20, lines 37 to 42: these provisions allow DTSC to make specific requests to individual responsible entities. How will DTSC ensure equal treatment of all responsible entities? For example, obligations on particular individual companies to generate new test data could have high economic impacts, whereas other companies would not be affected. How will DTSC avoid multiple testing involving vertebrate animals?

Page 22, line 13: is the publication of the name of the person that will fulfil the requirements of article 5 on DTSC's website compatible with rules on personal data protection?

Page 23, lines 25 to 27: how will this be implemented for companies operating in 3rd countries?

Article 2:

Page 24, lines 28-29: the reference to the ESIS PBT list needs to be clarified as the list published actually contains many substances that do NOT meet the PBT criteria. Only 27 out of 127 substances evaluated do meet the criteria. The text should read: 'substances identified as meeting the PBT criteria in the list of substances published in the European Chemical Substances Information System – PBT module' (available at: http://esis.jrc.ec.europa.eu/index.php?PGM=pbt)

Page 24, line 30: it should be noted that the list of endocrine disruptors referred to here is primarily a priority list for further evaluation and NOT a definitive list of recognised endocrine disruptors (see:http://ec.europa.eu/environment/endocrine/strategy/short_en.htm). An official designation as endocrine disruptors will be conducted under the REACH Regulation during the inclusion of substances into the so-called candidate list of substances of very high concern (SVHC) referred to in Article 57 of REACH. In fact, the first substance designated as endocrine disruptor has recently been included into the SVHC list. It might therefore be preferable to replace this reference by a reference to the *'list of substances of very high concern identified in accordance with Article 57 of the European Union REACH Regulation*'. In any case, it would be useful to add the SVHC list to this section.

Page 24, lines 31 to 32: should be deleted, as the Directive in question will soon be repealed and replaced by the CLP Regulation. The Reference to the CLP Regulation in lines 33-34 is the appropriate one.

Page 25, line 29: it is unclear what the term 'aggregate effects' relates to.

Article 3:

Page 26, lines 18 to 22: will there be a possibility to comment on the first list of substances of concern in a draft stage before it is finalised? This is foreseen for future additions, but not for the very first version. Given the large number of substances concerned, it would be advisable to publish a draft allowing for comments and corrections before finalisation.

Page 27, line 39 to Page 28, line15: It is unclear how this section can be applied in practice against a background of more than 3000 chemicals of concern. What will be the mechanism for DTSC to prioritise chemicals? Starting this process simultaneously for all 3000+ substances is rather impractical.

Page 28, lines 19-23: How will DTSC find the information to apply these provisions without a well functioning and populated product register? As mentioned before, there needs to be some prioritisation process for chemicals of concern as trying to establish the possibilities of exposure of the public or the environment to more than 3000+ chemicals all at once is impractical.

Page 31, lines 3-6: in the absence of a functioning and well-populated product register, how can DTSC ensure that **all** responsible entities will comply with this notification process?

Page 31, lines 22 and 27: including a reference to 'mode of action' introduces a significant complication. Whilst companies might be able to identify hazard traits of substance without disproportionate burden (e.g. by using Annex VI of the CLP Regulation or the EU's Classification & Labelling Inventory), establishing the 'mode of action' is much more complicated and requires significant expertise, which will not be available in most companies.

Page 33, line 29 and following: in the absence of a functioning and well-populated product register, how can DTSC ensure that **all** responsible entities will comply with this notification process?

Article 5

Page 35, lines 33-36: It will indeed be absolutely indispensable that DTSC develops guidance for the implementation of the very demanding alternative assessment that companies have to comply with under the draft Regulation. Stakeholders (and also third country authorities) should be involved in the process for the development of such guidance documents. In fact, the very extensive guidance that has been developed for the purposes of REACH and CLP could be a good starting point for DTSC, in particular the guidance on preparing a dossier for requesting authorisation for use of a chemical of very high concern placed on Annex XIV of REACH.

Page 35, line 39: is the publication of names of persons who have conducted an AA on DTSC's website compatible with rules on personal data protection?

Page 36, entire section § 69505.1: the timelines foreseen for the preparation of preliminary (6 months) and final AA reports (12 months) are impractically short – in particular when taking into account the high number of parameters to be evaluated and massive amount of work to be conducted. A timeframe of 36 months would probably be much more appropriate – and would be comparable to what is applied in the EU's REACH Regulation for substances listed in Annex XIV, which makes them subject to authorisation. Companies have a minimum of 18 months to prepare a dossier to request authorisation for continued use or a minimum of 36 months to substitute such substances in their products. Furthermore, as AAs have to be conducted by certified assessors, has DTSC estimated that a sufficient number of certified assessors will be available to deal with the expected number of AA's? Has DTSC made any estimates about how many AA's will be required following the publication of each list of priority products?

Page 37, line 12: This provision is unclear – what will be the consequence of DTSC's failure to take a decision within the given time frame?

Page 37, lines 18-19: This provision seems to imply that there will be absolutely no data protection for AA's conducted on behalf of a responsible entity, as apparently after publication of an AA, any other responsible entity can use the AA. This seems rather unfair as the first responsible entity might have invested considerable resources into the preparation of the AA. Consequently, during an appropriate period of data protection (e.g. 10 years), the consent of the responsible entity having prepared the first AA should be required before another responsible entity can simply re-use the AA.

Page 37, lines 35 to 39: again, this provision is very unclear: what will be the consequence of DTSC's failure to take a decision?

Page 40, line 3: as already mentioned before, a time period of 12 months for preparing a final AA report is probably much too short.

Page 41, lines 8 to 12: the required identification of 'externalised costs' is extremely demanding as the relevant data are not easily available. The range of factors to be analyzed during alternative assessments is very broad, which makes the analyses almost impossible to perform at reasonable costs and within a reasonable time. For many parameters it will be virtually impossible to find (or just model) the required data, and this will be even more complicated if products are manufactured in third countries. Has DTSC undertaken any feasibility analysis or 'beta-testing' to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an entire alternative assessment and whether these costs are proportionate? If so, would it be possible to receive such studies and feasibility considerations?

Page 43, line 12-15: why is the information regarding the location of production facilities relevant and why would it be important in the analysis that should identify 'safer consumer products'? What consequences would this have for production facilities that are located in third countries? It is also unclear what can be done about the proximity (or not) to certain raw materials that are not universally available. The entire point (e) should, therefore, be dropped.

Page 43, lines 37-38: requiring the identification of 'unavailable reliable information' seems a contradiction in terms. How can the reliability of information be judged, if it is not available?

Page 45, lines 17 to 20: a requirement to identify ALL chemical ingredients in a product is extremely burdensome, in particular for assembled articles such as electronics or household appliances, which can contain hundreds of different chemicals. Already the determination of the presence (or not) of chemicals of concern is a challenge for many companies, while providing a complete list of all ingredients will not be practical and serves no particular purpose.

Page 46, lines 1-3: the review period for DTSC to judge the quality of an AA report (60 days) is extremely short. How many resources will be available in DTSC to conduct this task? How many AA's are expected per batch of products to be listed as priority products? The same applies to all other time periods mentioned in section § 69505.6, which appear all to be impractically short.

Page 47, lines 9 to 17: the current wording seems to imply that all such decisions will concern responsible entities individually. How will DTSC ensure equal treatment of all responsible entities when requiring a particular regulatory response so as to avoid discriminatory treatment? As a more general comment: what will DTSC do in case of diverging or conflicting results of AA reports for the same / similar products and chemicals of concern? Given that many different actors will conduct AA, the risk that there will be diverging results will actually be quite high.

<u>Article 6:</u>

Page 47, lines 34-38: this provision gives large discretion to DTSC to request additional input from individual responsible entities. How will DTSC ensure equal treatment of all responsible entities?

Page 48, lines 11-15: can DTSC clarify whether the reference to 'a chemical of concern' has to be understood as (1) meaning 'any chemical of concern' on the entire list of 3000+ substances, or (2) 'any chemical of concern' due to which the product has been identified as a priority product? The second option would seem logical as the entire AA revolves around the chemicals of concern due to which the product was identified as a priority product. Furthermore, the first option would be disproportionate as it will be next to impossible for responsible entities to test their products for the absence of 3000+ substances.

Page 48, lines 23-26: it seems a bit illogical to refer in this provision to a situation where an alternative product has been selected, as the obligation to provide information on the presence of chemicals of concern is rather relevant for situations, where no alternative has been selected. Furthermore, in the entire section, it is again not clear whether the information obligation would apply to all 3000+ substances of chemicals of concern, or only to those due to which the product had been identified as a priority product. This should be clarified taking into account the arguments made in the previous comment.

Page 49, line 18 and entire Page 50: the 'regulatory response' to fund, establish and maintain an end-of-life management program for a particular product seems impossible for individual companies – in particular for manufacturers of products in third countries - and can probably only be achieved if DTSC establishes a rule applicable to (a range) of products that would apply to all responsible entities. Furthermore, the extensive reporting requirements linked to such end-of-life management programs will be very burdensome. Has DTSC undertaken any feasibility studies and cost analyses with regard to this particular 'regulatory response'?

Page 51, line 12: why is there only a reference to a possibility to establish a shorter phase-out period compared to the 1-year standard period when establishing product bans? There could also be cases where a longer period will be necessary.

Page 51, line 23: it should be clarified that this provision relates only to chemicals of concern due to which a product has been identified as a priority product and not to all 3000+ chemicals of concern.

Page 52, lines 20-22: According to which criteria will the obligation to fund 'Green Chemistry' Research be put into practice? How will the amounts be determined that a responsible entity will have to provide? As a share / percentage of overall sales? How will DTSC avoid discriminatory treatment of different responsible entities to which this regulatory response would apply?

Page 55, lines 2-7: it seems illogical to require that responsible entities inform their retailers about the regulatory response imposed by DTSC. This would again give advantages to non-compliant responsible entities, which never entered the system via product notification. It would be more logical that DTSC itself informs all retailers about the requirements established and then also requires them to notify priority products for which no AA has been conducted.

Article 8:

Page 59-64: dealing with qualifications of accreditation bodies and certified assessors. These sections are entirely unclear with regard to the possibilities for companies established in third countries to be designated as certified assessors and/or accreditation bodies. Will all of these possibilities be open to companies in third countries? This will be particularly important for 'accreditation bodies', which will act as multipliers to certify assessors. Furthermore, the required qualifications for accreditation bodies are very demanding and seem to be strongly in favor of universities or certain university institutes with the possibility to teach and offer courses with a particular curriculum as described on page 60 in section § 69508.1. Would the US bodies member of IAF (International Accreditation Forum) be eventually designated as "accrediting bodies"? Has DTSC conducted any studies to ascertain that there are a sufficient number of actors that could qualify to become accreditation bodies and certified assessors? In general, the provisions of the draft Regulation that alternative assessments must be conducted by certified assessors who can receive this designation only from accreditation bodies is potentially a higher barrier for products manufactured in third countries and would definitely be such a barrier if only companies established in the US could become accreditation bodies and/or certified assessors.

December 22, 2011

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
(via e-mail: gcregs@dtsc.ca.gov)

Re: Informal Draft Regulations for Safer Consumer Products

Dear Ms. Jones:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Informal Draft Regulations for Safer Consumer Products* released on October 31, 2011 by the California Department of Toxic Substances Control (DTSC or the Department) for the implementation of AB 1879 (2008).

ACI is the trade association representing the $30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy. As a trade association for a particular consumer product sector (cleaning products), we are acutely aware of the public's concern for the safety of the products they purchase both in their homes during use and in the environment following disposal. Human and environmental safety is at the core of the mission of our member companies and our association.

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

Notable Improvements

The Department has taken a very thoughtful and deliberate approach to this latest iteration of the Safer Consumer Product regulations. We commend DTSC 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. 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 DTSC has chosen the most efficient process, using publicly available data when it can and requiring submissions when needed. We believe this will result in more rapid identification of Chemicals of Concern and Priority Products with alternatives assessments being conducted more quickly and avoiding delay in regulatory decisions.
- The elimination of third-party verification makes the Alternatives Assessment process more efficient without compromising the level of quality of those submissions.

Unfortunately, a number of other areas in the regulations require further amendment or deletion entirely.

Processes to Identify Chemicals of Concern Are Still Needed
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." While appropriately identifying three component processes, DTSC has not sufficiently and transparently specified how each means of identification would work. It is irresponsible for the Department to cast aspersions on thousands of chemicals without context or acknowledgement of the innumerable safe and beneficial uses of those chemicals. This aspect still needs significant attention.

Further Need for Clear Definitions and Thresholds
The regulations continue to suffer from vague definitions and a lack of thresholds that the Department would use to make decisions on what chemicals and products will require an alternatives assessment. The "narrative standard" the Department has stated it will use to narrow the tens of thousands of potential chemical-product combinations to two to five is completely opaque and lacking in credibility. It will only garner mistrust from all stakeholders. Given the unique nature of AB 1879 and the Safer Consumer Product (SCP) regulations, the Department needs to foster confidence in its decision-making and demonstrate that there are material improvements in human and environmental health commensurate with regulatory burdens placed on consumer product manufacturers that will ultimately be borne by the citizens of California. As such, DTSC needs to establish transparent criteria for selecting Chemicals of Concern and the high priority products containing them as mandated by the statute.

The Alternatives Assessment Requirements and Regulatory Responses Remain Onerous
The Alternatives Assessment requirements and the Departmental regulatory responses remain very onerous and punitive. While a large company may be able to adapt to the regulations and its requirements, small and medium sized companies, which are more numerous in California, will be crushed by the imposed burdens for simply selling safe and legal products that have fallen out of favor with the Department. DTSC needs to adjust its perspective towards the regulated community to be the catalyst for change and a facilitator for that change in companies that would typically lack such expertise, rather than the enforcer of innovation-crushing regulations. The AA requirements should be streamlined so that companies can complete the reports quickly and efficiently and so they can rapidly take action to bring safer products to the market.

ACI would like to express, once again, its appreciation in being able to comment on the informal draft Safer Consumer Product regulations. We would be happy to further assist DTSC in the development of regulations implementing AB 1879 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Sincerely,

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

Enclosure

cc: The Honorable Matthew Rodriquez, Acting Secretary, CalEPA (MRodriquez@calepa.ca.gov)
Debbie Raphael, Director, DTSC (DRaphael@dtsc.ca.gov)
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ACI Comments

DTSC Informal Draft Regulations for Safer Consumer Products (released Oct. 31, 2011)

Article 1. General

Section 69501.2 – Definitions

- (2) Adverse air quality impacts – revise to read "means air emissions of any of the air contaminants listed below in quantities that present an unacceptable public health or environmental risk."
- (3) Adverse ecological impacts – this definition lacks clarity regarding the threshold at which the stated adverse impacts occur. If the definition is retained, it should be revised so that those thresholds are clearly identified.
- (5) Adverse public health impacts – We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.[1,2] We maintain that the regulations as proposed include many elements that are unauthorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. As such, the SCP regulations should not reference Chapter 54.
- (6) Adverse soil quality impacts – revise to read "means emissions to soil of contaminants in quantities that present an unacceptable public health or environmental risk." Also, the properties listed are poorly defined. In particular, the terms "biological contamination" and "chemical contamination" are not defined such as to clearly state the threshold at which contamination occurs.
- (7) Adverse waste and end-of-life impacts – revise paragraph (C) to read "…and that may result in the release of Chemicals of Concern to the environment in quantities that present an unacceptable public health or environmental risk."
- (8) "Adverse water quality impacts" – it should be clear that any of the "increases" cited in the definition should be of a magnitude that results in an unacceptably high increase in risk to public health or the environment. With respect to subparagraphs (A) "Increase in biological oxygen demand" and (B) "Increase in chemical oxygen demand," they are effectively measures of biodegradability and the oxidizeable (carbon) content of a chemical; these are generally not characterized as adverse impacts. Likewise, in subparagraph (D), "total dissolved solids" is simply a description of physical state of a material within water. These three subparagraphs should be eliminated.
- (9) Alternative – the definition should retain the concept that an alternative could include a chemical substitution or engineering controls [subparagraph (C)].

[1] http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf
[2] http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf

- (14) Bioaccumulation – 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.[3,4] 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 "food-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 "that 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." The SCP regulations should use a similar definition of bioaccumulation and accommodate these five criteria (TMF, BMF, BAF, K_{OW}, and K_{OA}) as 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}).
- (17) Chemical ingredient – revise to read "means a chemical <u>intentionally used</u> in a consumer product <u>to impart a particular function in the product</u>. This definition should be made consistent with other state or Federal statutes or regulations whereby ingredients are recognized as functional components of a product intentionally added to impart a function. For example, the FDA's cosmetics regulations provide the following definition for an ingredient: "The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product" [21 CFR 700.3(e)].
- (18) Chemical identification and description information – subparagraphs (B) and (D) should be eliminated from this definition. Information regarding impurities associated with a particular chemical will be specific to a particular chemical manufacturing process and are not inherent chemical properties. Environmental fate properties are interesting information

[3] 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.
[4] http://www.setac.org/sites/default/files/ExecutiveSummary.pdf

for a particular chemical but should not be included within this definition as they are typically wholly separate information.

- (19) Chemical of concern – revise to read "means a chemical ingredient identified as a Chemical of Concern under section 69502.2(a)…" In the spirit of the statute (AB 1879), Chemicals of Concern should be limited to those ingredients intentionally added to consumer product by a manufacturer in order to impart a function in the product. Moreover, by focusing the scope of the regulations, the stated intend of the Department to encourage manufacturers to consider the necessity of ingredients in their products will be better effectuated.
- (25) *De minimis* level – The selection of certain traits as the basis for a lower *de minimis* threshold is unclear and completely arbitrary. In particular, bioaccumulation and environmental persistence are inappropriate *de minimis* criteria on their own. However, the Department has not clearly justified the use of any hazard trait or chemical property as the basis for any *de minimis* threshold. Subparagraph (A) should be deleted.
- (32) Environmental fate properties – this definition is poorly conceived in that some of the proposed terms are related or similar (e.g., aerobic soil half-life, biodegradation, persistence). This definition should be revised and clarified.
- (33) Environmental or toxicological endpoints - We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.[5,6] We have noted the serious flaws in the process used by OEHHA, their unwillingness to consider comments from their peer-reviewers and the public at large including numerous subject matter experts, and the flawed science at the heart of the regulation. We urge DTSC to reject this definition and the entire OEHHA regulation, and to develop scientifically sound definitions of environmental and toxicological endpoints.
- (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.
- (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

[5] http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf
[6] http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf

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 to be designated as a persistent substance 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."

- (66) Reliable information – the proposed definition of "reliable information" relies on the flawed OEHHA Hazard Trait Regulation definition of a "well conducted study" which includes any study published in the open literature. Publication of a report or study, whether in a peer-reviewed journal or otherwise, is no guarantee that the underlying data and information are appropriate for regulatory decisions. While the information sources cited in the definition may be appropriate to consider in a weight-of-evidence decision-making scheme, an entirely separate process is necessary to ensure that the information used is in fact a well conducted study. We support definitions of "reliable information" and "a well conducted study" consistent with the approach used by the Organization of Economic Cooperation and Development (OECD) in their Manual for Investigation of HPV Chemicals. As such, we suggest: *"Reliable information" is from studies or data generated according to valid and 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 may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, December 2009) shall be used for the determination of reliable studies.*

  The definition of "authoritative organization" should include the Organization for Economic Cooperation and Development, and its member countries.

- (67) Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical – Revise subparagraph (C) to read "… that indicate biomagnification of a chemical in food chains." With this revision, subparagraph (F) can be deleted as it is redundant.

- (68) Responsible entity – The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the Federal Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (CARB, CPSC, etc.). All consumer commodities that are legally distributed in 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.

- (70) Safer alternative – revise to read "means a functionally acceptable alternative that, …"

- (73) Substance identification information – revise to read "means <u>any</u> of the following <u>that may be used individually or in combination to uniquely identify a chemical</u>:"

Section 69501.3 – Duty to Comply and Consequences of Non-Compliance

- In Section 69501.3(a)(1), the requirements for compliance should be limited to the manufacturer of the product. As such, references to the importer or retailer should be eliminated. The vast majority of reputable retailers will be responsive and take action against products where a manufacturer is out of compliance with state regulations by removing it from their shelves.
- Section 69501.3(c) should be removed since, based on the comment above, it is no longer relevant.

Section 69501.4 – Information Submission and Retention Requirements

- The certification statement would create a new crime, and DTSC does not have that authority. It is sufficient that an officer of the company responsible for the information submission sign the documents.

Section 69501.5 – Chemical and Product Information

- Under subparagraph (a)(4), the Department would give itself unlimited authority to require a manufacturer or importer to generate and obtain information with no accountability. There should be boundaries regarding the kind of information that the Department may seek, and due process for those for whom the Department is making the request.

Section 69501.6 – Availability of Information on the Department's Website

- The Department should use official state regulatory dissemination methods (e.g., California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the Safer Consumer Product regulations.
- The Department proposes to require itself to post non-critical information on its websites. These provisions should be eliminated from the regulations as requirements and the Department might optionally post them electronically as resources are available. As such, the following subparagraphs under Section 69501.6(a) should be eliminated: (3), (4), (7), (8), (9), (10), (11), (13), and (14). The following subparagraphs under Section 69501.6(b) should be eliminated: (4), (5), (6), and (8).

Article 2. Chemicals of Concern Identification Process

The mechanisms for identifying Chemicals of Concern, namely, an initial listing, a Departmental listing process, and a petition process are good components to this section.

Section 69502.2 – Chemicals of Concern Identification

- Section 69502.2(a): Initial Chemicals of Concern List – the process contemplated for initial listing of chemicals has some good core elements, namely the identification of severe hazard

traits and the use of existing authoritative listings to rapidly identify chemicals which have those severe hazard traits. However, we recommend additional criteria and screening parameters which will make the listing process more credible and transparent.

- We recommend that the initial listing focus on known carcinogens and reproductive and developmental toxicants. In addition, the list should focus on persistent, bioaccumulative and toxic (PBT) substances using criteria consistent with the US EPA's definition of PBT substances.
- A number of the proposed lists are not good sources and should not be used:
  - The EU Cat 1 and 2 endocrine disruptors list (1)(G) has been disavowed by EU authorities. Endocrine disruptors will be captured by those chemicals identified as developmental or reproductive toxicants.
  - The Washington State PBT list (1)(O) did not use criteria consistent with the US EPA PBT list (N).
  - The OSPAR lists (2)(B) and (C) are not authoritative lists.
  - The use of the Grandjean & Landrigan paper on neurotoxicants (3)(A) is completely arbitrary.
- Using the other lists identified in the draft regulation as potential sources to identify Chemicals of Concern, the Department further screen the chemicals included to only those permitted in commerce in the United States, those chemicals that are in commerce in California large volumes, and those chemicals that are known to be used in consumer products. By using such screens, the Department will be left with a manageable and meaningful list of Chemicals of Concern.

- Section 69502.2(b): Additions to the Chemicals of Concern List – the narrative standard for identifying additions to the Chemicals of Concern list is not sufficiently transparent. The Department needs to provide additional clarity to this process so that it is objective and repeatable if conducted by different sources.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

Section 69503.2 – Priority Product Prioritization

- While the principles embodied in this section are appropriate, the application of them is unclear. The decisions by the Department are likely to appear to be arbitrary if they are not *in fact* arbitrary. The Department should clarify how the prioritization of priority products will occur so that decisions are transparent <u>before</u> they are made.
- Subparagraph (a)(1)(B)4.e. should be revised to read "…and potential for <u>bio</u>accumulation and persistence in biological and or environmental components…"

Section 69503.5 – De Minimis Exemption Notifications

- The De Minimis Exemption Notification process should be eliminated in favor of a self-assessment process. OEHHA uses a self-assessment process under the Proposition 65 Safe Harbor provisions for companies to determine whether they have to label a product. This aspect of Prop 65 has been very successful and should be a model for the application of the de minimis provisions of the Safer Consumer Product regulations.

Article 5. Alternatives Assessments (AA)

Section 69505 – Guidance Materials

- Under subparagraph (a), it is critical that substantive guidance documents be prepared and disseminated prior to Priority Products subject to the Alternatives Assessment process being identified. <u>This provision should be retained</u>.

Section 69505.1 – Alternatives Assessments: General Provisions

- Subparagraph (e) requires that a responsible entity identify the "most appropriate regulatory response" along with an equivalent previously completed AA. A responsible entity cannot know what the Department might consider to be the most appropriate regulatory response. As such, this element should be eliminated in this provision.

- Subparagraph (f) would require the responsible entity consider all relevant information made available on the Department's website. The Department's website is quiet extensive and the Department intends to add at least 16 new elements under this program. This would be an enormous quantity of information for any entity to review. Since the Department will be best suited to know what materials on its website are appropriate for a particular Alternatives Assessment, they should specify them. Subparagraph (f) should be eliminated and the Department should instruct the AA preparer as to what information it believes is important for the preparer to consider in its assessment. Such guidance also will have the advantage of fostering consistency among assessments from multiple manufacturers for the same Chemical of Concern in a particular consumer product.

Section 69505.4 – Alternatives Assessment: Second Stage

- The Department proposes to require a number of elements in the Alternatives Assessment Report that consortia of companies will not be permitted to discuss and evaluate because of antitrust restrictions. Among those restrictions are communication or exchange of confidential competitive information (69505.4(a)(2)(B)1 and 2), prices of ingredients or products (Section 69505.4(a)(2)(B)3), and business plans (Section 69505.4(c)). 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 Sections 69505.4(a)(2)(B) and (C), and 69505.4(c). This will still test the more restrictive US 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 Section 69505.4(a)(2)(B) and (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.

- For Section 69505.4(a)(2)(A), the multimedia life cycle impacts and chemical hazards assessment should be limited to the chemical(s) of concern in the priority product that are the subject of the alternatives assessment, and not all ingredients in the product. Replace "chemical ingredients" with "Chemicals of Concern."
- For Section 69505.4(a)(2)(B)3, a responsible entity will have to consider the economic feasibility of any alternative before they commit to putting a product on the market. However, in the context of the timeframes required by the statute for the AA reports, the affordability and pricing information may not be reliable for the purpose of the decisions the Department requires later in the AA report. Subparagraphs b. and c. should be eliminated as the information will not be reliable.
- Section 69505.4(a)(2)(C) – Economic Impacts should be eliminated as this will be well beyond the expertise of most responsible entities and any consultants they may hire to help prepare the AA report. Further the information is not relevant to the selection of an alternative and represents an undue burden to the responsible entity. The information may be relevant to the Department with respect to a regulatory response however the Department should find a more appropriate means of generating this data.
- Section 69505.4(c) – Step 3, Alternative Selection Decision should be eliminated. It is inappropriate and impractical for responsible entities to be incorporating their business plans in an AA report.

Section 69505.5 – Alternatives Assessment Reports

- In Section 69505.5(a)(4), the Department would require the responsible entity to include sufficient information in the Final AA Report for the Department to determine the appropriate regulatory response. The responsible entity cannot know what information is sufficient for the Department to make a decision. This requirement is unnecessary and inconsistent with the statute and should be eliminated from the regulations.
- Section 69505.5(d)(3) would require the name and contact information of all persons to whom the manufacturer or importer directly sold the Priority Product in California. There are a number of large direct selling companies who do business in California and who have tens of thousands of independent business operators to whom they sell their products for further sale to consumers. For the state to require the name and contact information of potentially tens of thousands of private citizens is both impractical and unnecessary. This provision should be removed from the regulations.

- Section 69505.5(e) should be revised to read "A description and location of the facilities in California where the Priority Product is produced." The state cannot extend its authority beyond its borders.
- Section 69505.5(h)(2) would require the Final AA Report to identify "unavailable reliable information…" This requirement seems on its face to be a "Catch-22". How is any entity supposed to know the potential reliability of information that is unavailable to them? This section should be stricken from the regulation.
- Section 69505.5(l) would require the Final AA Report to identify and describe the alternative that is selected. This requirement is unnecessary for the effectuation of the regulations including the Regulatory Response from the Department. These kinds of business decisions are very sensitive and may be very fluid for a company. Moreover, the Department lacks the authority to "approve" whether a particular product is permitted to be on the market. The Department's authority is specific to requiring an alternatives analysis to be conducted and for the Department to make a Regulatory Response with respect to that analysis. The Department does not have the authority to pick winners and losers in the market place and to dictate what products a company may or may not produce. This section and its associated subparagraphs should be stricken from the regulation.
- Section 69505.5(l)(4) would require a list of all chemical ingredients known to be in the selected alternative, and all available chemical identification and hazard information for those chemicals. This information is completely irrelevant to the alternatives assessment or the regulatory response. It is completely unnecessary. This section should be eliminated from the regulations.
- Section 69505.5(n) would require the Final AA Report to contain the identification of regulatory responses. This requirement is inappropriate as responsible entities typically will not be well qualified to propose regulatory policy. This section should be eliminated.

Article 6. Regulatory Responses

Section 69506.1 – AA Report Supplementary Information Requirements

- This section would give the Department unlimited authority to obtain information from the responsible entity. The statute does not give the Department such unlimited authority. This section should be clarified to specify the boundaries of the Department's authority.

Section 69506.2 – No Additional Regulatory Response Required

- Subparagraph (b) should be eliminated. This requirement is unauthorized by the statute and is unnecessary. Once the manufacturer has met his regulatory burden by conducting an alternatives assessment, and if the manufacturer has eliminated the chemical of concern from his product, they should not be subject to further regulatory requirements from the Department. Moreover, the Department is placing an enormous, unachievable burden upon itself to conduct an assessment and reach affirmative findings of human and environmental

safety based on the dozens of endpoints in the proposed OEHHA Hazard Trait regulations and the additional impacts defined in this draft regulation.

Section 69506.3 – Product Information for Consumers

- The Consumer Product Safety Commission (CPSC) has regulations specific to the labeling of packages with ingredient information. CPSC requires identification on the label of those chemicals that are responsible for a hazard warning appearing on a label. They see this as critical to the consumer having access to essential, focused information that they can provide over the phone to medical personnel in the case of an accidental exposure. Likewise, Poison Control Centers share a similar concern regarding product labeling. The Department should reconsider whether it is wise (and consistent with Federal regulations) to require product labeling (Section 69506.3(b)(2)(A)) that distracts from important safety warnings. Furthermore, the regulations should permit the dissemination of this information through electronic (website) or telephonic means.

Section 69506.5 – Product Sales Prohibition

- Subsection (a) should include provisions that the Department has determined that a product containing a safer alternative is also acceptable to consumers and provides real mitigation of harm in addition to being functionally acceptable and technologically and economically feasible before prohibiting the sale of the Priority Product.
- The Department proposes an inventory recall requirement for Priority Products which have been prohibited. An inventory recall should only be used in the case where there is an immediate unreasonable risk to consumers. Otherwise, sell-through of remaining inventories should be permitted in the state.

Article 8. Accreditation Bodies and Certified 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.

Article 10. Trade Secret Protection

- Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes. In particular, Section 69510(a)(10), (11) and (12) are excessive requirements that should be eliminated from the regulations.

(IC)70- Breast Cancer Fund

December 30, 2011

Debbie Raphael
Director
California Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

Dear Ms. Raphael,

On behalf of the Breast Cancer Fund, I wish to commend the Department of Toxic Substances Control staff for its work on the Safer Consumer Product Regulations. The dedication that you have shown to ensuring practical, meaningful and legally defensible regulations are evident in this most recent informal draft.

Thank you for the opportunity to provide comments to you on the draft outline of the AB 1879 regulations. While this draft is a vast improvement over previous proposals, we note that the framework still has some shortcomings that need to be addressed before the formal draft is released in 2012. We appreciate your willingness to accept our critique and hope that the suggestions below are useful and are implemented in the next round of draft regulations.

Identifying and Prioritizing Chemicals of Concern in Consumer Products

We appreciate that DTSC has created such a comprehensive list of chemicals of concern (COC). This COC list will include several hazard traits that have traditionally been ignored by other regulatory agencies. While this list may contain as many as 3,000 chemicals, it is important to note that this is still a small fraction of the number of chemicals registered for use in the United States. A comprehensive list such as this will send a strong market signal to manufacturers to stop using these hazardous chemicals and to start searching for safer alternatives even before a product-chemical combination is prioritized. However, we note that such a scenario may drive manufacturers toward untested alternatives. We continue to believe that AB 1879 gives DTSC the authority to mandate a minimum data set for chemicals with limited information and urge DTSC to use its authority to establish such a requirement.

We also support the process DTSC has established for prioritizing product-chemical combinations and believe the timeline set out in the informal draft regulation for establishing the priorities is aggressive yet realistic. We strongly support DTSC's decision to use a narrative standard for choosing these priorities given that it is impossible to "rank" hazardous chemicals since they do not exhibit identical hazard traits and since they are used in a variety of ways. Moreover, establishing a complicated

numerical ranking system will take precious resources away from an already overly-stretched agency and will take far too much time.

While the Breast Cancer Fund supports DTSC's decision to start with a small number of product-chemical combinations, we are concerned that the prioritization list is only required to be updated every three years. Moreover, the department does not mandate the minimum number of product-chemical combinations that are required to be prioritized. As DTSC becomes more comfortable with the prioritization process and learns from early pilot tests, its ability to prioritize more product-chemical combinations will increase over time. We urge the department to mandate that the list of prioritized product-chemical combinations be updated every other year and that the department establish a minimum number of combinations that will be prioritized each year.

***De Minimis* Exemption**

We were dismayed to see that the informal draft still contained a *de minimis* exemption allowing manufacturers using small amounts of chemicals to be exempted from this regulation. While the exemption's structure is slightly improved over previous versions, the fact that DTSC is allowing any hazardous chemical that is intentionally added to a product to be exempted merely because the amount that is used is small is scientifically unsound and will not drive the development of safer alternatives. While we appreciate the strides DTSC has taken to ensure that chemicals that exhibit certain hazard traits will be assigned a lower *de minimis* level, this approach still ignores the effects that these chemicals can have during their production, use and disposal. The 0.01% standard for the more sensitive hazard traits also ignores scientific evidence demonstrating that certain chemicals, such as endocrine disruptors, can produce toxic effects at the part per billion or even part per trillion level. The fact that DTSC is authorized to set a lower *de minimis* standard does not address our concerns because decisions such as these can be easily politicized.

While we understand that it may be important to set a numerical value so that the regulation does not capture trace amounts of contaminants, we believe that the current draft will ultimately exempt far too many product-chemical combinations and urge DTSC to reconsider its approach on this issue. We continue to believe that the science justifies setting no *de minimis* level for persistent, bioaccumulative toxins (PBTs), carcinogens, mutagens, reproductive toxicants or endocrine disruptors. If that approach proves impossible, we urge DTSC to set the default *de minimis* at a lower level than 0.01% for these hazard traits with the possibility for raising the default *de minimis* level when evidence warrants.

Alternatives Analysis Process

The Breast Cancer Fund acknowledges the steps DTSC has taken to simplify the Alternatives Analysis (AA) process. We appreciate that DTSC will be providing manufacturers with guidance documents on how to produce AAs and we also acknowledge that starting in 2015, AA preparers must be certified by an independent third party. However, we remain concerned that manufacturers with a vested interest in maintaining the status quo will be preparing the AAs with only minimal oversight. By their very nature AAs are subjective and rely on many built-in assumptions. Such subjective analyses can easily result in a pre-determined outcome. We are concerned that DTSC has neither the expertise nor the resources to

review, and challenge where necessary, AAs that are based on faulty assumptions. Therefore, we recommend that DTSC institute an independent review of AAs paid for by the manufacturers so that the public and the agency can have the confidence that the AA reports are being prepared in a consistently sound manner.

Additionally, we are concerned that the AA process, while simplified, is still too time-consuming and has the potential to bury DTSC in paperwork. By requiring each company to submit both a preliminary report and a final report, both of which must be reviewed by DTSC, the staff will be spending more time reviewing paperwork than prioritizing products and issuing regulatory responses. We are concerned that allowing 12 months to produce a preliminary report and an additional 12-24 months to produce final report will allow toxic chemicals to remain in products for over three years while the reports are prepared and an unknown number of years following submittal of the AA report for DTSC to review and issue a regulatory response. We encourage DTSC to tighten these timelines. We recommend giving manufacturers 6 months for a preliminary AA and a maximum of 12 months to produce the final report. We also encourage DTSC to establish timelines for its own review of the AAs and issuing of a regulatory response so as to ensure the process moves quickly.

Regulatory Responses

We also encourage DTSC to reexamine the regulatory response section and to provide clear guidance on when specific regulatory responses will be taken based on the outcome of Alternative Analyses. In the current draft, it is unclear when regulatory responses will become effective and there is a further lack of clear guidance on which AA outcomes will result in which response. We urge the department to consider the recommendations that we have outlined here for inclusion in the regulatory response section.

1. If a safer alternative is found, any manufacturer who uses the chemical of concern that triggered the AA will be prohibited from using that chemical in future production of the prioritized product.
2. If a safer alternative is not found, DTSC will consider the societal utility of a product that is manufactured using a COC before issuing a regulatory response. Products manufactured with COCs where no alternative is found and that are not deemed to be critical for societal function should be severely restricted regardless of the outcome of the AA.
3. Labeling should be mandated when a selected alternative is not hazard-free.
4. Manufacturers implementing alternatives that still pose some level of hazard should be subject to green chemistry challenge grants in order to find alternatives with lower hazard profiles.

Dispute Resolution

Finally, DTSC should clarify its dispute resolution process to ensure that the entire program is not halted based on an individual challenge or dispute. As written, the informal draft regulations could allow for a single challenge or dispute to suspend the work of the program which is likely not DTSC's intent. We

urge that you clarify this language so as to allow for a thoughtful dispute resolution process without delaying implementation of the rest of the program.

Workers as vulnerable populations

We were pleased to see the informal draft regulation addressed worker exposure to chemicals of concern. However, we believe that DTSC should further strengthen worker protections since they are often the population that is the most exposed to chemicals of concern throughout the manufacturing process. First, DTSC should explicitly add workers as a vulnerable population in the definition section so as to ensure they are given the same consideration as other vulnerable populations. Second, we urge the department to delete exemptions to the definition of consumer product that have no basis in statute. Specifically, the provisions excluding products that are made in the state but not sold here (69501(b)(3)) and the provision excluding chemicals used to make consumer products that are exempted from the program (69501 (b)(2)). Specifically excluding these product categories has no statutory basis and precludes DTSC from addressing the threats posed to California workers and fence-line communities that may be exposed to any COCs used in manufacturing facilities or during transport of the COCs through the state. We urge the department to delete these provisions in the next draft of the regulations.

Resources

Perhaps the biggest limitation with the informal draft regulations is the absence of a funding source for the program. While DTSC has maintained that it does not have the authority to levy a fee on the manufacturers and users of toxic chemicals, we encourage the administration as a whole to work with the legislature to establish this authority. Without such an authority, the program will never be able to address the myriad threats posed by toxic chemicals in consumer products in a timely way.

Thank you again for the opportunity to provide you with comments on these regulations. Should DTSC make the suggested adjustments outlined in this letter, the program will be a model for the nation and the world and will signal a paradigm shift in chemical regulation toward the strongest possible protection of public health. We stand ready to assist you in ensuring such a program is implemented and funded into the future.

Very truly yours,

Gretchen Lee Salter

(IC)71-Air-Conditioning, Heating and Refrigeration Institute

Good morning,

I am a staff member at the Air-Conditioning, Heating and Refrigeration Institute (AHRI), the trade association representing manufacturers of heating, cooling, water heating, commercial refrigeration equipment and commercial HVAC pumps. More than 300 members strong, AHRI is an internationally recognized advocate for the industry, and develops standards for and certifies the performance of many of the products manufactured by our members. In North America, the annual output of the HVACR industry is worth more than $20 billion. In the United States alone, our members employ approximately 130,000 people, and support some 800,000 dealers, contractors and technicians. We have the following questions with respect to the informal draft regulations on safer consumer products (SCP):

1. The informal draft indicates that a list of approximately 3000 chemicals of concern (COCs) will be posted on the Department of Toxic Substances Control's (DTSC) website within 30 days after the effective date of these regulations. Additionally, the DTSC is expected to publish a priority product list within 180 days after the regulations effective date. The informal public comment period ends on December 30, 2011. We view the COC and the priority product lists as being essential pieces of the SCP regulations and would appreciate an opportunity to review and comment on these lists prior to the December 30 deadline. Is there any mechanism through which we can view the preliminary COC and priority product lists immediately?

2. § 69501.2.(a)(2) defines greenhouse gases like hydrofluorocarbons (HFC), nitrogen oxides and nitrous oxide (NOx) as air contaminants that have adverse impacts on air quality. What research study provides a basis for classifying greenhouse gases as air contaminants? Additionally, does the informal draft take into account the existing federal and state regulations on greenhouse gases?

Best Regards,
Aniruddh

Aniruddh Roy
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(IC)72-Waste Management

>>> "White, Chuck" <cwhite1@wm.com> 12/6/2011 5:05 PM >>>
Heather -

I spoke briefly to Odette at the recent Green Chemistry (GC) workshop. The concern I have is whether the regulations could be interpreted in any way to place a compliance obligation on recycling and reuse service providers that pull recyclable and reusable products out of the waste stream for reuse and/or recycling. The waste and recycling industry is challenged with finding ways to maximize the recovery and recycling of materials that would otherwise become wastes. These wastes would likely contain Products of Concern (POCs). If we recycle and sell POCs or their component parts to third parties, would we be somehow become a Responsible Party as a "Retailer" of the recyclable POCs or component parts. The list of recyclable or reusable items that might become POCs is huge, with the following limited examples:

* E-waste
* Paint
* Carpet
* Containers that previously held POCs (e.g., cosmetics)
* Automobiles and other vehicles
* Plywood
* Railroad ties
* Florescent lights
* Plastics
* The list goes on . . .

I don't think it is your intent to include waste and recycling operations as retailers, but the proposed regulations don't seem to provide a clear exemption for these types of operations - particularly if they sell the recycled or recovery materials that could include a POC. Although there is a definition of "Consumer Products", there is no definition of "Consumer". Thus anybody we sell a recycled or recovered POC or component part could be consider a "Consumer" and, hence, we would become a "Retailer" with responsibility for compliance under these regulations. It seems that the intent of the regulations is to capture OEM manufacturers, and importers/retailers of new unused POC's - NOT collectors and recyclers of discarded or wasted POC's at the end of their life or originally intended purpose.

I would suggest including an exemption for waste and recycling services from being considered manufacturers, importers, or retailers of POCs. What do you think? I will submit more formal comments as needed, but I wanted to get your read on this issue first. Thanks.

Chuck White, P.E.
Director of Regulatory Affairs/West
Waste Management
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Sacramento, CA 95814

Office: 916-552-5859
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Fax: 916-448-2470

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(IC)73-Volvo

Volvo Cars of North America, LLC
1 Volvo Drive, P.O. Box 914
Rockleigh, New Jersey, 07450

Department of Toxic Substances Control
1001 “I” Street
P.O. Box 806
Sacramento, California 95812-0806

December 6, 2011

Attention: Deborah O. Raphael, Director

Subject: Volvo Workshop Comments on
Informal Draft Safer Consumer Products Regulation
For presentation on December 5, 2011

Dear Ms. Raphael,

Volvo Car Corporation and Volvo Cars of North America, LLC, are pleased to offer the enclosed comments on the Informal Draft Safer Consumer Products Regulation. These will comprise Volvo's testimony at the December 5 workshop in Sacramento.

Please feel free to contact me for further information or for clarification.

Thank you and best regards,

Barry Morse,
Senior Regulatory Engineer
Product Safety & Compliance
Volvo Cars of North America, LLC

Tel.: (201) 768-7300 Ext 7823
E-Mail: bmorse3@volvocars.com

December 6, 2011. Volvo Comments to DTSC SCP Informal Draft.

My name is Barry Morse and I am a senior regulatory engineer speaking on behalf of Volvo Car Corporation. Volvo thanks the panel for this opportunity to comment on the upcoming Safer Consumer Products regulation. We support the goal of minimizing the health and environmental impacts of products we use. Approximately 87% of the material content in a vehicle is recycled, reused, or reclaimed at end-of-life.

Volvo recognizes the need for and supports product stewardship and end-of-life management of selective products. In fact, like other vehicle manufacturers, Volvo already exercises daily control and recovery, via dealership parts departments and automotive dismantlers, of a wide range of automotive components that have reached the end of their useful lives.

As currently drafted, End-of-Life Management Requirements, § 69506.4 would require manufacturers, to fund, establish, and maintain an end-of-life management program for any product required to be managed at the end of its useful life as hazardous waste in California. Section 69506.4 would require a comprehensive product stewardship plan, setting forth the means by which end-of-life management will be undertaken. It includes exhaustive definitions of roles and responsibilities for all involved parties, scope of products, and means of ensuring compliance with state and federal laws.

In our experience, a framework of program requirements is sufficiently effective. However, imposing a requirement for an up-front financial guarantee, we believe, is not customary, not necessary, even according to CalRecycling's EPR guidelines, not authorized by the statute, and inconsistent with the statute's goals and intent. In the already well-managed automotive industry, requirements already exist for management of most hazardous automotive wastes (oil, tires, brake fluid, filters, paints, solvents, coolant, etc.) without the imposition of financial guarantees.

Volvo is a very small player in the automotive market. Overhead costs are already substantial for us. As a smaller company, from an actuarial standpoint, Volvo could be evaluated as higher risk than a large manufacturer. This could result in discriminatory pricing of financial guarantee instruments and put Volvo, and all smaller manufacturers, at an unfair economic disadvantage.

Financial guarantees would also impose the impractical burden on manufacturers, importers, and retailers to continuously dedicate financial resources to nonperforming use, when such resources would be better spent on research and development of safer alternatives.

Section 69506.4 is sufficiently detailed and robust <u>without</u> the added requirement of a financial guarantee. Therefore, the concept of requiring a financial guarantee should be eliminated from the proposed regulation.

Thank you for your attention.

(IC)-74 Nancy Michelli

I want to make sure that the committee is aware of and gives consideration to the harmful effects that the chemicals in fragrance have had on me and are having on millions of people all across the world.

My personal story: I have never used much perfume or fragranced products in the past. In 1995 I changed employers. Many of my new co-workers were heavily fragranced with a variety of chemical fragranced products. Perfumes, colognes, shampoo, conditioner, body wash, hair gel/mousse, lotions, hand sanitizers laundry detergents, fragranced fabric softeners, etc. I had never been in such a highly fragranced environment in the past. Within 2 years of working in this environment and being consistently exposed to the chemicals in fragrance and over the subsequent 13 yrs of my employment I suffered the following due to my exposure to fragrance:

Asthma
Coughing
Difficulty Breathing
Headaches
Migraines
Nosebleeds
Dry Mouth/Throat
Laryngitis
Dangerously High Blood Pressure
Numbness and Tingling in the face and extremities
Oral and Nasal sores and irritation
Dry and cracked lips
Brain Swelling
Confusion and impaired thinking ability
Dizziness
Drowsiness
Ataxia
Rapid and Accelerated Heart Rate
Unconsciousness

When I am not exposed to fragrance chemicals I do NOT have any of these symptoms.

In December of 2009 I was forced into early retirement because of the serious reactions to these chemicals. It severely impacted my ability to do my job. My employer and my co-workers were unsympathetic and disbelieved that my symptoms and health problems were caused by their use of fragrance. The majority of people believe that there are regulatory agencies that are protecting them from harmful chemicals. They do not believe that fragrance is not regulated by any agency because shelves in every store are lined with these products. And you and I know that there is NO regulations of any of the chemicals used in fragrance either singly or in combination.

Because of the widespread use of these chemical fragrance I have not only had my health severely impacted but it has also severely impacted my life in every aspect. Because I cannot be exposed to fragrance chemicals at all I am unable to find gainful employment. I am on a limited income because I had to retire early with less income. Due to that I have been severely impacted economically and in the ability to support myself. I no longer have a "normal" life. I cannot do any of the following which the average person takes for granted.

I cannot:
Attend any public events such as street fairs, festivals, outdoor concerts, etc.
Visit friends or family members homes if they use fragrance. And they cannot come into my home.
Attend the theater, a movie, a concert, or any other event.
Shop in a mall or in most stores and when I take that chance I must wear a carbon filter mask.

Ride in other peoples cars and they cannot ride in my car unless they are 100% fragrance free as well as their vehicle and other passengers.
Walk in my neighborhood due to the venting of dryers with fragranced laundry products
Garden or enjoy my own yard on my own property due to fragranced laundry products in the air.
Pickup mail at the mailbox without using a mask.
Take a bus, train, rapid transit, plane, etc.
Stay in a hotel, lodge, etc. unless there are fragrance free rooms and spaces.
Grocery shop, clothes shop, and other errands without running the gauntlet and wearing a carbon filter mask.
Visit a park or walk on a trail due to the highly fragranced public.

This is the short list.

Fragrance chemicals are of the highest concern. None have been tested singly nor in combination. These chemicals are intentionally hidden under the trade secret laws. Thus companies have been given free reign to poison the public with no testing or regulation for well over 20 years. The use of these chemicals have increased immensely in the past 10-15 years. There is absolutely no excuse for this. Fragrance chemicals are ubiquitous in the world today. For example they are now being used in plastic that are used in food storage, garbage bags, etc. Fragrance is not necessary for any product. The public has been deceived by mass marketing to believe that they need to have fragrance in all of their products in order to "smell good".

The chemicals in fragrance include:

Carcinogens
Neurotoxins
Respiratory Irritants
CNS Depressants
Endocrine Disrupters
Narcotics

And again that is the short list. There is absolutely no need for chemical fragrance to be used other than to cover the negative smells of other chemicals in a products. People have been deceived my mass marketing to believe that they have to have these products in order to "smell acceptable". It has been proven by many companies that it is absolutely feasible to use natural essential oils rather than toxic chemicals if a fragrance in a product is so desired.

Most importantly I have always chosen safer products that are fragrance free even before I was chemically injured by fragrance. However I was injured from the use of these chemical by other people. I can choose to not use products with these chemicals but because of the use of them by others my health, finances and ability to enjoy a normal life have been severely impacted. There are millions of people across the world who are being impacted in similar ways. They are barely hanging on to their jobs, have lost the support of friends, family and many have already lost their jobs, homes, etc. Why should we be forced to suffer the choices of others. Just removing the chemicals under the umbrella of fragrance/perfume/parfum can make a big impact on improving the health of those who use them and those who around people that use them.

In listening to this live webcast today I am infuriated and disgusted to hear so many companies and organizations whining that it is too difficult to comply. Whether the companies are small, medium or large they really should have thought about this BEFORE they made the decisions to use toxic or unregulated chemicals. Due to my chemical injury caused by the reckless use of harmful chemicals I have absolutely no sympathy for any of these companies. Instead of complaining they should get busy fixing the devastation that they have caused to people and the environment.

Finally it is imperative that companies are no longer allowed to hide the chemicals in fragrance under the trade secret laws. All of the chemicals need to not only be tested individually but also in any combination that they use. AND even with testing the individual chemicals in each fragrance in a product should have ALL ingredients listed on the label.

Nancy Michelli
217 Brighton St.
Hercules, CA 94547

Email: njmichelli@att.net
Home: 510-245-0351
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I have recently started:

The Fragrance Free Project
P.O. Box 5654
Hercules, CA 94547

Ph; 510-245-3703
Fax: 510-245-0352
Email: <mailto:fragrancefreeproj@att.net> fragrancefreeproj@att.net

http://nonfumersunited.blogspot.com/
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<http://nonfumersunited.blogspot.com/>

(IC)75-TriQuint

Greetings,

Hello, I am watching the webcast of the Safer Consumer Products regulations hearing, and would like to offer a comment on some of the concerns.

I believe that DTSC really needs to look carefully at how the entire REACH process works, as both of these regulations are working in the same areas, both market-wise and desired outcome-wise.

As to the speaker's concerns about developing an AA, then DTSC posting it so that others could take advantage of her company's work, the obvious solution is to form SIEFs (Substance Information Exchange Forums), where only companies that are members of the SIEF can use the data developed by SIEF members. If someone comes along after the data was developed, they have to "buy" their way in by compensating other SIEF members for their previous expenditures. It also gets industry members to work together, pooling resources so that "many hands can make light work."

Take care,

John Sharp | Corporate Product Compliance Manager | TriQuint Semiconductor, Inc.
2300 NE Brookwood Parkway | Hillsboro, OR 97124 | (: 503-615-9712 |
Fax: 503-615-8902 | *: john.sharp@tqs.com <mailto:john.sharp@tqs.com>

(IC)76-Intercontinental Chemical Corp.

Dear Ladies & Gentlemen of DTSC: 12/5/11

Under §69502.2. Chemicals of Concern Identification:

You provide a great number of lists of chemical references that are not necessarily easily accessed. You are likely to add more lists as chemical concerns increase worldwide. Many lists require membership in organizations or information companies that lead to extra costs and expenses for small businesses, especially. By "incorporating by reference" you are referencing chemicals not readily available to the public as should be properly and easily seen within your regulation for public domain, consumption & review.

QUESTION:

Since you are stating these references in your regulation, why not permit these to be reachable (within the regulation's digital format) in the public domain as "hotlinks" which would make immediately available the complete contents of each list referenced in your regulation?

Respectfully submitted,

Gary Valasek

Staff Facilitator

INTERCONTINENTAL CHEMICAL CORP.

Cincinnati, Ohio 45232

(IC)77-Corporate Environmental

1) We are an electronic component manufacturer. We do not sell directly to the public; our products are not found in retail stores. However, our parts (trimming potentiometers, chip resistors...) are used by computer, cell phone, appliance and many other manufacturers of electronic equipment. While our consumer electronics manufacturer customers (HP, Dell, Apple, Motorola...) may ask us for information regarding materials used in our components for their consumer products, how will this rule affect us? Providing material information of our components to our customers is not new as European RoHS, REACH, ELV already require this of the electronics industry. But a clarification of how this regulation will affect companies like ours who do not manufacture products that, alone, are available to the consumer would be very helpful.

2) Some potential chemicals of concern may be hazardous as a raw material. In a finished state or incorporated into a matrix, they pose no hazard or offer no exposure pathway. An example is brass. Brass may contain contaminate levels of lead. But items made with brass do not have the same exposure pathway as raw lead or lead powders or paints. Some materials such as zinc and magnesium are hazardous in dust form. But in a finished product, they are not present in dust form. Will the state of chemicals in a finished product be considered and the potential lack of exposure pathways?

Regards,
Cathy Godfrey
Corporate Environmental, Health & Safety Manager

(IC)78-US EPA Region 9

Can you explain how the public will be informed of
a) priority chemicals
b) chemical / product combinations
c) changes made in products as a result of AAs

Thank you
John Katz
Pollution Prevention Coordinator
US EPA Region 9

(IC)79-California Stormwater Quality Association

DTSC - Please accept these comments from the California Stormwater Quality Association (CASQA*) and, as time allows, read the comments into the record of today's workshop:

December 5, 2011

On behalf of the California Stormwater Quality Association (CASQA), thank you for the opportunity to comment on these proposed regulations, which are vital to protecting water quality. Additionally, reducing or eliminating pollutants at their origin, through mechanisms such as safer consumer product regulations, is by far the most effective and efficient method for reducing the impacts of many if not most stormwater pollutants.

Virtually every municipality in California is under a National Pollutant Discharge Elimination System (NPDES) permit issued by the State under the Federal Clean Water Act. The basic charge of stormwater quality management agencies under these permits is to reduce the discharge of pollutants via runoff into our receiving waters. There are two general categories of Œbest management practices¹ (BMPs) to accomplish this charge: source and treatment controls. Source controls work by keeping potential pollutants out of stormwater while the other major category of BMPs - treatment controls work by removing potential pollutants once they are in stormwater. Most source controls are operational - focused on physically keeping potential pollutants out of contact with rainfall and stormwater runoff through covering, berming, or cleaning at commercial, industrial, and public facilities and in the public right-of-way and on roads. ŒTrue source control¹, a subset of source controls, focuses on the original source of a potential pollutant by eliminating or significantly reducing the existence of the potential pollutant, thereby negating the need to physically prevent contact with rain or runoff.

There are few viable treatment control options for many of the chemicals listed as impairing California¹s waters. For many of these chemicals that are highly soluble and widely responsible for impairment of receiving waters, true source control is the only currently available option to meet our water quality goals by complying with receiving water standards without widespread and substantial economic impact.

The focus of most true source control efforts to-date has been human-made products. Products are a natural for true source control because their source is clear and finite (e.g., a company, a factory). Many times it is not the product per se that is the problem but a particular form of the product or a particular ingredient in the product. This fact lends itself to product substitution in which substitute forms or ingredients are designed, developed, and then promoted or required to be used. Clearly, green chemistry and true source control are the same basic environmental strategy and as stated on the Cal/EPA website in reference to green chemistry, they represent a ³fundamentally new approach to environmental protection, transitioning away from managing toxic chemicals at the end of the lifecycle, to reducing or eliminating their use altogether.²

Given the vital nature of safer consumer product regulations to water quality protection, CASQA has the following brief comments today:

(1) Funding. DTSC currently does not have sufficient resources to implement the regulations at a level necessary to respond to problems from products. DTSC will need funding to conduct the analyses. Stormwater quality agencies believe that this funding should come from the private companies that have interests in the products.

(2) Lack of funding. If DTSC does not obtain sufficient funding to implement the regulations, stormwater quality agencies may seek help from legislation on products.

(3) Definitions. The definitions section needs clarification on potential water quality impacts (e.g., effects on aquatic life like reproduction and development) and potential NPDES violations. The current definitions are too narrow.

(4) Outside expertise. DTSC needs to have technical expertise from the Water Board and Fish & Game closely involved as DTSC crafts the regulations.

Thank you again for the opportunity to provide comments at today's workshop. We will provide details and recommendations on our brief comments as well as additional comments in writing by the December 30 deadline. In the meantime, if you have any questions, please contact us.

Thank you,

Geoff Brosseau

Executive Director
California Stormwater Quality Association (CASQA)
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650-366-1042 (Voicemail box only)
info@casqa.org
www.casqa.org

CASQA is a 501(c)(3) non-profit organization dedicated to the advancement of stormwater quality management, science, and regulation.

* CASQA is comprised of stormwater quality management organizations and individuals, including cities, counties, special districts, industries, and consulting firms throughout California. Our membership provides stormwater quality management services to more than 22 million people in California. CASQA was originally formed in 1989 as the Stormwater Quality Task Force to recommend approaches for stormwater quality management to the California State Water Resources Control Board.

(IC)80-Sudeep Motupalli Rao

Questions for Dec 5th Workshop:

1) Will DTSC conduct training and certify assessors?

2) What is the timeline for such training of assessors?

Thank You.

Sudeep

.....

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.....

(IC)81-Association of Woodworking & Furnishings Suppliers

December 12, 2011

Debbie Raphael, Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814

DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL
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RE: Informal Draft Safer Consumer Product Regulations

Dear Director Raphael:

On behalf of the Association of Woodworking and Furnishings Suppliers (AWFS), I am pleased to submit comments regarding the recently released Draft Safer Consumer Product Regulations (Regulations). AWFS is a national trade association representing the interests of the broad array of companies that supply the home and commercial furnishings industry. While we appreciate the opportunity to submit comments, we continue to have a number of concerns with the regulations as drafted.

The Department has identified an ambitious "list of lists" to use as its initial Chemicals of Concern (COC) list. All told, the draft Regulations will list more than 3,000 chemicals as Chemicals of Concern. We fear that the use of such an expansive list without any prioritization process for COCs will make it difficult for DTSC to effectively focus its energies on hazard identification.

In addition, the regulations call on the Department to use what they have dubbed a "narrative standard" for the prioritization of products. The regulations call for the evaluation of adverse impacts of COCs, potential exposures, and market presence among other factors in the product prioritization process. The regulations do not however contain clear and explicit criteria for the evaluation or weighting of those factors when prioritizing products. AWFS believes that the use of objective scientifically driven criteria for the prioritization of products under the Regulations is essential. If DTSC relies on a process that may be subject to individual bias and subjective judgments as proposed, the legitimacy of the Green Chemistry Initiative will be seriously undercut.

Finally, the continued reference by DTSC staff to formaldehyde containing products as examples of priority products is deeply concerning for AWFS. While we understand that an initial priority products list will not be drafted until after regulations have become effective, the consistency with which specific products are already being referenced is alarming. As a result, we feel it is necessary to remind you that it would be inappropriate to list composite wood made with resins

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containing formaldehyde as a priority product since it is already subject to regulation under the California Air Resources Board's Composite Wood Products Airborne Toxic Control Measure.

Once again, we appreciate the opportunity to comment. We look forward to engaging with you on the development of the Safer Consumer Products Regulations in the future.

Sincerely,

Angelo Gangone
Executive Vice President, AWFS

cc: Edelstein, Gilbert, Robson & Smith

(IC)82-Stoner

Stoner

January 2, 2012

DIRECTOR'S OFFICE
DEPT OF TOXIC SUBSTANCES CONTROL
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Odette Madriago
Acting Chief Deputy Director
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812

Subject: Informal Draft Regulation for Safer Consumer Products and Meeting on December 15, 2011

Dear Ms. Madriago,

Stoner Incorporated appreciates the opportunity to comment on the Informal Draft of the Safer Consumer Products regulation. In addition, we thank you for making the time to meet with us on December 15, 2011 to discuss this draft. The meeting was informative and beneficial for Stoner. During the meeting, we highlighted four major issues that will have significant negative impact on Stoner and other small companies.

For over 70 years, Stoner has been committed to manufacturing and marketing safe and effective products to our customers. We operate two facilities in Lancaster County, Pennsylvania. Stoner is continually improving our manufacturing processes and our products to better serve the consumer. Included in these improvements are the protection of human health and the environment. As noted in our meeting, Stoner is a 2003 recipient of the Malcolm Baldrige National Quality Award. Some of our many, useful products are found in retail stores such as AutoZone, Target and Wal-Mart. Stoner pursues a mission of helping our customers save time, increase their productivity, and improve the quality of their work.

The following are our comments on this draft regulation.

1. Chemicals of Concern

The comments in this section relate to Section 69502.2 Chemicals of Concern Identification. This section identifies the lists defining Chemicals of Concern (CoC). During our meeting, we discussed that including all these lists is overwhelming to a manufacturer—especially a small or mid-sized one. The many lists should be focused on a more reasonable and manageable number of substances. If a reduction is not possible, please remove some of the chemicals per the discussion in our meeting. We suggest that chemicals that inherently are less toxic and have a lower risk profile be removed. Examples of chemicals that should be removed would include, but not be limited to the following:

1. Acetone
2. Heptane
3. 1,2-trans-dichloroethylene

1070 Robert Fulton Highway, Quarryville, PA 17566 · 717-786-7355 · 717-786-9088 FAX

Malcolm Baldrige National Quality Award 2003 Award Recipient

4. d-limonene
5. isopropyl alcohol
6. xylenes
7. naphtha
8. cyclic siloxanes
9. glycol ethers
10. mineral oils

Stoner agrees that there are many chemicals that should not be used as ingredients in consumer products. As discussed in the meeting, a cross reference of the lists should be done to determine the chemicals that are contained on numerous lists. Chemicals that are included on all of the qualified lists represent a reasonable starting point.

2. <u>De Minimus Exemption</u>

The comments in this section relate to Section 69503.4 De Minimus Exemption. This section states the De Minimus level as 0.01%. The draft regulations refer to raising or lowering this level. Our concern is that the proposed 0.01% level is a magnitude lower than the current standard which is 0.1%. The proposed, lower level (0.01%) moves the requirements for testing to a new, unreasonable condition. Our suggestion is to move the De Minimus level to 0.1% as a starting point. Our concern here is not a CoC that is intentionally added, but a CoC that could be a contaminant in another raw material. Currently, the 0.01% limit would be almost impossible for a smaller company to monitor for unintentionally added chemicals and would provide minimal (if any) additional safety for the consumer.

3. <u>Qualifications for Assessors</u>

The comments in this section relate to Section 69508 Qualifications and Certification of Assessors. This section deals with the Qualifications for an assessor to perform an Alternative Assessment (AA). Currently, these certifications are too burdensome for companies such as ours. We are a small company, and our R&D staff (as well as management) has diverse backgrounds. The current draft requires that after January 1, 2015, 20 hours of continuing education be completed every two years. This is an excessive amount for a staff person who is also required to perform a daily job. This type of requirement is for someone who would be performing AA on a daily basis. Our company, for example, has a PhD chemist on staff with over twenty years of R&D background. This person is more than capable of performing an AA for us if any of our products are targeted (in addition to his normal job duties). This person should not be required to have 20 hours of continuing education every two years. There should be credit granted experience and an exception to some of the continuing education requirements. Below are some suggested guidelines to consider.

Proposed Initial AA Certification Requirements:

- 20 hours with Bachelor's Degree in scientific field, or
- 10 hours with a Master's Degree in a scientific field, or
- 10 hours with a PhD in a scientific field
- Complete an eight-hour refresher course every five years

4. Confidential Business Information

The comments in this section relate to Section 69510 Assertion of a Claim of Trade Secret Protection. This section deals with Confidential Business Information (CBI). For a small company such as ours, our product formula is a vital part of the success of our business. We compete with large corporations as discussed in the meeting. Some formulas we patent, some formulas we do not patent. The formulas we do not patent are trade secreted. We object to the disclosure of our formulas. We need to be assured that any information disclosed to your agency will be guarded against disclosure to our competitors. Currently, we are very concerned as to how this information will be kept confidential. In addition, it appears that the process to maintain this type of confidentiality is long and burdensome. This section needs to be revised and clarified to ensure that formulas and sales information, if ever shared, will be kept confidential.

Conclusion

Stoner Incorporated supports the goal of the DTSC to manufacture safer consumer products. The current draft regulation, if adopted, will cripple a small company such as ours and keep us from doing business in California.

We look forward to working with you in the future on this issue. If you have any questions or comments, I can be reached at 717-786-7355 ext. 3514 or email at hzechman@stonersolutions.com or contact our consultant Doug Raymond at 440-474-4999 or email at djraymond@reg-resources.com.

Sincerely,

Harry Zechman
Chief Operating Officer

cc: Laurie Nelson – Randlett/Nelson/Madden
Doug Raymond - Raymond Regulatory Resources (3R)
Debbie Raphael – Department of Toxic Substances Control
Matt Rodriquez – California Environmental Protection Agency
Dr. Bob Sweger – Stoner Incorporated

Alliance OF AUTOMOBILE MANUFACTURERS

January 13, 2012

VIA EMAIL

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draphael@dtsc.ca.gov
hjones@dtsc.ca.gov

VIA HAND DELIVERY

Debbie Raphael
Director
Department of Toxics Substance Control
1001 I Street, 25th Floor
Sacramento, CA 95812-2806

Re: Comments on October 31, 2011 Draft Safer Consumer Products Regulation

Dear Ms. Raphael:

On behalf of the Alliance of Automobile Manufacturers ("Alliance"), I am pleased to submit the following comments and attached redline mark-up of the regulation in response to the latest draft of the Department of Toxic Substances Control's ("Department" or "DTSC") green chemistry regulation, Safer Consumer Products (the "October 31 Informal Draft") which implement California's green chemistry statute (the "Statute"). We recognize and appreciate that the October 31 Informal Draft incorporates many of the suggestions provided by the Alliance and other concerned industry groups as well as the Department's willingness to meet with us.

Based on our recent meetings, we understand that your intent to limit the chemical and priority product combinations will be addressed via a priority product listing cycle, and that the homogenous materials within a component will be the focus of the effort for assembled products. We also understand that the regulation is forward looking and that it is not your intent to address legacy/historic products. As a direct result of our discussions with both the Department and consultation with other respected industry groups, we have made the following conceptual changes within the marked-up regulation in attempts to codify those items on which we have reached consensus:

- Homogenous materials within a component are the focus of regulation in regard to assembled products (see definition in section 69501.2 with similar language carried throughout the attached redline);
- Chemical/priority product combinations will be limited per listing cycle (see section 69503.1); and
- Legacy/historic vehicles and their associated service parts are exempt (see added text in sections 69501 and 69501.2).

Additionally, the following changes are necessary to ensure that the regulation is practical and effective:

- Scientifically reliable information on chemical exposure should form the basis for action (text revision starts with a revision to the reliable information definitions in section 69501.2. Similar language carried throughout the attached redline);
- The current definition of "de minimis" should be replaced with three definitions along with test methods specified for concentrations below 0.1% (definitions for Alternative Assessment Threshold, Practical Quantitation Limit ("PQL"), and Maximum Concentration Values are added and these terms replace de minimis throughout the text; see sections 69501.2, 69503.3 through 69503.6); and
- Changes in timelines and compliance deadlines throughout the regulation. Increases in lead time are necessary for compliance (e.g., six or more months' notification of upcoming priority products; and potential regulatory responses take into account product complexity and design lead time see section 69506.5).

The changes listed above are crucial issues to the members of the Alliance. If these issues are not addressed, the regulation will be unworkable.

Background and Summary

The Alliance submitted extensive comments on all prior versions of draft regulations[1]. Throughout the regulatory development process, the Alliance has advocated for revisions that will render the proposed green chemistry regulations more effective, efficient and expedient, while maximizing the potential for the public health and environmental benefits envisioned by the Statute. However, the Alliance still has concerns about whether implementation of these regulations, as proposed in the October 31 Informal Draft, can be accomplished successfully, either by industry or by the Department. There remain several areas that are infeasible, as well as areas that are not expressly authorized nor implied by AB1879 (e.g., financial guarantees for end-of-life collection programs and product recalls). Without significant changes in the draft regulation, the Department and industry will become frustrated in their inability to implement the rule and the Statute's laudable goals will be thwarted.

In the attached redline draft of the regulation, we provide suggestions for additional revisions to enhance the draft and assist the Department in creating a successful regulatory

[1] All previous comments and draft redlines on previous versions of the draft regulations, in straw, informal and formal form, are incorporated by reference.

program. In addition, some of those issues are discussed in further detail below. Our comments on various sections are provided in chronological order.

About the Alliance

The Alliance is a trade association of 12 car and light truck manufacturers, consisting of BMW Group, Chrysler Group LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda North America Operations, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars North America, Inc., Toyota Motor North America, Volkswagen of America, Inc., and Volvo Cars of North America. The members of the Auto Alliance are committed to developing and implementing constructive solutions to public policy challenges that promote sustainable mobility and benefit society in the areas of human health, environment, energy and motor vehicle safety. The Alliance embraces the goals and vision for safer consumer products embodied in the Statute.

Comments on October 31 Information Draft (in Chronological Order)

Article 1. General.

Purpose and Applicability (Section 69501)

Given the Department's intent that the regulation is forward looking, the following statement has been added to this section: "This chapter does not apply to any historic product that is placed into the stream of commerce in California."

Definitions (Section 69501.2)

The Alliance is pleased that the October 31 Informal Draft includes and adds several definitions making the distinction between formulated and assembled products, and that require the component manufacturers to take responsibility for regulatory compliance where their component parts are concerned. Specifically, in the attached redline, we provide some suggested refinements in the attached redline to definitions including: "Assembled Product;" "Component;" "Consumer Product;" "Formulated Product;" and "Manufacturer" provide clarity where these issues are concerned. However, it appears that legacy or historic products and second-hand products were inadvertently excluded from being exempt and thus we provide suggested language in the attached redline to address them.

Notwithstanding the above, however, the Alliance has concerns about the following definitions.

"*Accreditation Body"/"Certified Assessor"* – The Certified Assessor model is far superior to the third-party verification requirement contained in previous drafts of the regulations. That said, there remain some issues of concern in these definitions, which are discussed in further detail in this letter on page 14 below.

"Adverse ecological impacts"/"Adverse public health impact"/"Physical chemical hazards"/"Physicochemical properties" – The Alliance has concerns about these rules referencing OEHHA public health goals and hazard traits. OEHHA regulations are also being

amended as part of the larger California green chemistry initiative. The Department should coordinate with OEHHA on these issues, and provide an opportunity for the public to comment on both sets of draft regulation in the same rulemaking process. This would ensure that definitions and standards are consistent and work in concert with the Statute's prioritization mandate. In addition to the lack of due process provided by referencing another agency's proposed rulemaking, the OEHHA definitions are too broad, lack a scientific basis, and exceed the authority granted by the Statute.

"Chemical identification and description information"/"Purity" – The term Purity as utilized in both of these definitions is unclear, and will render it difficult for responsible entities to understand their obligations under the October 31 Informal Draft. The key concern for the Alliance is the lack of a quantitative benchmark for determining what is pure. There are multiple uses of the term "purity" in various environmental contexts, with "purity" typically defined as a percentage. As an example, the Stratospheric Ozone Regulations, 40 CFR Part 82, Subpart A, App. G, the Appendix G to Subpart A of Part 82--UNEP Recommendations for Conditions Applied to Exemption for Essential Laboratory and Analytical Uses, requires certain percentages of purities for substances:

> "Production for essential laboratory and analytical purposes is authorized provided that these laboratory and analytical chemicals shall contain only controlled substances manufactured to the following purities:
>
> CTC (reagent grade)--99.5
> 1,1,1,-trichloroethane--99.5
> CFC-11--99.5
> CFC-13--99.5
> CFC-12--99.5
> CFC-113--99.5
> CFC-114--99.5
> Other w/ Boiling P>20 degrees C--99.5
> Other w/ Boiling P<20 degrees C--99.0"

A quantitative benchmark should be provided in the October 31 Informal Draft, as well.

"Chemical of Concern" – This definition references the provisions of section 69502.2(a), which dictate how the Department will identify Chemicals of Concern ("COCs"). However, the provisions fail to prioritize chemicals as required by the Statute. As currently drafted, the definition would include more than 3,000 chemicals. This list can and should be refined and prioritized as mandated by the Statute. Without the necessary refinement, this definition is overly broad.

"Component" - This definition has been modified to better reflect the Department's stated intent as follows:

"Component" means a homogeneous material of a uniquely identifiable part or piece of an assembled consumer product that performs a distinctive and necessary function in the operation of a system . . . "

"*Consumer product"* - This definition has been modified to better reflect the Department's stated intent by adding new subsections (D) and (E) which clarify that for an assembled product, it is a homogeneous material within a component, and that consumer product does not include historic products or second-hand products.

"*De Minimis"* - This definition is replaced with the following:

(11) "Alternatives Assessment Threshold" means the amount of a chemical of concern in an assembled or formulated product above which an alternatives assessment must be completed for a chemical of concern in a listed Priority Product, and below which an exemption for the use/presence of a chemical concerned may be relied upon.

(54) "Practical Quantitation Limit (PQL)" means the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the chemicals of concern in the listed priority product results in an exemption for that product from the alternatives assessment process..

(55) "Maximum Concentration Value (MCV)" means the maximum allowable level of a chemical of concern in a component or formulated product that is set as part of a regulatory response after an alternative assessment has been completed. The Maximum Concentration Value will not be set below the Practical Quantitation Limit.

The rationale for this change is explained by Hewlett-Packard ("HP") in their December 21, 2011 letter to the Department. In the attached redline, the term "de minimis" has been replaced with Alternative Assessment Threshold, Practical Quantitation Limit, or Maximum Concentration Value as appropriate. We believe that this language better reflects the Department's intent and may serve to alleviate any confusion with de minimis applicability.

"*De Minimis Exemption Notification*" – This definition has been removed in the attached redline and replaced with "Alternative Assessment Threshold" language referenced above. The need for a notification prior to relying on the exemption constitutes an unnecessary step that will burden both the Department and responsible entities. Self-policing combined with the threat of enforcement for improper reliance, is a more practical alternative, which the Department should institute.

"*Financial guarantee"* – The Alliance has consistently taken issue with the financial guarantee provisions contained in Article 6 in its previous comments. The Financial Guarantee is impractical and duplicative given that hazardous wastes are already governed by the requirements of the Resource Conservation and Recovery Act ("RCRA") and other waste regulatory regimes. It is not necessary to implement the statute which seeks cradle-to-cradle

innovation into new safer materials and product designs, not cradle-to-grave caretaking of yesterday's goods. Moreover, they are not authorized by the statute. The only reference to end-of-life requirements for the manufacturer of a product is found at Health & Safety Code Section 25253(b)(7). This section gives the Department the authority to adopt regulations, here specifically "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." This could be read to require the manufacturer of a product to accept the product from the consumer at the end of its useful life, and then see to its recycling or proper disposal. However, it does give DTSC the authority to promulgate a sweeping regulation (section 69506.4) that imposes requirements well beyond that, nor impose onerous financial requirements by posting bonds or providing other assurances. This requirement must be deleted as it is neither authorized by nor necessary to implement the goals of the Statute.

We agree with the Global Automakers comment that: "The financial impacts of an up-front financial guarantee will impose significant and disproportionate hardships on the manufacturing sector. The automotive sector has already demonstrated a commitment to end of life management of wastes and believes the financial guarantee provisions are inappropriate."

"Inventory recall" – The product recall program established in section 69506.5 of the October 31 Informal Draft exceeds the authority granted to the Department and the regulatory responses permitted under the Statute. Also, the Department lacks the requisite product safety standards to implement a recall.

"*Reliable information"* – As currently drafted, this definition is extremely arbitrary, and not based on science. There is no clear indication about why the listed sources would constitute Reliable Information. As an alternative, the Alliance offers suggested edits in the attached redline, including using the term "scientifically reliable information" but in the alternative, also supports the definition proposed by the Green Chemistry Alliance ("GCA") in prior comments:

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

In either case, the statute requires a scientifically-based definition that is widely accepted in a regulatory context.

"*Responsible entity"* – Given that the definition of manufacturer is provided in two parts, to be consistent, the assignment of duties also needs to make this two-part distinction. Additionally, if the intent of section 69501.5 and other related provisions is only to require manufacturers, importers and retailers of Priority Products to provide the Department

information, the words "Consumer Product in this definition should be replaced with "Priority Product."

"*Substance identification information*" – It is not clear why all of this information is necessary, particularly since much of the data is not applicable to a large majority of products. Suggested changes to reflect this concern is in the attached redline.

"*Technologically and Economically Feasible Alternative*" – The definition lacks clarity. There is no definition for or standards that explain the meaning of a "reasonable rate of return, over a reasonable period of time". Without a definition of the phrase or clear standards, there is no way for responsible entities to know what might or might not by the Department to be considered a Technologically and Economically Feasible Alternative.

Duty to Comply and Consequences of Non-Compliance (Section 69501.3)

Subsection (a)(1) describes the duty to comply under the regulations. Because importers have been added back into the hierarchy of liability, joint and several liability under the October 31 Informal Draft is broader than it was in the prior draft. To assure due process, liability must be limited to the parties in a position to make decisions about the use of chemicals.
The Alliance appreciates the fact that subsection (a)(2) continues to provide that regulatory requirements may be fulfilled by consortiums, trade associations, public-private partnerships, or other group entities acting on behalf, or in lieu of one or more Responsible Entity(ies). This continues to be a positive aspect of the regulations.

The Alliance is concerned about the requirements contained in subsection (b)(2). Given the current framework for establishing the COC list, this overbroad, burdensome provision would require providing a notification for virtually any alternative that is ultimately placed into the stream of commerce. Note, however, that the problems with this provision could be rectified if the process for generating the list of COCs were appropriately refined. As shown in the attached redline, this section should be deleted in its entirety.

Chemical and Product Information (Section 69501.5)

Per recent statements by the Department, it is the understanding of the Alliance that the intent of these provisions is to request the gathering of existing information generated in connection with Priority Products, and not to require the generation of new information by responsible entities prior to initiation of the Alternatives Analysis ("AA") process. As currently drafted, subsection (a) is much broader than this stated intent. First, subsections (a)(3) and (a)(4) permit the Department to request a Responsible Entity to make available/generate information without specifying when this power might be invoked. In addition, the definition of Responsible Entity is not limited to manufacturers, importers and retailers of Priority Products, but rather, manufacturers, importers and retailers of any "Consumer Product." Finally, if the Department's intent is as it suggests, no new information should be required to be generated in response to any request. Therefore, the intent of this provision (as applied to manufacturers, importers and retailers of Priority Products) can and should be accomplished without including subsection (4).

The language in subsection (a) must be revised for consistency with the Department's stated goals, and the Statute.

In addition, subsection (c) provides for a "Failure to Respond" list if requested information is not provided by a Responsible Entity. The Department has indicated that providing this information would be voluntary, however the title "Failure to respond" conveys a form of punishment to those who might not be able to satisfy such requests. In the Alliance's assessment, if the intent is to request (not require) information, there should be no need to generate a Failure to Respond list. If the Department is to publish any list, it should be to reward entities that voluntarily comply with the Department's information requests, and voluntarily expend their own resources to assist the Department in obtaining information helpful in its regulatory tasks. One suggestion is to call it, in a more positive light, a "Data Generator's List." This type of change is a good example of one simple way for the Department to provide an incentive for such research. Incentives have been recommended by the Initiative's Science Advisory Panel and in the Departments Final Report on Green Chemistry in November 2009.

Availability of Information on the Department's Website (Section 69501.6)

Two subsections in this provision reference "De Minimis Exemption Notifications." As explained in detail above, the Alliance continues to question the necessity of this requirement.

Article 2. Chemicals of Concern Identification Process

General (Section 69502)

As currently drafted, this section explains that information obtained or reviewed pursuant to section 69501.5 may be considered as part of the process of identifying COCs. Insofar as the current version of section 69501.5 is overly broad, this provision would only be acceptable if section 69501.5 were ultimately refined.

Applicability (Section 69502.1)

For reasons discussed in further detail below, this definition of applicability is too broad. The intent of this process is prioritization, which this Article does not accomplish where chemicals are concerned.

Chemicals of Concern Identification (Section 69502.2)

Generally, this section does not prioritize or otherwise provide a means to limit the list of chemicals ultimately contained on the COC list. The result is that 3,000 or more chemicals will be on the list. The list can and should be refined in order to facilitate efficiency in implementation of the regulations. Absent revision, this section is overbroad and does not reflect the requirement of the Statute.

Subsection (b)(3) references the "reliable information" standard set forth above. Absent a revision to the definition of "reliable information," this standard is unclear, lacks a scientific basis, and places the legal defensibility of this and other similar provisions in jeopardy.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process.

General (Section 69503)

As currently drafted, this section also explains that information obtained or reviewed pursuant to section 69501.5 may be considered as part of the process of identifying COCs. Insofar as the current version of section 69501.5 is overbroad, this provision would only be acceptable if section 69501.5 were ultimately refined.

Priority Products Prioritization/Priority Products List (Sections 69503.2 and 69503.3)

Generally, the Alliance is pleased with the fact that new section 69503.2 is much more focused on exposures, potential exposures, and pathways for exposure. These changes set the stage for a program that appropriately limits the universe of products to those with the greatest potential harm to the public and the environment, and is consistent with the goals of the Statute.

Similar to the COC context, however, subsection (a)(2) references the Reliable Information standard set forth above. Absent a revision to the definition of Reliable Information, this standard is unclear, lacks a scientific basis, and places the legal defensibility of this and other similar provisions in jeopardy.

In addition, rather than actually prioritizing products, the October 31 Informal Draft merely identifies a number of factors the Department's staff will consider. The specific prioritization process by the Department is not apparent. The approach fails to give any design criteria to manufacturers seeking to get ahead of these regulations and accelerate their design of green safer products or their choice of greener safer chemical ingredients. We urge the Department to completely reconsider this process, and design one that engages in prioritization based on sound scientific principles, robust peer review and timely public review.

For instance, in multiple public forums, the Department has repeatedly stated its intention to limit the initial list of Priority Products to 2-5 product categories. The Department has also stated that it will issue work plans in advance of the Priority Products List. We agree that both of these intentions are good steps to include in a prioritization process; however, neither is codified in the regulations. Working with the October 31 Informal Draft as it is currently drafted, we provide some suggested language in the attached redline to, at least, move the regulations in the right direction for creating a science-based prioritization process.

Subsection (f) continues to require responsible entities associated with Priority Products to provide a De Minimis Exemption Notification if they plan to take advantage of the exemption. Again, this requirement seems unnecessary and overly burdensome.

De Minimis Exemption (Section 69503.4)

As discussed in the "Definitions Section" above, the Alliance has suggested rewording of the regulations removing the use of "de minimis." Consistent with those suggestions, this section would now be titled "Alternative Assessment Threshold." Subsection (c) explains that the

Department may specify an Alternatives Assessment Threshold Level that is lower or higher than the level specified in the definition. As explained above, we agree with the recommendations of HP to change the terminology so that the use of this threshold is clearly understood, and we recommend that the Reliable Information standard should be further clarified and based on scientific criteria.

De Minimis Exemption Notification (Section 69503.5)

We urge deletion of the notification requirement, and instead make it a determination that each responsible entity must make. This section could easily be revised to allow for self-reliance, and to provide that the Department be notified, and a preliminary AA Report be provided, within 180 days of a chemical change resulting in the de minimis exemption no longer applying to a Responsible Entity. *See* subsection (d). For an illustration of the inefficiency associated with the De Minimis Exemption Notification requirement, see subsection (c) which currently requires that De Minimis Exemption Notifications to continue to be revisited and refined over the life of any product. Again, self-policing under the threat of enforcement is more practical, and would eliminate a significant administrative burden. The Department also needs to provide test methods to ensure that these determinations can be feasibly and reliably made.

Article 4. Petition for Inclusion of a Chemical or Product in the Identification and Prioritization Processes.

This Article still contains no requirement that the Department include affected manufacturers and importers in the petition process. In order to comply with due process requirements, the provisions in this article - and specifically section 69504 - should be revised to provide for affected manufacturer/importer participation as early as possible, and should include a scientific peer review process. Similarly, if the Department includes language to include priority chemicals and products, complimentary language to de-list said chemicals and products must also be included. Suggested language is provided in the attached redline.

Article 5. Alternatives Assessments.

Alternatives Assessments ("AA"): General Provisions (Section 69505.1)

Subsection (c) does not appear to contain any standards or criteria applicable to the assessment of requests for extension. Standards will prevent arbitrary decisions by the Department and should be provided. Additionally, the AA process is going to be new to many responsible entities affected by the regulations. That said, a hard cap on the length of any extension granted pursuant to subsection (c)(3) may be impractical. The Alliance urges the Department to consider revisions that address these concerns.

Subsection (d) requires that each AA completed by January 1, 2015 be conducted by a Certified Assessor. While a Certified Assessor can be someone employed by a Responsible Entity, and the Alliance prefers the Certified Assessor model to the third-party verification model included in prior versions of the regulations, Article 8 sets forth rigorous certification requirements that may result in higher costs.

Subsection (g) explains that the failure of the Department to make a compliance determination, within the deadlines set forth in this section, does not render a Preliminary or Final AA Report to be deemed compliant. To the extent responsible entities are subject to deadlines as part of the AA process, the Department should be held to the same; a deemed compliant provision is the appropriate mechanism to ensure this is the case. Expediency is critical to ensuring certainty for businesses ultimately affected by the regulations – especially in the area of product development. Deemed compliant provisions are used in multiple regulatory contexts and one is appropriate in this context.

Assessment of Priority Products and Alternatives (Section 69505.2)

The Alliance commends the Department on the inclusion of subsection (b). Flexibility is critical to ensuring that responsible and forward thinking companies are permitted to continue the AA processes they have already expended millions of dollars implementing. This provision ensures that flexibility.

Alternatives Assessment: First Stage (Section 69505.3)

While subsection (b)(3) allows the Responsible Entity to eliminate alternatives during this initial screening phase, it does not allow for eliminating alternatives based upon economic, consumer acceptance or performance considerations. These are important factors in choosing an alternative and without having them as a screen, the alternatives analysis could become a fictional writing exercise resulting in no actual implementable regulatory responses. Additionally, subsection (b)(3)(A) is overly broad and would require a review of chemicals not on the chemical of concern lists. Suggested revisions to address these issues are in the attached redline.

Similarly, other places in the October 31 Informal Draft, subsection (b)(4) provides for requesting an extension of time. Once again, however, it does not appear to include standards for assessing any request, which leaves room for uncertainty and arbitrary decisions. In addition, this provision sets a hard cap on the length of any extension. As explained above, the newness of the AA process may dictate that a hard cap is impractical. The Alliance encourages the Department to consider revisions that address each of these issues.

Alternatives Assessment: Second Stage (Section 69505.4)

Subsection (a)(1) discusses the identification of factors relevant for comparison of alternatives, and describes a factor as being relevant if it would constitute a "demonstrable contribution" or a "demonstrable difference." Neither of the terms is defined; there are no standards, scientific or otherwise, for determining whether a factor would constitute either. This needs to be rectified so that industry knows what is expected at this stage of the AA process.

Alternatives Assessment Reports (Section 69505.5)

Subsection (h)(2) requires industry to find and report on "unavailable reliable information that, if available . . . "might have been included in the AA. It appears to ask the AA to invent

potential alternative realities to the present state of knowledge. This requirement is vague, open-ended and unclear. We suggested deleting this in its entirety.

Also, insofar as this section references the ability to request trade secret protection for information contained in AA Reports, that term is not broad enough to protect all categories of information warranting such protection in this context. In order to ensure innovation is not stifled, the Alliance suggests that this section reference the broader category of "Confidential Business Information." See below for further discussion.

Article 6. Regulatory Responses.

AA Report Supplemental Information Requirements (Section 69506.1)

This section provides that the Department "may at any time" require the Responsible Entity to "provide any information" and/or "obtain or develop information to fill one or more of the information gaps…" The Department has indicated that its intent is not to require the generation of information in order to fill data gaps. This provision appears overly broad and contrary to that stated intent. Accordingly, the Alliance requests that the Department revise this section for consistency with prior statements of intent.

Production Information for Consumers (Section 69506.3)

Subsection (a)(1)(D) provides that the information made available to consumers include identification of any end-of-life management program. To the extent there is a disagreement about inclusion of the end-of-life management requirement, this provision is also objectionable and should be revised. See below for further discussion.

End-of-Life Management Requirements (Section 69506.4)

This section requires manufacturers to develop, fund and manage an end-of-life stewardship program for their products that generate hazardous waste. This provision is unnecessary, and appears to be pre-empted by the Resource Conservation and Recovery Act ("RCRA") insofar as it may conflict with many of RCRA's provisions. It may also be in conflict with the Electronic Waste Recycling Act and associated regulations promulgated by the Department. For this reason, the requirement is not legally defensible and this provision must be revised. In addition, secondary and end-of-life markets already exist for many products, and it would be redundant and contrary to the free market to restrict these existing economies by requiring only the product manufacturers to manage end-of-life recycling, etc.

Finally, subsection (d) provides that a Responsible Entity may request an exemption from the requirement to provide an end-of-life management program. Once again, however, the subsection provides no standards or clear criteria for obtaining the same. This provides industry no direction with respect to what might be considered compelling, and breeds a system where there are no clear arguments in the event of an arbitrary decision.

For each of the reasons set forth above, this section requires extensive revisions. One of these revisions is included in section 69506.4 which addresses the Department's concern

regarding the possibility that a responsible entity should enter bankruptcy is:

> "A responsible entity shall be exempt from the requirements to provide a financial guarantee to the extent that they have an established market-based end-of-life management program that recycles the Priority Product and that will continue regardless of a potential bankruptcy of a responsible entity."

Product Sales Prohibition (Section 69506.5)

In the event of a sales prohibition, in order for responsible entities to comply, timeframes for compliance must be set based on the complexity of the product redesign which will differ for various products. The Global Automakers have also commented on this in their letter. We have added the following language to address this issue:

> "Effective no sooner than one (1) year after the Department issues a notification pursuant to subsection (a), any responsible entity for the product that is the subject of the notification shall cease to place the product into the stream of commerce in California. The Department shall establish product-specific timeframes based on the complexity of the redesign and reformulation of the product. Longer timeframes of at least three to five years will be established for products requiring extensive performance and safety testing."

Exemption from Regulatory Response Requirements (Section 69506.7)

Subsection (b)(6) provides that if a regulatory response would conflict with, or be duplicative of, other applicable state or federal laws, then a Responsible Entity must submit a formal request for exemption from the Department. The Statute specifically precludes the Department from requiring a regulatory response where either of these two scenarios occurs. Accordingly, no notification should be required, nor does requiring one appear to be authorized by the Statute. This requirement should be deleted.

Regulatory Response Determination Process (Section 69506.8)

The Alliance appreciates the fact that this section continues to provide for a regulatory response determination process that requires a public workshop and the opportunity for comment prior to issuance of a "final regulatory response determination." It also appreciates this section's clarity with respect to the deadlines that will be attached to the same (e.g., public comments will be due 45 days from the date the proposed regulatory response determination is issued).

Regulatory Response Report Notifications (Section 69506.9)

This section does not provide clear direction with respect to how any "notice" must be sent. In order to eliminate the potential cost, waste and burden associated with notifying retailers via postal delivery, this provision should make it clear that other forms of notice (e-mail, telephone messaging, etc.) also are acceptable means of providing the required notification.

Article 8. Accreditation Bodies and Certified Assessors.

Qualification and Certification of Assessors (Section 69508)

The Department should review the requirements for certification, as they are unduly onerous and restrict qualified people who may have received their scientific education in post-graduate (as opposed to undergraduate) work. Also, the certification model is inconsistent with other product safety laws and regulations, which only require internal review for compliance with standards and associated certifications confirming the same. Given the dearth of people that currently have the equivalent of four (4) years of professional experience performing AAs, it is not realistic to assume there will be an adequate number of these professionals in 2015, when the Certified Assessor requirement is triggered. Finally, in order for there to be a common understanding on the scientific criteria to be used in AAs, it is essential that all Department auditors be trained as Certified Assessors; also via an objective third-party not affiliated with the Department or State of California.

Qualifications for Accreditation Bodies (Section 69508.1)

Consistent with the comments provided above, the standards for receiving accreditation are not realistic given the newness of AA and the scarcity of people with experience in the same. At a minimum, subsection (a)(6) should be deleted as too broad since, as written, it would result in disqualifying virtually every possible organization that could become an accredited institution. Eventually, organizations will have to pay an accredited body to train their employees as assessors. Once that payment is made, a financial association is made with the accredited body that would then disqualify them based upon this relationship.

Article 10. Trade Secret Protection.

This Article addresses trade secret protection. While the existing provisions are not objectionable, the Article would be more appropriately protective if it covered a broader category of information. As a means to being appropriately protective, this Article should address "Confidential Business Information," a term that includes not only trade secrets, but also commercial or financial information that is privileged or confidential.

Assertion of a Claim of Trade Secret Protection (Section 69510)

Notwithstanding the above, the amount of information that must be provided to assert trade secret protection appears more cumbersome than necessary. As an example, see federal regulations at 49 CFR Part 512, which provide for protection of the broader category of "Confidential Business Information," and require far less information to support a claim.

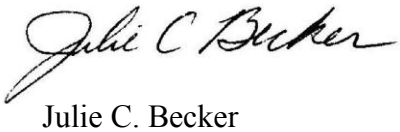
Conclusion

The October 31 Informal Draft brings the Department one step closer to development of a green chemistry regulation that fully implements the vision set forth in the Statute. To that end, this letter and the attached redline serve to move the Department closer to that goal and solidify the language, concepts and direction that has been mutually expressed as positive. The Alliance

greatly appreciates the Department's efforts toward facilitating an open and collaborative public process, and looks forward to continued communication as the Department works to redraft this regulation.

As always, thank you for your time and consideration of our comments. If you have any questions, please contact Filipa Rio of my staff at frio@autoalliance.org or (202) 326-5551.

Sincerely,



Julie C. Becker
Vice President, Environmental Affairs

Attachment: Suggested Redline of October 31 Informal Draft

DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS
CHAPTER 55. SAFER CONSUMER PRODUCTS

Amend the Table of Contents by adding chapter 55, articles 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, and sections 69501, 69501.1, 69501.2, 69501.3, 69501.4, 69501.5, 69501.6, 69502, 69502.1, 69502.2, 69502.3, 69503, 69503.1, 69503.2, 69503.3, 69503.4, 69503.5, 69503.6, 69504, 69504.1, 69505, 69505.1, 69505.2, 69505.3, 69505.4, 69505.5, 69505.6, 69506, 69506.1, 69506.2, 69506.3, 69506.4, 69506.5, 69506.6, 69506.7, 69506.8, 69506.9, 69507, 69507.1, 69507.2, 69507.3, 69507.4, 69507.5, 69507.6, 69508, 69508.1, 69508.2, 69508.3, 69508.4, 69509, 69510, 69510.1, 59511, and 69512 through 69599 to division 4.5 of California Code of Regulations, title 22, to read:

Table of Contents

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Chapter 55. Safer Consumer Products

Article 1. General **4**
§ 69501. Purpose and Applicability. 4
§ 69501.1. Acronyms 4
§ 69501.2. Definitions 5
§ 69501.3. Duty to Comply and Consequences of Non-Compliance. 17
§ 69501.4. Information Submission and Retention Requirements. 20
§ 69501.5. Chemical and Product Information. 20
§ 69501.6. Availability of Information on the Department's Website. 21

Article 2. Chemicals of Concern Identification Process **23**
§ 69502. General. 23
§ 69502.1. Applicability. 24
§ 69502.2. Chemicals of Concern Identification. 24
§ 69502.3. Chemicals of Concern List 26

Article 3. Chemicals of Concern and Consumer Product Prioritization Process **27**
§ 69503. General. 27
§ 69503.1. Applicability. 27
§ 69503.2. Priority Products Prioritization. 27
§ 69503.3. Priority Products List. 30
§ 69503.4. Alternative Assessment Threshold~~De Minimis Exemption~~ 31
§ 69503.5. ~~De Minimis~~Alternative Assessment Threshold ~~Exemption Notifications~~Determination 32
§ 69503.6. Priority Product Notifications. 33

Article 4. Petition for Inclusion of a Chemical or Product in the Identification and Prioritization Processes 34

§ 69504. Applicability and Petition Contents. 34
§ 69504.1. Technical Review of Petitions. 35

Article 5. Alternatives Assessments 35

§ 69505. Guidance Materials. 35
§ 69505.1. Alternatives Assessments: General Provisions. 36
§ 69505.2. Assessment of Priority Products and Alternatives. 38
§ 69505.3. Alternatives Assessment: First Stage. 38
§ 69505.4. Alternatives Assessment: Second Stage. 40
§ 69505.5. Alternatives Assessment Reports. 41
§ 69505.6. Department Review and Determinations for AA Reports. 46

Article 6. Regulatory Responses 47

§ 69506. Applicability. 47
§ 69506.1. AA Report Supplemental Information Requirements. 47
§ 69506.2. No Regulatory Response Required. 48
§ 69506.3. Product Information for Consumers. 48
§ 69506.4. End-of-Life Management Requirements. 49
§ 69506.5. Product Sales Prohibition. 51
§ 69506.6. Other Regulatory Responses. 52
§ 69506.7. Exemption from Regulatory Response Requirements. 53
§ 69506.8. Regulatory Response Determination Process. 54
§ 69506.9. Regulatory Response Report and Notifications. 55

Article 7. Dispute Resolution Processes 56

§ 69507. Dispute Resolution. 56
§ 69507.1. Informal Dispute Resolution Procedures. 56
§ 69507.2. Appeal to the Director. 57
§ 69507.3. Formal Dispute Resolution. 57
§ 69507.4. Time Lines for Requests for Review. 57
§ 69507.5. Contents of Request for Review. 58
§ 69507.6. Department Procedures for Requests for Review. 58

Article 8. Accreditation Bodies and Certified Assessors. 59

§ 69508. Qualification and Certification of Assessors. 59
§ 69508.1. Qualifications for Accreditation Bodies 60
§ 69508.2. Accreditation Body Designation Requirements. 61
§ 69508.3. Accreditation Bodies Designation Process. 64
§ 69508.4. Filing a Complaint. 65

Article 9. Audits **65**
§ 69509. Audit of Alternatives Assessments and Regulatory Responses. 65

Article 10. Trade Secret Protection **66**
§ 69510. Assertion of a Claim of Trade Secret Protection. 66
§ 69510.1. Department Review of Trade Secrecy Claims. 67

Article 11. Severability **68**
§ 69511. Severability. 68

Article 12. [Reserved] **68**
§§ 69512 -- 69599. [Reserved] 68

Add California Code of Regulations, title 22, division 4.5, chapter 55 to read:
Chapter 55. Safer Consumer Products

Article 1. General

§ 69501. Purpose and Applicability.

(a) This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying potential alternatives for Priority Products to determine how best to limit potential exposures or the level of potential adverse impacts posed by the Chemical of Concern in the product. This chapter also specifies the types of regulatory responses that ~~will be imposed by operation of article 6 or may be required by~~ the Department may consider following completion of an alternatives assessment.

(b)(1) Except as provided in paragraphs (2) through (4), this chapter applies to all consumer products placed into the stream of commerce in California.

(2) This chapter does not apply to any product that is exempted from the definition of "consumer product" specified in Health and Safety Code section 25251, or to any product that is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and Safety Code section 25251.

(3) This chapter does not apply to any consumer product manufactured or stored in, or transported through, California solely for use outside of California.

~~(3)~~(4) This chapter does not apply to any historic product that is placed into the stream of commerce in California.

(4~~5~~)(A) This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination:

1. Address the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and

2. 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 was listed as a Priority Product.

(B) The Department may re-evaluate a determination previously made pursuant to this paragraph and rescind the determination if the Department finds that the facts and/or assumptions upon which the determination was based were not, or are no longer, valid.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.

§ 69501.1. Acronyms.

CEPA Canadian Environmental Protection Act
CRNR California Regulatory Notice Register

DOT	Department of Transportation (US)
EC	European Commission
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency (US)
IUPAC	International Union of Pure and Applied Chemistry
IUBMB	International Union of Biochemistry and Molecular Biology
MITI	Ministry of International Trade and Industry (Japan)
NLP	No Longer Polymers
OECD	Organization of Economic Cooperation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OSPAR	Convention for the Protection of the Marine Environment for the Northeast Atlantic REACH Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No. 1907/2006 of the European Parliament and the Council
RTECS	Registry of Toxic Effects of Chemical Substances
TSCA	Toxic Substances Control Act
US	United States
UN	United Nations

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69501.2. Definitions.

(a) When used in this chapter, the following terms have the meanings specified in this section:

(1) "Accreditation body" means an organization that meets the requirements of section 69508.2 and administers a program designed to train, evaluate, assist, and certify assessors.

(2) "Adverse air quality impacts" means significant air emissions in excess of quantitative standards of any of the air contaminants listed below:

(A) California Toxic Air Contaminants;
(B) Greenhouses gases, which means any of the following gases:
1. Carbon dioxide;
2. Hydrofluorocarbons;
3. Methane;
4. Nitrogen trifluoride;
5. Nitrous oxide;
6. Perfluorocarbons;
7. Sulfur hexafluoride;
(C) Nitrogen oxides;

(D) Particulate matter, with an aerodynamic diameter of ten (10) micrometers or less;
(E) Stratospheric ozone-depleting compounds;
(F) Sulfur oxides; or
(G) Tropospheric ozone-forming compounds.

(3) "Adverse ecological impacts" means any of the following significant direct ~~or indirect~~ effects on
living organisms and their environments:
(A) Acute or chronic toxicity to aquatic, avian, or terrestrial animal or plant species;
(B) Adverse impacts on aquatic and terrestrial ecosystems;
(C) Deterioration or loss of environmentally sensitive habitats;
(D) Impacts that cause population loss, reductions in biodiversity, or changes in ecological communities;
(E) Impacts that cause vegetation contamination or damage;
(F) Impairment of the ability of an endangered or threatened species to survive or reproduce; or
(G) Any other impact specified in article 4 of chapter 54.

(4) "Adverse environmental impacts" means any of the following:
(A) Adverse air quality impacts;
(B) Adverse ecological impacts;
(C) Adverse soil quality impacts; or
(D) Adverse water quality impacts.

(5) "Adverse public health impacts" means significant impacts that directly ~~or indirectly~~ cause ~~any~~

~~of~~ the toxicological effects on public health listed in articles 2 and 3 of chapter 54.

(6) "Adverse soil quality impacts" means significant ~~any of the following~~ effects on soil function or
soil chemical, physical or biological characteristics or properties:
(A) Biological contamination;
(B) Chemical contamination;
(C) Compaction or other structural changes;
(D) Erosion;
(E) Loss of organic matter; or
(F) Soil sealing, meaning the covering of the soil surface with a layer of impervious material or changing the nature of the soil so that it behaves as an impermeable medium.

(7) "Adverse waste and end-of-life impacts" means significant adverse impacts associated

with any of the following:

(A) The amount of waste and byproducts generated, and any special handling required for the waste and byproducts, during the life cycle of the Priority Product and each alternative being considered;

(B) Disposal, treatment or use of waste and byproducts, including solid waste, wastewater and storm water discharge streams; and

(C) Disposal of the Priority Product in the trash, down the sewer, or down the storm drain that interferes with the proper operation of solid waste, wastewater or storm water treatment facilities, and that may result in the release of Chemicals of Concern to the environment.

(8)"Adverse water quality impacts" means ~~any of the following~~significant adverse effects on the beneficial uses, as specified in Water Code section 13050(f) or adopted in a Water Quality Control Plan pursuant to article 3 of chapter 3 and/or article 3 of chapter 4 of division 7 of the Water Code, of the waters of the State, which include groundwater, fresh water, brackish water, marsh lands, wetlands, or coastal bodies or systems:

(A) Increase in biological oxygen demand;

(B) Increase in chemical oxygen demand;

(C) Increase in temperature;

(D) Increase in total dissolved solids; or

(E) Introduction of, or increase in, any of the following:

1. Chemicals identified as priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act;

2. Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303(d) of the federal Clean Water Act;

3. Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act;

4. 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; or

5. Chemicals for which OEHHA has published public health goals for drinking water.

(9) "Alternative" means any of the following:

(A) Removal of the Chemical(s) of Concern in the Priority Product, with or without adding or increasing the concentration of an existing or substitute chemical;

(B) Reformulation 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;

(C) Redesign of the product and/or manufacturing process, using different materials to reduce the potential for public health and/or environmental exposures to the Chemical(s) of Concern in the Priority Product; or

(D) Any other change to the Priority Product or the manufacturing process that reduces the potential for adverse public health and/or environmental impacts or exposures associated with the Chemical(s) of Concern in the Priority Product.

(10) "Alternatives assessment" or "AA" means an evaluation and comparison of a product and alternative products, pursuant to article 5.

(11) "Alternatives Assessment Threshold" means the amount of a chemical of concern in an assembled or formulated product above which an alternatives assessment must be completed for a chemical of concern in a listed Priority Product, and below which an exemption for the use/presence of a chemical concerned may be relied upon.

(11) "Aqueous hydrolysis half-life" means the time required for the concentration of a chemical to be reduced to one-half of its initial concentration after being introduced into water.

(12) "Assembled product" means a heterogeneous product consisting of two or more components.

(13) "Atmospheric oxidation rate" means the rate of change or degradation of a chemical through the interaction with oxygen in the atmosphere.

(14) "Bioaccumulation" means the accumulation of a chemical substance in an organism, or an individual component of the environment, which absorbs the chemical at a rate greater than that at which the chemical is lost.

(15) "Certified assessor" means an individual that is qualified by education, experience and examination, and has been issued a certificate by an accreditation body, pursuant to article 8, to perform one or more of the functions or procedures used to conduct or audit an AA, or verify an AA Report.

(16) "Chemical" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.

(17) "Chemical ingredient" means a chemical in a consumer product.

(18) "Chemical identification and description information" means all of the following:

(A) Substance identification information;

(B) Information on the ~~purity~~PQL of the chemical and identification of known impurities and additives in the chemical;

(C) Physicochemical properties; and

(D) Environmental fate properties.

(19) "Chemical of Concern" means a chemical ~~identified as a Chemical of Concern under section 69502.2(a), or a chemica~~prioritized pursuant to the methodology developed ~~listed~~ by the Department pursuant to section 69502.3. (69502.2(a)

(20)(A) "Component" means a homogeneous material of a uniquely identifiable part or piece of an assembled ~~y or subassembly, system or subsystem of a~~ consumer product that performs a distinctive and necessary function in the operation of a system, and:

Comment [A&B1]: Per HP Comments. Homogenous material added as definition (42) and is same meaning as under California RoHS see: http://www.dtsc.ca.gov/hazardouswaste/rohs.cfm

1. Is required to complete or finish an item; or
2. ~~Performs a distinctive and necessary function in the operation of a system~~Is intended to be included as a part of a finished item.

(B) "Component" does not include a chemical ingredient in a formulated consumer product.

(21) "Consumer product" or "Product" means ~~any of~~ the following:

(A) A "consumer product" as defined in Health and Safety Code section 25251;

(B) A component that meets the definition of a "consumer product" as defined in Health and Safety Code section 25251; or

(C) A component that is identified, pursuant to section 69503.3(a)(2)(C), as the minimum required focus of the AA.

(D) For an assembled product, a homogeneous material within a component.

~~(C)~~(E)A~~, a~~ consumer product does not include historic products or second-hand products.

(22) "Contact information" means mailing and electronic address, headquarters location, phone number(s), title(s) if applicable, and website address.

(23) "Day" means calendar day. Periods of time are calculated by excluding the first day and including the last. Except, if the last day is a Saturday, Sunday, or other holiday specified in Government Code section 6700, it is excluded.

~~(24) "De Minimis Exemption Notification" means a notification submitted to the Department pursuant to section 69503.5.~~

~~(25) "De minimis level" means a concentration equal to whichever of the following is applicable:~~
~~(A) 0.01% by weight for chemicals exhibiting any of the following hazard traits or environmental or toxicological endpoints pursuant to Title 22, California Code of Regulations, Division 4.5, chapter 54:~~
~~1. Bioaccumulation, as defined in paragraph (14);~~
~~2. Carcinogenicity, as defined in section 69402.1, and that meets one or more of the criteria in section 69402.2(a);~~
~~3. Developmental toxicity, as defined in section 69402.3, and that meets one or more of the criteria in section 69402.4(a);~~
~~4. Endocrine toxicity, as defined in section 69403.3, and that meets one or more of the criteria in section 69403.17(a);~~
~~5. Environmental persistence, as defined in paragraph (55);~~
~~6. Genotoxicity, as defined in section 69403.5, and that meets one or more of the criteria in section 69403.17(a);~~
~~7. Immunotoxicity, as defined in section 69403.8, and that meets the criteria in section 69403.17(a);~~
~~8. Neurotoxicity, as defined in section 69403.12, and that meets one or more of the criteria in section 69403.17(a); or~~
~~9. Reproductive toxicity, as defined in section 69402.5, and that meets one or more of the criteria in section 69402.6(a).~~
~~(B) 0.1% by weight for chemicals that do not exhibit any of the hazard traits or environmental or toxicological endpoints listed in subparagraph (A).~~

~~(C) The de minimis level concentration specified by the Department pursuant to section 69503.4(c).~~

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

(27) "Economic impacts" means an increase or decrease in one or more of the following:

(A) Capital investments;
(B) Cost of goods to consumers;
(C) Cost of marketing;
(D) Energy costs;
(E) Jobs or businesses;
(F) Operation and maintenance costs;
(G) Resource costs; or
(H) Waste disposal and treatment costs.

~~(28) "Economic interest" in an entity means that an individual, or that individual's spouse or dependent child:~~

~~Has a direct or indirect investment worth two thousand dollars ($2,000) or more in the entity;~~

~~Is a director, officer, partner, trustee, employee, or holds a position of management in the entity;~~

~~Receives a source of income from the entity; or~~

~~Has an economic interest, as defined in subparagraphs (A) through (C), in a business entity that is a parent or subsidiary of, or is otherwise related to the entity, as defined in section 18703.1(d) of Title 2 of the California Code of Regulations.~~

(29) "End-of-life" means the point when the product is discarded by the consumer or the end of the useful life of the product, whichever occurs first.

(30) "Energy efficiency" means the reduction of energy usage while maintaining a comparable level of service.

(31) "Environment" means the land, air, water, soil, minerals, flora and fauna.

(32) "Environmental fate properties" means all of the following:

(D) Aerobic and anaerobic soil and sediment half-lives;
(C) Aqueous hydrolysis half-life;
(H) Atmospheric oxidation rate;

(F) Bioaccumulation in organs and tissues;
(A) Biodegradation;
(E) Mobility among and between individual components of the environment;
(G) Persistence; and
(B) Photodegradation.

(33) "Environmental or toxicological endpoint" means any environmental or toxicological endpoint identified by the OEHHA pursuant to Health and Safety Code section 25256.1 and specified in chapter 54

(34) "Failure to Comply List" means the list prepared by the Department pursuant to section 69501.3(d).

(35) "~~Failure to Respond List~~"Data Generators List" means the list prepared by the Department pursuant to section 69501.5

~~(36) "Financial guarantee" means any mechanism to ensure that adequate funding is available to pay for future end-of-life management costs for products placed into the stream of commerce in California.~~

(37) "Formulated product" means a homogeneous product, often, but not always, intended to be consumed through use.

(38) "Functionally acceptable " means that a product that has been altered by a chemical or component substitution, or that has replaced another product, substantially equals or exceeds the performance and functionality of the original product.

(39) "Green chemistry principles" means the twelve principles of green chemistry specified in "Green Chemistry: Theory and Practice" (Anastas, P.T. and Warner, J.C.; Oxford University Press: New York, 1998, p. 30).

(40) "Hazard trait" means any hazard trait identified by the OEHHA pursuant to Health and Safety Code section 25256.1 and specified in chapter 54.

(41) "Historic product" means a product that is manufactured or produced prior to the date the product is listed as a Priority Product, and its service, replacement and repair parts produced after that date to repair as-built the historic product.

(42) "Homogeneous material" means one material of uniform composition throughout or a material, consisting of a combination of materials that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes.

(~~41~~43) "Import" means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce. "Import" includes reimporting a consumer product manufactured or processed, in whole or in part, in the

United States.

(~~42~~44) "Importer" means a person who imports a consumer product into the United States. The term "importer" does not apply to an importer of historic or second hand products.

(43) "Information" means data, documentation, records, graphs, reports or any other depiction of specific pieces of knowledge.

~~(44) "Inventory recall" means to cause the return, directly or indirectly, of a consumer product that has not been sold at retail back to the responsible entity or the manufacturer or importer of the consumer product.~~

(45) "Legal requirements" means specifications and/or performance standards that a product is required to meet by federal or California law.

(46) "Life cycle" means the sum of all activities in the course of a consumer product's entire life span, including raw materials extraction, resource inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal.

(47) "Life cycle thinking" means the examination and consideration of public health and environmental impacts over a product's entire life cycle.

(48) "Listserv" means an electronic mailing list that a person may subscribe to on the Department's website in order to automatically receive electronic notification of the posting of documents and other information on that website.

(49) "Manufacture" means to make, produce, or assemble. "Manufacture" does not include any of the following actions, unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:

(A) Repair or refurbishment of an existing consumer product including the manufacture of historic products in connection with the same;

(B) Installation of standardized components and upgrades to an existing consumer product; or

(C) Making non-material alterations to an existing consumer product.

(50) "Manufacturer" means any person who manufactures a product, or any person that controls the chemical specifications and design of, or use of ~~materials~~ chemicals in, a product.

(51) "Market presence information" means all of the following:

(A) Statewide sales by volume;

(B) Statewide sales by number of units; and

(C) Intended product use(s) and types and age groups of targeted customer base(s).

(52)(A) "Materials and resource consumption" means the consumption of renewable and nonrenewable resources that are used for a consumer product during its life cycle.

(B) Except as specified in subparagraph (C)2., a renewable resource is a resource that is capable of being replaced by natural processes at a rate equal to or faster than its consumption rate. Renewable resources include solar and wind energy, timber, agriculture, and water.

(C) Both of the following are nonrenewable resources:

1. An inherently finite resource that is formed over long periods of geologic time. This includes petroleum, coal, metals (mined and recycled), minerals, and other finite resources.

2. A resource that meets the definition of a renewable resource, specified in subparagraph (B), but the resource is consumed at a rate that exceeds the rate at which it is replaced such that its continued use may drive the resource to exhaustion.

(53) "Materials and resource consumption impacts" means all of the following:

(A) Energy consumption and efficiency;

(B) Production, in-use, and transportation energy inputs;

(C) Reusability and recyclability; and

(D) Consumption and conservation of renewable and nonrenewable resource.

(54) Maximum Concentration Value (MCV) means the maximum allowable level of a chemical of concern in a component or formulated product that is set as part of a regulatory response after an alternative assessment has been completed. The Maximum Concentration Value will not be set below the Practical Quantitation Limit.

(554) "Mode of action" means the mechanism by which a chemical produces an effect on a living organism or in an environmental compartment.

(565) "Persistence" means the propensity for a chemical substance is able to exist in the environment in an unchanged form.

(576) "Person" has the same meaning as in Health and Safety Code section 25118.

(587) "Physical chemical hazards" means physical hazard traits specified in article 6 of chapter 54.

(598) "Physicochemical properties" means the physicochemical properties specified in section 69407.2.

(6059)(A) "Place into the stream of commerce in California" means to sell, offer for sale, distribute, supply, or manufacture a consumer product for use in the state of California.

(B) "Sale or offer for sale" means any transfer or offer to transfer for consideration of title or the right to use, by lease or sales contract, including transactions conducted and offers made through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not include resale, used or second-hand sales conducted through garage sales, swap meets,

classifieds, Craigslist, Ebay, or any other means..

(61) "Practical Quantitation Limit (PQL)" means the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the chemicals of concern in the listed priority product results in an exemption for that product from the alternatives assessment process.

(60) "Priority Product" means a product or a component of a product listed by the Department pursuant to section 69503.3.

(61) "Processing agent" means a chemical used in a product manufacturing process to promote chemical or physical changes.

(62) "Product function and performance" means the principal use(s) or application(s) of a product by a consumer, as intended by the manufacturer, including function and, and legal requirements.

~~"Purity" means the relative freedom from extraneous matter in the product~~.

(63) "Recycled material" means a product or material that has been separated from a waste stream for the ~~purpose of recycling~~use as ~~the material as~~ feedstock.

(64) "Release" means an intentional or unintentional ~~liberation,~~ emission, or discharge of a reportable quantity of a chemical into the environment.

(66) "Scientifically reliable information" means well-conducted studies grounded in methods and procedures of science and subjected to peer review, as defined in section 69401.2, or any other information that meets one or more of the following criteria:

(A) Relied on or used by an authoritative organization~~,as defined in section 69401.2~~, to protect public health or the environment;

(B) Generated using one of the following:

1. US Food and Drug Administration Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations);
2. US EPA's Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines;
3. TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations);
4. TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations);

(C) Published and accepted in scientifically peer reviewed reports or other literature;

(D) Published in a report of the US National Academies;

~~(E) Published in reports by international, federal, state and local agencies that implement laws and programs governing chemicals;~~

(F) Developed, or reviewed and accepted, by an authoritative organization ~~international organization, federal agency, state or local agency~~ for compliance or other regulatory purposes; or

(G) Developed 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, including:

1. OECD Guidelines for Testing of Chemicals;
2. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring;
3. OECD Manual for Investigation of High Production Volume Chemicals;
4. REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council; or
5. CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.

(67) "Scientifically r~~R~~eliable information -demonstrating the occurrence, or potential occurrence, of exposures to a chemical" means any of the following ~~that are established by reliable information~~:

(A) Monitoring data ~~that~~ where the weight of evidence shows the chemical to be present in household dust, indoor air, or drinking water, or on interior surfaces in concentrations or levels that exceed regulatory thresholds and have direct and significant adverse public health or environmental impacts;

(B) Monitoring data where the weight of evidence ~~that~~ shows the chemical to be present in, or released in a reportable quantity from, products used in or present in the home in concentrations or levels that exceed regulatory thresholds and have direct and significant adverse public health or environmental impacts;

(C) Environmental monitoring data, or environmental modeling results, where the weight of evidence ~~that~~ indicate environmental accumulation of a chemical in concentrations or levels that exceed regulatory thresholds and have direct and significant adverse public health or environmental impacts;

(D) California Environmental Contaminant Biomonitoring Program data, Center for Disease Control's National Health and Nutrition Evaluation Survey biomonitoring data, or other biomonitoring data, that where the weight of evidence show the chemical to be present in human organs, tissues or fluids in concentrations or levels that exceed regulatory thresholds and have direct and significant adverse public health or environmental impacts;;

(E) Scientifically r~~R~~eliable information that provides evidence that a chemical exhibits the lactational or transplacental transfer hazard trait specified in section 69405.5;

(F) Environmental monitoring data where the weight of evidence ~~that~~ shows the accumulation of the chemical in aquatic, avian, animal or plant species in concentrations or levels that exceed regulatory thresholds and have direct and significant adverse public health or environmental impacts;;

(G) Exposure modeling that indicates exposure point concentration(s) associated with adverse public health or environmental impacts; or

(H) Monitoring data indicating the presence of a chemical or its degradation products in California solid waste, wastewater or storm water streams collected or managed by California State or local agencies in concentrations or volumes that:

1. Present ~~potential~~ adverse public health or environmental impacts;
2. May require the expenditure of public funds to mitigate ~~potential~~ adverse public health or environmental impacts;
3. Increase the costs of reusing or recycling materials containing the chemical; or

4. Interfere with the proper operation of solid waste, wastewater, or storm water treatment systems and may result in the discharge of the chemical to the environment.

(68) "Responsible entity" means any of the following, in order of duty to comply:
(A) The manufacturer who controls the chemical specifications and design of, or use of chemicals in, a Priority Product.
(B) The manufacturer of a ~~manufacturer of a consumer~~ Priority P~~p~~roduct.
~~(A)~~
~~(B)~~(C) The importer of a ~~consumer~~ Priority P~~p~~roduct.
~~(C)~~(D) The retailer of ~~a consumer~~ Priori~~ir~~ty P~~p~~roduct.

(69) "Retailer" means a person to whom a consumer product is delivered or sold for purposes of sale or distribution by the person to a consumer.~~.~~ The term "retailer" does not apply to seller or distributor of historic or second-hand products.

(70) "Safer alternative" means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or ~~potential~~ exposures to, one or more Chemical(s) of Concern, so as to reduce ~~potential~~ adverse public health and environmental impacts.

(71) "Sales outlet" means any place at which consumer products are sold, supplied, or offered for sale directly to consumers in California.

(72) "Sensitive subpopulations" means subgroups that comprise a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait or toxicological endpoint, including, but not limited to, infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness that renders them as being at greater risk of adverse health effects when exposed to chemicals.

(73) "Substance identification information" means ~~all~~ any of the following that are applicable:
(A) Chemical abstract services number;
(B) Structural formula;
(C) Molecular weight;
(D) Synonyms;
(E) IUPAC name;
(F) EC number;
(G) RTECS number;
(H) IUBMB number;
(I) MITI number;
(J) Number assigned by the UN Experts on the Transport of Dangerous Goods;
(K) North America DOT number;
(L) EINECS number;
(M) ELINCS number;
(N) NLP number; and

(O) Other commonly recognized substance identification system numbers.

(74) "Technologically and economically feasible alternative" means an alternative product or chemical for which:

(A) The current technological knowledge, equipment, materials and other resources available to the manufacturer are sufficient to develop and implement the alternative;

(B) The manufacturer may earn no lessera reasonable rate of return, over a reasonable period of time after the alternative has been implemented; and

(C) The alternative does not increase aggregate externalized costs to consumers, public health, and the environment.

(75) "Trade secret" means a "trade secret" as defined in the Government Code section 6254.7(d).

(76) "Useful life" means the period of time during which a product can be used for its intended use, expressed in either terms of a single use, number of applications, days, months or years of use.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25251, 25252, 25253, and 25257, Health and Safety Code, Section 1060, Evidence Code, and Sections 3426 through 3426.11, inclusive, Civil Code.

§ 69501.3. Duty to Comply and Consequences of Non-Compliance.

(a)Duty to Comply with this chapter.

(1) A manufacturer who controls the chemical specifications and design of, or use of chemicals in, a product has the principal duty to comply with requirements applicable to a responsible entity. In the event the initiala manufacturer does not comply, it shall be the duty of the importer, if any, to comply. A retailer is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer, if applicable, have failed to comply and the Department notifies the retailer of the manufacturer's and the importer's, if applicable, non-compliance by posting the information on the Failure to Comply List, pursuant to subsection (d)(4)(C).

(2) 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 the responsible entity.

(b)(1) Manufacturer or Importer Option.

A responsible entity that is the manufacturer or importer of a Priority P-product shall not be held responsible for complying with requirements of this chapter applicable to a responsible entity if the manufacturer or importer provides a notice to the Department containing information demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California. The notice shall include all of the following:

(A) The manufacturer's or importer's name and contact information;

(B) The name of, and contact information, for all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;

(C) 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, if applicable; and

(D) Information describing the product, including the brand name(s) and product name(s) under which the product was placed into the stream of commerce in California.

~~(2)If the manufacturer or importer places into the stream of commerce in California a product that replaces, in terms of use and customer bases, the removed Priority Product and that contains the same or different Chemical(s) of Concern, the manufacturer or importer shall provide a notice to the Department at the same time as the notice required pursuant to paragraph (1) or within thirty (30) days after the replacement product is first placed into the stream of commerce in California, whichever is later. The notice shall include all of the following information:~~

~~The manufacturer's or importer's name and contact information;~~

~~The name of, and contact information, for all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;~~

~~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, if applicable;~~

~~Information describing the Priority Product that is replaced by the new product, including the brand name(s) and product name(s) under which the Priority Product was placed into the stream of commerce in California; and~~

~~Information describing the new product that replaces the Priority Product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and the Chemical(s) of Concern in the new product.~~

~~(3)Paragraph (2) does not apply to a replacement product first placed into the stream of commerce in California prior to the issuance of the applicable proposed Priority Product list, unless there is a two-fold or greater increase in the sales of the replacement product in California within one year after the date of the notice required pursuant to paragraph (1).~~

(c) Retailer Option.

A retailer of a ~~consumer~~ Priority P~~p~~roduct for which the Department has provided notice pursuant to subsection (a), shall not be held responsible for complying with the requirements specified in the notice if:

(1) The manufacturer or importer complies with the requirement specified in the Department's notice, or fulfills the requirements of subsection (b), within sixty (60) days after the Department issues the notice; or

(2) The retailer complies with both of the following requirements:

(A) The retailer ceases ordering the product no later than sixty (60) days after the Department has provided notice pursuant to subsection (a)(1); and

(B) No later than sixty (60) days after the Department has provided notice pursuant to subsection (a)(1), the retailer notifies the Department that it has ceased ordering the product, and provides the following information to the Department:

1. The retailer's name and contact information;
2. The manufacturer's and importer's name and contact information;
3. Identification and location of the retailer's sales outlets where the product is sold, supplied or offered for sale in California;
4. Name of, and contact information for, the person immediately upstream from the retailer in the supply chain for the product;
5. Information describing the product, including the brand name(s) and product name(s) under which the retailer placed the product into the stream of commerce in California;

and

6. A statement certifying that the retailer will not re-initiate ordering the product unless and until information posted on the Department's website indicates that the non-compliance has been remedied.

(d) Failure to Comply List.

(1)(A) If the Department determines that one or more requirements of this chapter have not been complied with for a Priority Product~~specific chemical or product~~, the Department shall issue a notice of non-compliance to the manufacturer and the importers, if applicable, for the product.

(B) A notice of non-compliance shall describe the nature of the non-compliance and the Department's intent to place information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4).

(2) If the non-compliance has not been remedied to the satisfaction of the Department, the Department shall post information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4). The Department shall post the information on the Failure to Comply List not less than 45 days and not later than 90 days after issuing the notice of non-compliance. The non-compliance shall be deemed to be remedied if the Department determines that the requirements of subsection (b)(1) have been fulfilled, or that the condition of non-compliance has been fully remedied.

(3) Paragraph (2) does not apply if there is pending dispute under article 7 concerning the notice of non-compliance.

(4) The Department shall post and maintain on its website a Failure to Comply List that includes all of the following information for each product covered by a notice of non-compliance:

(A) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;

(B) The requirement(s) of this chapter, and the applicable due date(s), that are the basis for the notice of non-compliance;

(C) A statement placing retailers of the product on notice of the Failure to Comply by the manufacturer and, if applicable, importers, pursuant to subsection (a)(1), including identification of the requirement with which the retailer shall comply and the timeframe for compliance, which shall be no less than sixty (60) days after the notice is posted on the Department's website;

(D) The Chemical(s) of Concern known to be in the product;

(E) The name of and, if known, the contact information for the person listed on the product label as the manufacturer and the person, if any, listed as the distributor;

(F) The name of and contact information for any manufacturer or importer that has been notified by the Department, pursuant to paragraph (1);

(G) The name of, and contact information for, retailers of the product known to the Department who have not fully complied with the requirements of subsection (c); and

(H) The date the product is first listed on the Failure to Comply List.

(5) The Department shall remove a product, and the associated information, from the Failure to Comply List if the Department determines that the condition of non-compliance has been fully remedied, or that the requirements of subsection (b)(1) have been fulfilled.

(6) The Department shall remove information concerning a retailer who is a responsible

entity from the Failure to Comply List if the Department determines that the retailer has complied with the applicable requirements of subsection (c).

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69501.4. Information Submission and Retention Requirements.

(a) All information required to be submitted to the Department by a responsible entity pursuant to the chapter must be signed by the responsible individual in charge of preparing or overseeing the preparation of the information and by the owner, or an officer of the company, or an authorized representative. All information submitted to the Department must be in English, and must be generated and submitted in a manner and in an electronic format specified by the Department.

(b) All ~~De Minimis~~ ~~Exemption Notifications~~Preliminary and Final AA Reports, Priority Product Notifications, and submissions of information claimed to constitute trade secrets must include the following certification statement, signed by an officer, or authorized representative, of the entity submitting the document and by the responsible individual in charge of preparing, or overseeing the preparation of, the information:

"I certify under penalty of perjury that this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that submitting false information or statements is a punishable offense."

(c) A person who is subject to a requirement to obtain or prepare information, but who is not required to submit the information to the Department or has not yet been requested to submit information to the Department, shall retain the information for a period of three (3) years following the date the person was required to obtain or prepare the information.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69501.5. Chemical and Product Information.

(a) The Department shall seek to obtain and/or review information that it determines is necessary to implement this chapter using one or more of the following approaches, in the following order:

(1) Obtain and/or review information -on chemical production and product inventory in the public domain that is readily available in a usable format, without a subscription or other charge;

(2) Obtain and/or review information on chemical production and product inventory in the public domain that is readily available in a usable format, with a subscription or other charge, to the extent resources are available to pay the required costs;

(3) Request a responsible entity or a chemical manufacturer or importer to make existing information available to the Department, in accordance with a schedule specified by the Department; and

(4) Request a responsible entity or a chemical manufacturer or importer to generate new information of select chemicals of concern and provide it to the Department, in accordance with a schedule specified by the Department.

(b) The Department may request that information be made available to it pursuant to this section by ~~either or both of~~ the following method~~s~~: c ~~C~~orrespondence sent to all ~~n individual~~ responsible entity~~ies~~ and~~or~~ chemical manufacturers electronically or by United States mail. Copies of the correspondence shall be posted on the Department's website; and/or

(c) In order to inform the public and consumers, the Department ~~Information call-ins that, unless otherwise specified, apply to all responsible entities and/or all chemical manufacturers and importers of a specific chemical or product or group of chemicals or products. The Department~~ shall post information call-ins on its website, provide notice to individuals on the listservs established by the Department related to this chapter, and provide notice in the CRNR.

(d~~e~~) The Department shall post on its website on the ~~Failure to Respond~~ Data Generators List a notice that the responsible entity or the chemical manufacturer or importer has ~~not~~ made the requested information available to the Department, if that person, or person acting on behalf of or in lieu of that person, does ~~not~~ make the requested information available by the date specified by the Department~~, unless the responsible entity or the chemical manufacturer or importer demonstrates to the Department's satisfaction that is does not have and is unable to produce the requested information~~. The Department shall also post information identifying the responsible entity or the chemical manufacturer or importer, and the chemical or product that is the subject of the request. ~~The Department shall remove this information from its website upon determining that the responsible entity, or the chemical manufacturer or importer, or another person has fulfilled the request for information.~~

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69501.6. Availability of Information on the Department's Website.

(a) The Department shall post on its website, and update as appropriate, all of the information and documents listed below, except as otherwise provided in article 10. The Department shall also provide notice of the availability of these documents and information, including the availability of updates to the information and documents, in the CRNR and to individuals on the listserv(s) that the Department establishes related to this chapter.

(1) The Failure to Comply List prepared pursuant to section 69501.3(d).

(2) The ~~Failure to Respond~~Data Generator's List prepared pursuant to section 69501.5(c).

(3) Requests for information made pursuant to section 69501.5.

(4)(A) Exemption determinations made pursuant to section 69501(b)(4), and the rationale for the determinations; and

(B) Determinations made pursuant to section 69501(b)(4), rescinding previously made exemption determinations.

(5) Proposed and final Chemicals of Concern and Priority Products lists and revisions to the lists, and supporting rationales and documentation, prepared pursuant to sections 69502.3 and 69503.3, copies of all written comments received during the public comment period for the proposed list, and copies of any written responses the Department provides to the comments.

As the following information becomes available, the Department shall add it to the Priority Products list for each product that is a Priority Product, and shall maintain and update this information for as long as the Priority Product continues to be placed into the stream of commerce in California:

(A) Brand name(s) and product name(s) for the product;

(B) Product manufacturer(s) and, if applicable, importers, except for those manufacturers or importers that have complied with the requirements of section 69501.3(b);

(C) Other responsible entities for each product, except for the responsible entities that have complied with the requirements of section 69501.3(c); and

(D) Whichever of the following is applicable:

~~1. A copy of, and link to, the De Minimis Exemption Notification for the product, unless subsections (d) or (e) of section 69503.5 apply; or~~

2.a. The identity of the person that has been identified as being the person that will fulfill the requirements of article 5; and

b. The due dates for, and the dates of receipt of, the Preliminary AA Report and the Final AA Report.

(6) Petitions designated as complete pursuant to section 69504(b), and notices of decision and statements of basis prepared by the Department pursuant to section 69504.1(d).

(7) The due date for each Preliminary and Final AA Report.

(8) A list of extension requests approved, pursuant to section 69505.1(c), for submission of the Preliminary and Final AA Reports.

(9) A list of, and copies of, Priority Product Notifications submitted to the Department under section 69503.6.

~~(10) A list of, and copies of, De Minimis Exemption Notifications submitted to the Department under section 69503.5(a), notices submitted to the Department under subsections (c) and (d) of section 69503.5, and notices issued by the Department under section 69503.5(e).~~

~~(11)~~(10) AA Report notices of compliance and notices of deficiency issued pursuant to section 69505.6.

~~(12)~~(11) Proposed and final regulatory response determination notices issued by the Department pursuant to article 6, copies of all written comments received during the public comment period for a proposed notice, and copies of any written responses the Department provides to the comments.

~~(13)~~(12) A list of regulatory response exemption requests submitted to the Department pursuant to section 69506.7(a), and copies of all notifications issued by the Department granting, denying, or rescinding a regulatory response exemption pursuant to sections 69506.7(c) and 69506.7(e).

~~(14)~~(13) Copies of all disputes and Requests for Review filed with the Department pursuant to article 7, and copies of all Department decisions issued in response to disputes and Requests for Review.

(15) A list of accreditation bodies whose designation has been rescinded by the Department pursuant to section 69508.3(g), and a list of certified assessors whose accreditation has been rescinded pursuant to section 69508(c).

(b) The Department shall also post on its website, and update as appropriate, all of the following information and documents, except as otherwise provided in article 10:

(1) Information concerning notices submitted to the Department pursuant to section 69501.3 (b) and (c).

(2) Guidance documents prepared by the Department pursuant to section 69505(a).

(3) AAs made available by the Department pursuant to section 69505(b).

(4) A list of all Preliminary AA Reports that have been submitted to the Department pursuant to article 5, and a full or redacted copy of each Preliminary AA Report, including both the originally submitted Preliminary AA Report and the Preliminary AA Report approved by the Department, if different.

(5) A list of all Final AA Reports that have been submitted to the Department pursuant to article 5, the executive summary for each Final AA Report, and a full or redacted copy of each Final AA Report, including both the originally submitted AA Report and the Final AA Report approved by the Department, if different.

(6) A list of all work plans submitted to the Department pursuant to section 69505.2(b), and a full or redacted copy of each work plan, including both the originally submitted work plan and the work plan approved by the Department, if different.

(7) The Regulatory Response Report prepared and updated pursuant to section 69506.9(d).

(8) Links to product stewardship plans provided to the Department pursuant to section 69506.4(a)(2)(C).

(9) A list of entities that have been designated as accreditation bodies pursuant to section 69508.3.

(10) A list of certified assessors who have been accredited pursuant to section 69508.

(11) Findings of audits conducted by the Department pursuant to section 69509.

(c) All documents and information posted on the Department's website pursuant to this chapter shall include the date the document or information is first posted and the date(s) of any revised postings.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

Article 2. Chemicals of Concern Identification Process

§ 69502. General.

(a) This article specifies the process by which the Department shall identify Chemicals of Concern.

(b) The Department may use, but is not limited to using, information obtained and/or reviewed pursuant to section 69501.5 to perform its duties under this article.

NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference: Section 25252, Health and Safety Code.

§ 69502.1. Applicability.

This article applies to all chemicals that exhibit a hazard trait or an environmental or toxicological endpoint, and that may be used in products placed into the stream of commerce in California.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25257.1, Health and Safety Code.

§ 69502.2. Chemicals of Concern Identification.

(a) Initial Chemicals of Concern List. As of the effective date of these regulations, a chemical is identified as a Chemical of Concern if it exhibits a hazard trait or an environmental or toxicological endpoint, and meets one or more of the following criteria:

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

(A) California Safe Cosmetics Program's Chemicals Known or Suspected to Cause Cancer or Reproductive Toxicity;

(B) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65);

(C) Canadian Environmental Protection Act Environmental Registry's Persistent, Bioaccumulative, and Inherently Toxic to the Environment (CEPA PBiT);

(D) Category A and B Carcinogens, Report on Carcinogens, US Department of Health and Human Services, Public Health Service, National Toxicology Program;

(E) Chemicals for which primary Maximum Contaminant Levels (MCLs) have been established under the federal Safe Drinking Water Act;

(F) European Chemical Substances Information System Persistent Bioaccumulating Toxins (ESIS PBT);

(G) European Commission Category 1 and Category 2 endocrine disruptors;

(H) European Union Directive on Dangerous Substances (Directive 67/548/EEC), Category 1 Carcinogens, Category 1 Reproductive toxins;

(I) European Union EC 1272/2008 Annex VI, Category 1A and 1B carcinogens, Category 1A and 1B reproductive toxins, Category 1A and 1B mutagens;

(J) International Agency for Research on Cancer (IARC), Groups 1, 2A, and 2B carcinogens;

(K) Pollutants listed by California or the United States Environmental Protection Agency for one or more water bodies in California pursuant to section 303 (d) of the federal Clean Water Act;

(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;

(M) Priority toxic pollutants for California pursuant to section 303(c) of the federal Clean Water Act;

(N) US EPA Toxics Release Inventory Persistent, Bioaccumulative and Toxic Chemicals; and/or

(O) Washington Department of Ecology Persistent Bioaccumulative Toxin List.

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

(A) National Report on Human Exposure to Environmental Chemicals, Center for Disease Control,

(B) OSPAR List of Chemicals for Priority Action;

(C) OSPAR List of Substances of Possible Concern;

(D) US EPA National Waste Minimization Program list of Persistent; and/or Bioaccumulative and Toxic Priority Chemicals.

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

(A) ~~Grandjean & Landrigan identification of Neurotoxicants~~;

(B) National Toxicology Program, Office of Health Assessment and Translation (formerly the Center for the Evaluation of Risks to Human Reproduction (CERHR)) reports; and/or

(C) US EPA Integrated Risk Information System (IRIS) identification of carcinogens.

(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 one or more hazard traits or environmental or toxicological endpoints, as Chemicals of Concern by considering the following factors for which information is available:

(1) Potential Chemical Adverse Impacts.

(A) The potential for the chemical to cause adverse public health and/or environmental impacts, considering:

1. The chemical's hazard traits and environmental or toxicological endpoints, and modes of action;

2. The chemical's aggregate effects;

3. The chemical's cumulative effects with other Chemicals of Concern with similar modes of action;

4. The chemical's physicochemical properties;

5. The chemical's environmental fate properties; and

6. The relative degree to which populations and/or environmental receptors that are potentially adversely impacted.

(B) The Department shall give special consideration to the type, frequency and severity of potential adverse impact(s) and the potency of the chemical associated with the adverse impact(s) for all of the following:

1. Children, pregnant women, and other sensitive subpopulations;

2. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and

3. Widespread adverse public health and/or environmental impacts.

(2) Potential Number of Exposures. The potential public and/or environmental exposures to the chemical in quantities that could result in adverse impacts, considering relevant scientifically reliable information that indicates the possibility for public or environmental exposures to the chemical, and scientifically reliable information demonstrating the occurrence, or potential occurrence, of exposures to the chemical.

(3) Availability of Information. The Department shall consider the availability of scientifically reliable information to substantiate the potential adverse impacts and exposures.

(4) Safer Alternative. The Department may, in its discretion, adjust the prioritization prior to listing a chemical as a Chemical of Concern by considering whether there is a readily available safer alternative chemical that is functionally acceptable for one or more common uses of the chemical in consumer products.

NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference: Sections 25252 and 25257.1, Health and Safety Code.

§ 69502.3. Chemicals of Concern List.

(a) An informational list of the chemicals identified as Chemicals of Concern pursuant to section 69502.2(a) shall be posted on the Department's website within thirty (30) days after the effective date of these regulations. The Department shall periodically update the list to reflect changes to the underlying lists and sources from which it is drawn, using the procedures specified in subsection (c) and (d).

(b) The Department may expand the Chemicals of Concern list pursuant to section 69502.2(b), using the procedures specified in subsections (c) and (d).

(c) The Department shall make proposed revisions to the Chemicals of Concern list available on its website for public review and comment, along with supporting documentation, including the Department's rationales, information, and information sources, prior to finalizing the revisions to the Chemicals of Concern list. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed revisions to the list. The Department shall publish in the CRNR, send to individuals on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed revisions to the list and supporting documentation. The notice must include:

(1) The last day for the public to submit written comments on the proposed revisions to the Chemicals of Concern list. The last day for submission of public comments shall be forty-five (45) days from the date the availability of the proposed list is published in the CRNR;

(2) The method(s) for submitting comments to the Department; and

(3) The date, time and location of the public workshop(s).

(d) The Department shall post the final revisions to the Chemicals of Concern list on its website after review of public comments. The Department shall ~~may~~ respond to ~~some or~~ all public comments received.

(e) The Department shall review and revise, as appropriate, the chemicals listed on the Chemicals of Concern list at most ~~least~~ once every three (3) years using the procedures specified in this section. Revisions may include additions and deletions.

NOTE: Authority cited: Sections 25252 and 58012, Health and Safety Code. Reference: Sections 25252 and 25257, Health and Safety Code.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

§ 69503. General.

(a) This article specifies the process by which the Department shall evaluate and prioritize products containing Chemicals of Concern.

(b) The Department may use, but is not limited to using, information obtained and/or reviewed pursuant to section 69501.5 to perform its duties under this article.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

~~**§ 69503.1. Applicability.**~~

~~Except as provided otherwise in section 69501(b), this article applies to all products that contain one or more Chemicals of Concern, and that may be placed into the stream of commerce as a consumer product in California.~~

~~NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25251, 25252, 25253, and 25257.1, Health and Safety Code.~~

§ 69503.1~~2~~. Prioritization Process to Select Priority Products ~~Prioritization~~.

(a)Product Prioritization Criteria. Every three years, t~~T~~he Department will evaluate products to determine the potential significant adverse impacts and ~~potential~~ exposures by considering the factors listed in paragraphs (1) through (3) for which information is available. Based on that evaluation the Department may identify and list as many as five (5) Priority Products every three years, consistent with the provisions of subsections (b) and (c) and the procedures specified in section 69503.3, products that it determines to be of high priority.

(1)Potential Significant Adverse Impacts and Exposures. The Department shall consider the potential adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to potential exposures during the manufacture, useful life, and end-of-life disposal or management of the product. The evaluation of the potential adverse impacts and exposures shall consider both of the following and those products causing the greatest potential adverse impacts and exposures shall be the priority products:

(A) Potential Chemicals Adverse Impacts from Chemicals of Concern.

1. The potential for the Chemical(s) of Concern in a product to cause adverse public health and/or environmental impacts, considering:

a. The Chemical(s) of Concern's hazard trait(s) and environmental and toxicological endpoint(s), and mode(s) of action;

b. The Chemical(s) of Concern's aggregate effects;

c. The Chemical(s) of Concern's cumulative effects with other Chemicals of Concern with similar modes of action;

d. The Chemical(s) of Concern's physicochemical properties;

e. The Chemical(s) of Concern's environmental fate properties;

~~e.~~f. The accessibility and the availability of the Chemical of Concern for uptake; and

~~f.~~g. The relative degree to which populations and/or environmental receptors that are potentially adversely impacted.

2. In selecting Priority Products, t~~T~~he Department shall give special consideration to the type, frequency and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for ~~all of~~only the following:

a. Children, pregnant women, and other sensitive subpopulations;

b. Environmentally sensitive habitats, endangered and threatened species, and environments in California that have been designated as impaired by a State or federal regulatory agency; and

~~Widespread adverse public health and/or environmental impacts.~~

(B)Potential Number of Exposures. The potential for public and/or environmental exposures to the Chemical(s) of Concern in the product in quantities that could result in adverse impacts shall be the Priority Products. The Department shall consider~~ing~~:

1. Accessibility and availability of the chemical of concern in the product for uptake;

~~1.~~2. Market presence information for the product;

~~2.~~3. Relevant scientifically reliable information that indicates the possibility for public or environmental exposures to the Chemical(s) of Concern in the product, and scientifically reliable information demonstrating the occurrence, or potential occurrence, of exposures to the Chemical(s) of Concern in the product;

~~3.~~4. Relevant scientifically reliable Information concerning the household presence of the product, , including the number of such of products, how common their household presence is, the frequency of use, and the concentration of the chemical in those products; and

~~4.~~5. The potential for public or environmental exposures to the Chemical(s) of Concern in the product, during the useful life of the product, considering the following factors:

a. Manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices.

~~b. The types of uses that could result in public exposure to the Chemical(s) of Concern in the product, considering the following factors:~~

~~Household and recreational use;~~

~~Sensitive subpopulation potential use or exposure at locations frequented by members of sensitive subpopulations; and~~

~~Workers, customers, clients and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other location.~~

c. Frequency, route (such as dermal, ingestion and/or inhalation) and duration of exposure

for each use scenario and end-of-life scenario.

d. Containment of the Chemical(s) of Concern within the product, and engineering and administrative controls.

e. Potential for release in a reportable quantity into, migration from, or distribution across environmental media, and rate thereof, and potential for accumulation and persistence in biological and/or environmental components or systems of the Chemical(s) of Concern or its/their degradation products, considering the environmental fate properties of the Chemical(s) of Concern and its/their degradation products.

(2) Availability of Information. The Department shall consider the availability of scientifically reliable information, including toxicological, to substantiate the potential adverse impacts and exposures.

(3) Other Regulatory Programs. The Department shall consider the scope of federal and/or other California State regulatory programs, and any applicable international trade agreements ratified by the United States Senate, under which the product or the Chemical(s) of Concern in the product is regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a potential basis for the product being listed as a Priority Product.

(b) Key Prioritization Criteria. In using the factors specified in subsection (a) to prioritize products, the Department shall give further priority to products meeting one or more of the following criteria:

(1) The Chemical(s) of Concern in the product have a significant potential to cause adverse public health and environmental impacts;

(2) The product is widely distributed in commerce, and widely used by consumers;

(3) There is a significant potential for public and environmental exposures to the Chemical(s) of Concern in the product in quantities that can result in adverse public health or environmental impacts;

(4) For assembled products, the product contains one or more Chemical(s) of Concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in significant adverse public health or environmental impacts; and/or

(5) For formulated products, the product is intended to be:

(A) Applied directly to the body;

(B) Dispersed as an aerosol or a vapor: or

(C) Applied to hard surfaces with the likelihood of runoff or volatilization.

(c) Process for Consideration of the Prioritization Factors.

(1) Potential Adverse Impacts and Exposures and Availability of Information. The Department shall begin the product prioritization process by evaluating products based on the factors specified in subsection (a)(1) in conjunction with subsection (a)(2)), and then include all the prioritization factors in this section.

(2) Other Regulatory Programs. Having considered the potential adverse impacts and the potential exposures for the product and its Chemical(s) of Concern, the Department shall then determine which of these potential adverse impacts and exposures are addressed by consideration of subsection (a)(3), and adjust the prioritization accordingly.

(3) Priority Products. Products determined to be of high priority after completion of the steps specified in paragraphs (1) and (2) may be listed as Priority Products.

(4) Safver Alternative. The Department ~~may, at its discretion,~~shall consider whether

there is a readily available safer alternative, that is functionally acceptable and technologically and
economically viable, to further adjust the prioritization prior to listing a product as a Priority Product.

(5) Key Prioritization Factors. Prior to issuing the proposed and final Priority Products lists, the Department shall review the list for consistency with subsection (b), and make adjustments as needed.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

§ 69503.3. Priority Products List.

(a)(1) The Department shall use the procedures specified in this section and the factors specified in section 69503.2 to identify and list products as Priority Products.

(2) At least six months prior to creation of the initial Priority Product list, the Department shall publish its work-plan on the products and product categories under consideration for listing. Thereafter, the Department shall publish its work-plan at least two years in advance of any listing. Those work plans shall include level of product specificity (e.g., general application type, representative product).

(3~~2~~) The Department shall specify in the proposed and final Priority Product lists the following for each listed product:

(A) The Chemical(s) of Concern that is/are the basis for the ~~product being~~ listing~~ed~~ as a Priority Product.

(B) The ~~de-minimis~~alternatives assessment threshold ~~level~~ and for the Chemical(s) of Concern. If the alternative assessment threshold is below 0.1%, the Department shall also specify the practical quantititation limit and the preferred test method(s) to the specified concentration.

(C) For each assembled product, the Department shall specify the component(s) that is/are the basis for the product being listed as a Priority Product. In no case shall the Department specify more than five components. This/these component(s) is/are the component(s) to which the ~~de-minimis~~alternatives assessment threshold ~~level~~ applies, and which is/are the required minimum focus of the AA.

(D) The due date for submission of the Preliminary AA Report, required pursuant to article 5. The due date for the Preliminary AA Report shall be 180 days after the date the product is listed on the final Priority Products list, unless the Department specifies a ~~shorter or~~ longer period of time.

(b) The Department shall make the proposed Priority Products list available on its website, for public review and comment, along with supporting documentation, including the Department's rationale, information, and information sources, prior to finalizing the Priority Products list. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed list. The Department shall publish in the CRNR, send to individuals on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed list and supporting documentation. The notice must include:

(1) The last day for the public to submit written comments on the proposed Priority Products list. The last day for submission of public comments shall be at a minimum forty-five (45) days

from the date the availability of the proposed list is published in the CRNR;

(2) The method(s) for submitting comments to the Department; and

(3) The date, time and location of the public workshop(s).

(c) ~~(c)~~ The Department shall post the final Priority Products List on its website after review of public comments. The Department ~~may~~ shall respond to ~~some or~~ all public comments received.

(d) The initial proposed list of Priority Products shall be made available for public review and comment pursuant to subsection (b) no later than 180 days after the effective date of these regulations.

(e) The Department shall review and revise, as appropriate, the Priority Products list at ~~least~~ most once every three (3) years, using the procedures specified in this section.

(f) Each responsible entity for a product listed on the Priority Products list shall provide to the Department a Priority Product Notification as specified in section 69503.6 ~~or a De Exemption Notification as specified in section 69503.5 within sixty (60) days after the product is listed as a Priority Product~~.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69503.4. ~~De Minimis Exemption~~Alternative Assessment Threshold.

(a) A responsible entity is exempt from the requirements of article 5 with respect to a product that is listed as a Priority Product and that is below the alternatives assessment threshold ~~meets the criteria for a de minimis exemption~~ specified in subsection (b), ~~if one of the responsible entities for the product submits a complete and timely De Minimis~~Alternatives assessment threshold ~~Exemption Notification to the Department pursuant to section 69503.5~~, unless subsection (d) or (e) of section 69503.5 apply.

(b) An ~~de minimis~~alternatives assessment threshold ~~exemption~~ applies only to products meeting one of the following criteria as of the date of the applicable Priority Products listing or the date the product is first placed into the stream of commerce in California, whichever is later:

(1) For a formulated product, the cumulative concentration in the product of all Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological endpoint, and mode of action shall not exceed the ~~de minimis~~alternatives assessment threshold ~~level~~.

(2) For an assembled product, the cumulative concentration in the homogeneous material of the ~~each~~ component that is ~~a basis for the~~ listed as a Priority Products ~~listing,~~ of all Chemicals of Concern that are a basis for the Priority Products listing and that exhibit the same hazard trait, or environmental or toxicological endpoint, and mode of action shall not exceed the ~~de minimis~~alternatives assessment threshold ~~level~~.

(c)(1) The Department may specify an alternatives assessment threshold ~~de minimis level~~ that is lower or higher than the level specified in subparagraph (A) or (B) of section 69501.2(a)(25) for the Chemical of Concern in the Priority Product, if the Department determines based on ~~available~~ ~~information~~scientifically reliable information that a lower or higher ~~de minimis~~alternatives assessment threshold ~~level~~ is warranted.

(2)The Department may specify a lower ~~de minimis~~alternatives assessment ~~level~~threshold if it ~~can~~ provides the practical quantitation limit and reliable and feasible test methods at the lower level and one or both of the following

criteria apply:

(A) The Chemical of Concern is found in concentrations at or below the level specified in subparagraph (A) or (B) of section 69505.2(a)(25), whichever is applicable, in products that are common and are frequently used, and scientifically reliable information shows that, even when individual product concentrations of the Chemical of Concern are below the ~~de minimis~~alternatives assessment ~~level~~threshold, there is the potential for significant adverse impacts from potential exposures to the Chemical of Concern, or releases of the Chemical of Concern, due to one or more of the following:

1. Potential aggregate or cumulative exposures;
2. The inherent potency of the Chemical of Concern;
3. Potential bioaccumulation; or
4. The unintended presence of the Chemical of Concern in organs, tissues, or fluids.

(B) Scientifically r~~R~~eliable information shows the Chemical of Concern poses, or potentially poses,

adverse impacts in concentrations at or below the level specified in subparagraph (A) or (B) of section 69505.2(a)(25), whichever is applicable.

(3)~~(A)~~ The Department may specify a higher ~~de minimis~~alternatives assessment ~~level~~threshold if all of the following criteria apply:

1. The source of the Chemical of Concern is one of the following:

a. A naturally occurring contaminant in raw materials that are common and are frequently used to produce the product;

b. Air or water frequently used as a processing agent or an ingredient;

c. A contaminant in recycled materials that are common and are frequently used to manufacture the product; or

d. A processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended;

2. The concentration of the Chemical of Concern in the Priority Product does not exceed the concentration of the Chemical of Concern in the source; and

3. The Chemical of Concern cannot reasonably be removed from the product.

(d) At such time the product no longer meets the criteria for an alternatives assessment threshold exemption specified in section 69503.4, the responsible entity shall notify the Department of this change within 180 days of the change, and shall submit a Preliminary AA Report to the Department within 180 days after the change.

~~(B) The Department may not specify a higher de minimis level if this would result in~~

~~increased adverse public health or environmental impacts.~~

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

~~§ 69503.5. De MinimisExemption Alternative Assessment Threshold Determination Notifications.~~

~~(a) A De MinimisExemption Notification required under section 69503.4(a) must be submitted to the Department within sixty (60) days after the product is listed as a Priority Product. The notification must include all of the following:~~

~~Name and contact information for the person submitting the De Minimis Exemption Notification.~~

~~Name and contact information for the manufacturer and, if applicable, importer(s).~~

~~Name and contact information for all responsible entities for the product, to the extent known.~~

~~The source of the Chemical(s) of Concern in the product.~~

~~Information concerning any attempts taken to eliminate or reduce the amount of the Chemical(s) of Concern in the product.~~

~~Responsible entities should identify tThe maximum concentration at which the Chemical(s) of Concern is/are present in the product, and with a listing and description of all information used to determine and substantiate this concentration. A description must be included of whichever of the following is applicable:~~

~~(A) For a formulated product, the maximum concentration in the product of each Chemical of Concern that is a basis for the Priority Product listing., and a description of the information used to detect and measure this concentration.~~

~~(B) For a component which is part of an assembled product, the maximum concentration in each the component, that is a~~

~~(b) basis for the Priority Product listing, of each Chemical of Concern that is a basis for the Priority Product listing.and a description of the information used to detect and measure this concentration.~~

~~(c) Laboratory analytical testing protocols and results used to detect and measure the concentration of the Chemical of Concern in the product, including quality control and quality assurance protocols and information concerning the testing laboratory.~~

~~(d) A demonstration and certification that the responsible entity does and will continue to meet the criteria, assumptions and conditions that are the basis for the exemption.~~

~~(e) The responsible entity bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in the Priority Product does not exceed the applicable de minimisalternatives assessment levelthreshold., and will not pose a potential adverse public health or environmental impact.If any of the information listed in subsection (a) significantly changes, a revised De Minimis Exemption Notification shall be submitted to the Department within thirty (30) days of the change.~~

~~(f) At such time If the product no longer meets the criteria for an de minimisalternatives assessment threshold exemption specified in section 69503.4, the responsible entity shall notify the Department of this change within thirty 180(30) days of the change, and shall submit a Preliminary AA Report to the Department within 180 days after the change.~~

~~The exemption provided under section 69503.4(a) does not apply if the Department determines, and notifies the person who submitted the De MinimisAlternatives assessment threshold Exemption Notification, that the information or findings contained in the notification responsible entity that are inaccurate, invalid, or inadequate to support an de minimisalternatives assessment threshold exemption has failed the designated testing method.~~

~~NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.~~

§ 69503.6. Priority Product Notifications.

(a) Within ~~sixty~~ ninety (9~~6~~0) days after a product is listed as a Priority Product, each responsible entity for such a Priority Product shall notify the Department that its product is a Priority Product, unless the responsible entity determines the ~~has submitted a~~ alternatives assessment threshold is met. ~~De Minimis Exemption Notification pursuant to section 69503.5~~. For a Priority Product that is first manufactured or first placed into the stream of commerce in California after the date the product is listed as a Priority Product, the responsible entity shall provide the notice within ninety~~sixty~~ (9~~6~~0) days after the product is first placed into the stream of commerce in California. The notification shall include all of the following:

(1) The responsible entity's name and contact information, and a statement indicating whether the responsible entity is the product manufacturer, importer, or retailer;

(2) The type, brand name(s), and product name(s) of the Priority Product~~and, if applicable, information specifically identifying the component(s) triggering the product's listed as a Priority Product~~; and

(3) The name of, and contact information for, the person that will be complying with the requirements of article 5 on behalf of or in lieu of the responsible entity, if someone other than the responsible entity.

(b) If the Department determines that the notice requirements specified in subsection (a) have not been complied with for ~~a particular product that is a~~ Priority Product, the Department shall post this information on the Failure to Comply List pursuant to section 69501.3(d).

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

Article 4. Petition for Inclusion of a Chemical or Product in the Identification and Prioritization Processes

§ 69504. Applicability and Petition Contents.

(a) Any person may petition the Department to evaluate a claim that a chemical or a product that contains a chemical should be listed as a Chemical of Concern or a Priority Product, whichever is applicable, using the processes specified in articles 2 and 3 of this chapter. The Petition must include all of the following:

(1) The name of, and contact information for, both of the following persons:

(A) The petitioner; and

(B) The person responsible for the contents of the petition, if different from the petitioner, and the affiliation of this person with the petitioner.

(2) A description of the chemical and/or product that is the subject of the petition.

(3) A description of the uses and applications of the chemical and/or product.

(4) The basis for the petition, including an analysis of potential adverse public health and/or environmental impacts associated with the chemical and/or product.

(5) Scientifically r~~R~~eliable information supporting the petition.

(6) Identity of any known manufacturers and importers of the chemical or product.

(b) Within sixty (60) days after receiving a petition, the Department shall review the petition and shall designate the petition complete if it contains all of the items specified in subsection (a). If the Department determines that a petition is complete, the Department shall notify the petitioner that it will conduct a technical review to determine whether to grant or deny the petition on its merits. The Department shall notify all potential responsible entities that a petition has been received. If the Department determines that the petition is incomplete, the Department shall notify the petitioner of this determination and shall specify the basis for the determination.

(c) The Department is not prohibited from requesting additional information during the technical review conducted pursuant to section 69504.1 due to determining a petition to be complete pursuant to subsection (b).

(d) The Department shall make the proposed petition, along with all supporting documentation available on its website, for public review and comment, prior to making its final determination. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed petition. The Department shall publish in the CRNR, send to individuals on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed petition and supporting documentation. The notice must include:

(4) The last day for the public to submit written comments on the proposed petition. The last day for submission of public comments shall at a minimum forty-five (45) days from the date the availability of the proposed list is published in the CRNR;

(5) The method(s) for submitting comments to the Department; and

(6) The date, time and location of the public workshop(s).

(7) The Department shall post the final decision on the petition on its website after review of public comments. The Department shall respond to ~~some or~~ all public comments received.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code.
Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69504.1. Technical Review of Petitions.

(a) The Department shall prioritize the technical review of complete petitions based on their comprehensiveness.~~High priority shall be given to petitions by federal and other California State regulatory programs that relate to the petitioning agency's statutory and/or regulatory mandates.~~

(b) The Department shall conduct a technical review of each complete petition to determine whether to grant or deny the petition on its merits based on:

(1) The comprehensiveness of the information submitted that pertains to the factors specified in sections 69502.2 and/or 69503.2, as applicable;

(2) The quality of the information submitted; and

(3) The availability of information, other than that submitted with the petition, that supports the petitioner's claims that:

(A) The chemical exhibits one or more hazard traits or environmental or toxicological endpoints; and

(B) An evaluation of the chemical and/or the product, based on the factors specified in sections 69502.2 and/or 69503.2, as applicable, indicates a potential for adverse public health and/or environmental impacts.

(c) The Department shall employ a randomized peer review process to review each petition, conducted by groups of three anonymous experts selected from standing panels established by the National Research Council. The peer review panel would not be asked to conduct a de novo review of the agency's entire record and decision, but to evaluate the agency's protocol for identifying relevant scientific data and research, its rationale for selecting and prioritizing data and research from the identified pool, and its interpretation of this body of science. Peer review shall be completed within 90 days, and would not be subject to the Federal Advisory Committee Act

(d~~c~~) The Department may request that the petitioner provide additional information to complete the technical review within a timeframe specified by the Department.

(e~~d~~) After completing the technical review, the Department shall do both of the following:

(1) Prepare a notice of decision to grant or deny the petition and a statement explaining the basis for the decision; and

(2) Notify the petitioner of the decision.

(3) Notify all potentially responsible entities by written correspondence.

~~(2)~~(4) Notify the public in the California Register and on its website and in its listserv.

(e) After granting a petition, the Department shall evaluate and, if applicable, list the chemical and/or the product in accordance with the processes specified in articles 2 and/or 3.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

Article 5. Alternatives Assessments

§ 69505. Guidance Materials.

(a) Before finalizing the initial list of Priority Products pursuant to section 69503.3,

the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article. The Department shall periodically revise and update the guidance materials.

(b) The Department shall also post on its website AAs that the Department is aware of, and that are available in the public domain, at no cost, and are supported by scientifically reliable information. The posting shall indicate, for each AA, the name of the person that prepared the AA.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69505.1. Alternatives Assessments: General Provisions.

(a)(1) The requirements of this article applicable to a responsible entity may be fulfilled by the responsible entity, or by a person acting on behalf of or in lieu of the responsible entity.

(2) Except as otherwise provided in subsections (b) and (e), a responsible entity for a product that contains one or more Chemicals of Concern that is/are the basis for designation as a Priority Product shall conduct an AA for the Priority Product, and shall comply with all applicable requirements of this article.

(3) A responsible entity subject to the requirements of paragraph (2) shall prepare, sign and submit to the Department a Preliminary AA Report and a Final AA Report, meeting the requirements of section 69505.5, as follows:

(A) Except as provided in subsection (b), the responsible entity shall submit the Preliminary AA Report no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department's website, unless the Department specifies a different due date for the product in the Priority Products list.

(B) Except as provided in subsection (b), the responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, pursuant to section 69505.3(b)(4), and the Department approves, pursuant to section 69505.6(a)(3), a longer period of time.

(b) The requirements of this article do not apply to any of the following:

(1) A product that is no longer placed into the stream of commerce in California by any person on and after the date that the product is listed as a Priority Product.

(2) A bulk chemical that is placed into the stream of commerce in California and that meets the definition of a "consumer product", as defined in Health and Safety Code section 25251, but that is not packaged for sale to, or end use by, a retail consumer.

(3) A product that meets the ~~de minimis~~alternatives assessment threshold exemption criteria specified in section 69503.4~~, if a complete and timely De Minimis~~Alternatives ~~assessment threshold Exemption Notification has been submitted to the Department satisfying the requirements of section 69503.5, unless subsection (d) or (e) of section 69503.5 applies~~.

(c)(1) A responsible entity may request a one-time extension to the submission deadline for the Preliminary or Final AA Report, or both, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. The Department must receive the extension request at least sixty (60) days before the applicable due date.

(2) The extension request must include all of the following:

(A) The name of, and contact information for, the person filing the extension request;

(B) The name of, and contact information for, the responsible entity(ies) on whose behalf the Preliminary and Final AA Reports will be submitted;

(C) If different from subparagraphs (A) and (B), the name of, and contact information for, the manufacturer and the importer, if applicable, of the product;

(D) Information identifying and describing the Priority Product and, if applicable, the assembled product ~~component(s) subject to the AA requirement, including the~~ brand name(s) and product name(s) in~~under~~ which the Priority Product is contained, and is placed into the stream of commerce in California;

(E) The due date for the Preliminary or Final AA Report, as applicable;

(F) The amount of additional time requested, not to exceed ninety (90) days; and

(G) The reason the extension is needed.

(3) The Department shall approve or deny, in whole or in part, the extension request, and notify the person submitting the extension request of the decision, within thirty (30) days of receipt of the extension request. Failure by the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request. The one-time extension for a Preliminary or Final AA Report, or both, shall not exceed ninety (90) days.

(d) Each AA completed after January 1, 2015 shall be performed, and each Preliminary and Final AA Report submitted after January 1, 2015 shall be prepared by, or under the responsible charge of, one or more assessor(s) certified pursuant to article 8 for the appropriate product type or industry sector.

(e) A responsible entity may fulfill the requirements of subsection (a) by submitting to the Department a report for a previously completed AA for the Priority Product, if the Department determines that the report is substantially equivalent to the Final AA Report requirements of section 69505.5 and that the report contains sufficient information for the Department to identify the most appropriate regulatory response(s) pursuant to article 6.

(1) A responsible entity submitting a report pursuant to this subsection shall submit the report no later than the deadline for submitting a Preliminary AA Report, pursuant to subsection (a)(3)(A), except that a one-time extension may be requested pursuant to subsection (c).

(2) A responsible entity submitting an existing report pursuant to this subsection may supplement the report with additional information to render the report substantially equivalent to the Final AA Report requirements of section 69505.5.

(f) A responsible entity conducting an AA, pursuant to subsection (a), shall consider ~~all~~ relevant information ~~made available on the Department's website,~~ including ~~any~~ relevant public comments, and any additional information or technical assistance the Department may provide regarding alternatives assessments. The responsible entity shall summarize these efforts in the AA Report.

(g) Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination within sixty (60) days from receipt of the Preliminary or Final AA Report, or failure of the Director to respond to an appeal submitted under section 69507.2 within sixty (60) days, shall ~~not~~ cause a Preliminary or Final AA Report to be deemed compliant.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

§ 69505.2. Assessment of Priority Products and Alternatives.

(a)(1) The AA required to be performed pursuant to section 69505.1(a) shall be conducted in two stages, as specified in sections 69505.3 and 69505.4.

(2) The responsible entity shall complete the first stage of the AA, and submit a Preliminary AA Report that complies with sections 69505.1(a)(3)(A) and 69505.5.

(3) The responsible entity shall next complete the second stage of the AA, and submit a Final AA Report that complies with sections 69505.1(a)(3)(B) and 69505.5.

(b) A responsible entity may use an AA process that differs from the process specified in sections 69505.3 and 69505.4, if all of the following requirements are met:

(1) The responsible entity's alternate process provides the information needed to prepare an AA Report that substantially meets the requirements of section 69505.5.

(2) The responsible entity's alternate process compares the Priority Product and the alternatives using, at a minimum, the same factors, and associated exposure pathways and life cycle segments, specified in sections 69505.3 and 69505.4.

(3) The responsible entity submits a work plan to the Department with sufficient information to demonstrate that the alternate process will meet the requirements of paragraphs (1) and (2), and sufficient information for the Department to specify an appropriate due date for submittal of the Final AA Report The due date shall be eighteen (18) months after the date the Department issues a notice of compliance for the work plan, unless the responsible entity requests, pursuant to section 69505.3(b)(4), and the Department approves, pursuant to section 69505.6(a)(3), a longer period of time. The additional time shall not exceed thirty (30) months after the Department issues a notice of compliance for the work plan. The work plan must be submitted to the Department no later than sixty (60) days after the product is included on the Priority Product list. Upon receipt of a work plan pursuant to this subsection, the Department shall follow the steps specified for the review of Preliminary AA Reports in section 69505.6(a).

(4) The responsible entity submits a Final AA Report to the Department that substantially meets the requirements of section 69505.5 by the due date specified by the Department pursuant to paragraph (3).

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

§ 69505.3. Alternatives Assessment: First Stage.

(a) All references in this section to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.

(b) The first stage of the AA shall include all of the following steps:

(1) Step 1, Identification of Product Criteria.

(A) The responsible entity shall identify the function, performance, technical feasibility, and legal requirements associated with the Priority Product that must be met by potential alternatives.

(B) The responsible entity shall identify the function of the Chemical(s) of Concern in meeting the Priority Product's function, performance, technical feasibility, and legal requirements.

(C)1. The responsible entity shall determine if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, technical feasibility, and legal requirements.

2. If the responsible entity determines that neither the Chemical(s) of Concern nor substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, technical feasibility, and legal requirements, the responsible entity shall evaluate as one of the alternatives to the Priority Product the removal of the Chemical(s) of Concern from the Priority Product without the addition of substitute chemical(s).

(2) Step 2, Identification of Alternatives.

(A) In addition to the alternative identified pursuant to paragraph (1)(C)2., if applicable, the responsible entity shall identify alternatives for consideration that meet the product criteria identified pursuant to paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce the potential for public and/or environmental exposures to the Chemical(s) of Concern in the Priority Product. The responsible entity shall research available information that may identify existing potentially viable alternatives, including information posted on the Department's website pursuant to section 69505(b). The responsible entity shall include in the AA consideration of any identified existing potentially viable alternatives.

(B)The comparison of the Priority Product and any alternative that does not involve the addition of a substitute chemical does not require completion of the step specified in paragraph (3).

(3) Step 3, Initial Screening of Alternative Chemicals.

For those alternatives being considered that involve substituting the Chemical(s) of Concern with other chemical(s), the responsible entity shall do all of the following:

(A) Collect and use available information to identify the adverse public health and environmental impacts associated with <u>any Chemical of Concern</u>~~each chemical~~ being considered as a possible alternative to the Chemical(s) of Concern in the Priority Product.

(B) Compare each of the potential alternative chemicals with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated pursuant to subparagraph (A).

(C)1. Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines may pose greater adverse public health and/or environmental impacts than the Chemical(s) of Concern.

<u>2. Eliminate from further consideration in the AA any alternative chemical(s) that is not commercially available, is infeasible based on costs, consumer acceptance or other performance basis.</u>

2. Subparagraph 1. does not apply to a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern. However, a responsible entity is not required to retain, for further consideration in the AA, a chemical that poses both greater and lesser individual adverse impacts relative to the Chemical(s) of Concern.

(4) Step 4, Next Steps. The responsible entity shall develop a work plan and proposed implementation schedule for completion of the second AA stage, as specified in section

69505.4, and preparation of the Final AA Report. The work plan must specify the proposed submission date for the Final AA Report, and must ensure that the Final AA Report will be submitted to the Department no later than twelve (12) months after the Department issues a notice of compliance for the Preliminary AA Report. The responsible entity may request approval from the Department for a longer period of time to submit the Final AA Report, not to exceed twenty-four (24) months from the date the Department issues a notice of compliance for the Preliminary AA Report. Such a request shall include a detailed explanation as to why the additional time is needed. If the Priority Products list identifies more than one component that is contained in an assembled product ~~that must be included in the AA for the Priority Product~~, separate submission dates may be proposed for each component.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

§ 69505.4. Alternatives Assessment: Second Stage.

The second stage of the AA shall include all of the following steps:

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.

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

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

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

(2) The responsible entity shall collect and use available quantitative information, supplemented by available qualitative information and analysis, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage as specified in section 69505.3:

(A) Multimedia life cycle impacts and chemical hazards, for Chemicals of Concern~~chemical ingredients~~ known to be in the Priority Product and the alternatives being considered based on available information:

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

(B) Product function and performance:

1. Useful life, expressed in single use or number of applications, days, months or years, of the Priority Product, and that of the potential alternatives;
2. Functional and performance comparison of each alternative relative to the Priority Product; and

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.

(C) Economic impacts. The responsible entity's evaluation and comparison of economic impacts shall take into account both internalized and externalized costs during the life cycle of the Priority Product and all alternatives being considered, and shall include an evaluation of the range of projected costs. Evaluation and comparison of externalized costs shall include costs to government agencies, the public, businesses, and consumers.

(3) The responsible entity's identification of relevant exposure pathways shall consider both of the following:

(A) Chemical quantity information:

1. Quantities of the Chemical(s) of Concern or alternative chemical(s) necessary to manufacture the Priority Product, or alternative; and

2. Estimated volume and/or mass of the Chemical(s) of Concern or substitute chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product or potential alternatives.

(B) Exposure potential factors specified in subsections (a)(1)(B), (b)(4), and (b)(5) of section 69503.2.

(b) Step 2, Comparison of the Priority Product and Alternatives to Chemicals of Concern. The responsible entity shall use available quantitative information, supplemented by available qualitative information and analysis, to evaluate and compare the Priority Product and each of the alternatives to use of the chemical of concern under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments identified pursuant to subsection (a). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives to the use of the chemical of concern being considered.

(c) Step 3, Alternative Selection Decision. The responsible entity shall select ~~the~~ alternatives that will replace or modify the Priority Product, unless the decision is to retain the existing Priority Product. The selection of an alternative or the decision to retain the Priority Product shall be based on and supported by the comparative analysis conducted pursuant to subsection (b).

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

§ 69505.5. Alternatives Assessment Reports.

(a)(1) The Preliminary and Final AA Reports must include, as applicable, all of the information specified in subsections (b) through (n).

(2) The responsible entity must include in both reports sufficient information for the Department to determine compliance with this article.

(3) The responsible entity must include in the Preliminary AA Report sufficient information for the Department to assess the appropriateness of the due date for submission of the Final AA Report.

(4) The responsible entity must include in the Final AA Report sufficient information for the Department to determine the appropriate regulatory response(s), if any, pursuant to article 6.

(5) The responsible entity must identify and explain in the Final AA Report all differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report. The responsible entity must identify in the Final AA Report the information sources used to support changes from the Preliminary AA Report to the Final AA Report.

(6) If the responsible entity selects a different alternative from the one identified in the Final AA Report submitted to the Department prior to introduction of the originally selected alternative into the California marketplace, the responsible entity shall submit a revised Final AA Report with an explanation of the change. The revised Final AA Report must be submitted to the Department within sixty (60) days after the date the responsible entity decides to select a different alternative. The responsible entity shall also submit a revised Final AA Report if the original alternative selection decision was to retain the Priority Product and the responsible entity later decides to select an alternative to replace the Priority Product.

(b)(1) All AA Reports must be accompanied by an executive summary. The executive summary must be sufficient to convey to the public a general understanding of the scope and results of the AA.

(2)(A) The executive summary must be organized in conformance with the organization of the AA Report and must include, for each section of the AA Report, a detailed summary of the information presented in the AA Report. The responsible entity may not include in the executive summary any information for which trade secret protection is claimed pursuant to article 10.

(B) If the Department subsequently rejects a trade secret claim, the responsible entity shall, at the Department's request, submit a revised executive summary within thirty (30) days of the request to add any information for which a trade secret claim is rejected and which the Department determines, and specifies in its request, must be included in the executive summary.

(c) Preparer Information.

(1) The name of, and contact information for, the person submitting the AA Report;

(2) If applicable, the name of, and contact information for, all responsible entities on whose behalf the AA Report is being submitted; and

(3) The names of the parties that were involved in funding, directing, overseeing, preparing and/or reviewing the AA, and qualifications and certification information for, the individuals in charge under whose direction the AA was conducted and the AA Report was prepared.

(d) Supply Chain Information.

(1) The name, contact information, and headquarters location of the manufacturer(s), and, if applicable, the importer. If the AA Report is prepared on behalf of a consortium of

manufacturers or other persons in the Priority product's supply chain, a list of the participants along with their corresponding contact information;

(2) The name of, and contact information for, the person identified on the Priority P~~p~~roduct label as the manufacturer, and the person, if any, identified as the distributor, if different from paragraph (1);

(3) The name of, and contact information, for all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months; and

(4) Identification and location of the manufacturer's and/or importer's retail sales outlets where the manufacturer and/or importer sold, supplied or offered for sale the product in California, if applicable.

(e) Facility Description and Location. A description and location of the facility(ies) where the Priority Product is produced. This description must also indicate the proximity to raw or recycled materials that directly or indirectly influences the type and amount of Chemical(s) of Concern in the Priority Product.

(f) Product Information. The following information identifying and describing the Priority Product that is the subject of the Final AA Report:

(1) The brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;

(2) ~~If applicable, the component(s) that is/are the focus of the AA.~~ The AA shall, at a minimum, focus on the Priority Product~~component(s) specified in section 69503.3(a)(2)(C)~~, but may be expanded by the responsible entity to include additional components or an ~~the~~ entire assembled product;

(3) Identification of the Chemical(s) of Concern ~~in the product or component(s), whichever is applicable~~, that are the basis for the product being listed as a Priority Product, and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the Priority Product that is the focus of the AA; and

(4) The information specified in section 69505.3(b)(1).

(g) Methodology. The AA Report shall identify and describe the assessment tools, models, or software used to conduct the AA, and discuss any limitations of these tools, models and software. The AA Report shall also identify any published methodologies or guidelines used, and any deviations taken from the published methodologies or guidelines.

(h) Supporting Information.

(1) All information used as supporting information in performance of the AA and preparation of the AA Reports must be cited in the AA Reports and made available to the Department, upon request. The AA Reports shall include a brief summary of the information reviewed and considered pursuant to section 69505.1(f).

~~The Final AA Report must include the identification of unavailable reliable information that, if available, could be used to:~~

~~Validate information used for purposes of sections 69505.3(b) and 69505.4;~~

~~Address any uncertainties in the analyses conducted pursuant to sections 69505.3(b) and 69505.4; and~~

~~(C) Ensure that the list of chemical ingredients required to be identified for the Priority Product and its alternatives during the conduct of the AA and the preparation of the AA Reports is complete~~(i) Scope of Alternatives. The AA Reports must identify and describe the alternatives chosen to be evaluated and compared, and explain the rationale for selecting and screening out specific alternatives at each stage of the alternative comparison process.

(j) Scope of Comparison Factors. The Final AA Report must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant, pursuant to section 69505.4(a), for evaluation and comparison of the Priority Product and its alternatives. ~~For each factor, exposure pathway, and life cycle segment determined not be relevant, the Final AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.~~

(k) Comparison of Alternatives.

(1)(A) The Preliminary AA Report must include all of the following information for the evaluation and comparison, conducted pursuant to section 69505.3(b)(3), of the Chemical(s) of Concern in the Priority Product and possible alternative chemical(s):

1. The information collected for the Chemical(s) of Concern and alternative chemical(s); and

2. The comparative results of evaluating the information presented pursuant to subparagraph 1.

(B) The information required under subparagraph (A) must be presented in a matrix, or other format, that provides the reviewer with an easily understood visual comparison of the chemicals and their adverse impacts.

(2) The Final AA Report must include all of the following information for the evaluation and comparison of the Priority Product and its alternatives conducted pursuant to sections 69505.3(b)(3) and 69505.4(b):

(A) A matrix, or other format, that provides the reviewer with an easily understood visual comparison that presents all of the following, as applicable, for the evaluations conducted pursuant to sections 69505.3(b)(3) and 69505.4(b):

1. The relevant exposure pathways and life cycle segments for each relevant comparison factor;

2. The information collected for each relevant factor, and associated exposure pathways and life cycle segments, for the Priority Product and each alternative considered; and

3. The comparative results of evaluating the information presented pursuant to subparagraph 2.

(B) A description, if applicable, of how safeguards provided by other federal and California State regulatory programs were considered in the AA, including identification of those programs and safeguards considered.

(l) Selected Alternative. The Final AA Report must identify and describe the alternative, if any, selected, and the rationale for the selection decision. The description of the selection decision must include an assessment that evaluates and compares the selected

alternative against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. The Final AA Report must also include all of the following:

(1) The information specified in section 69505.4(a)(2)(B) for the selected alternative. If no alternative is selected, this information must be provided for each alternative considered.

(2) If section 69505.3(b)(1)(C)2. applies, and the selected alternative retains the Chemical(s) of Concern, that is/are the basis for the product being listed as a Priority Product, or uses substitute chemical(s), the Final AA Report must explain the rationales for deciding to retain the Chemical(s) of Concern or to use substitute chemical(s), whichever applies.

(3) A demonstration that the manufacture, use, and disposal of the selected alternative, in conjunction with any regulatory response(s) proposed pursuant to subsection (n), will have no greater significant adverse public health or environmental impacts than the impacts associated with the Priority Product. For purposes of this paragraph only, "environment", as it pertains to California's environment, means "environment" as defined in section 21060.5 of the Public Resources Code.

(4) A list of all chemical ingredients known, based on available information, to be in the selected alternative that differ from the chemical ingredients in the Priority Product or that are present in the selected alternative at a higher concentration than in the Priority Product, and both of the following for those chemicals:

(A) All available and applicable chemical identification and description information; and

(B) Available hazard trait and environmental and toxicological endpoint information for any of those chemicals for which such information has not already been provided to the Department pursuant to this chapter.

(m) Implementation Plans.

(1) The Preliminary AA Report must include the work plan and proposed implementation schedule required to be prepared pursuant to section 69505.3(b)(4).

(2) The Final AA Report must include a detailed plan, including key milestones and dates, for implementing the selected alternative, if applicable. The implementation plan must include any steps necessary to ensure compliance with applicable federal, state or local laws.

(n) 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 Chemical of Concern that will be in the selected alternative or that is in the Priority Product if the decision resulting from the AA is to retain the Priority Product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

§ 69505.6. Department Review and Determinations for AA Reports.

(a)(1) Within sixty (60) days of receiving a Preliminary AA Report, the Department shall review the Preliminary AA Report for compliance with this article, and issue a notice of its findings with either a notice of compliance or a notice of deficiency.

(2)(A) The Department shall specify in a notice of deficiency the areas of deficiency and the due date for submitting the necessary information to complete the Preliminary AA Report. The due date for correcting the areas of deficiency may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised Preliminary AA Report within the time specified and address the areas of deficiency.

(B) Within thirty (30) days of receipt of the requested additional information, the Department shall issue either a notice of compliance or a notice disapproving the Preliminary AA Report. If the Preliminary AA Report is disapproved, the Department shall explain the basis for the disapproval in the notice. The Department shall also issue a notice of disapproval if a revised Preliminary AA Report is not submitted by the due date specified pursuant to subparagraph (A). A disapproved Preliminary AA Report is not in compliance with section 69505.1(a)(2).

(3) The Department shall specify in a notice of compliance the date for submitting the Final AA Report. The Department shall specify a due date that is twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify more time for submission of the Final AA Report if it determines based on information in the Preliminary AA Report that more time is needed. The Department may not establish a due date for the Final AA Report that is more than twenty-four (24) months from the date the Department issues the notice of compliance for the Preliminary AA Report, except as provided in section 69505.1(c).

(b)(1) Within sixty (60) days of receiving a Final AA Report, the Department shall review the AA Report for compliance with the requirements of this article, and shall issue a notice of its findings with either a notice of compliance or a notice of deficiency.

(2) The Department shall specify in a notice of deficiency the areas of deficiency and the due date, not to exceed sixty (60) days from the date the notice of deficiency is issued, for submitting the necessary information to complete the Final AA Report. The responsible entity shall submit a revised Final AA Report within the time specified and address all areas of deficiency. If requested, the Department may, at its discretion, approve a one-time extension, of not more than sixty (60) days, for submission of the revised Final AA Report to correct the deficiencies.

(3) Within sixty (60) days of receipt of the requested additional information, the Department shall issue either a notice of compliance or a second notice of deficiency.

(A) If the Department issues a second notice of deficiency, the notice must grant no more than thirty (30) days for resubmission of the requested information.

(B) Within sixty (60) days of receipt of the requested additional information, the Department shall issue either a notice of compliance or a notice of disapproval for the Final AA Report. If the Final AA Report is disapproved, the Department shall explain the basis for the disapproval in the notice. The Department shall also issue a notice of disapproval if a revised

Final AA Report is not submitted by the due date specified pursuant to paragraph (2) or subparagraph (A), whichever is applicable. A disapproved Final AA Report is not in compliance with section 69505.1(a)(2).

(c)(1) If the Final AA Report is determined to be in compliance with this article, the Department shall include in the notice of compliance, or in a separate notice sent to the manufacturer and all responsible entities known to the Department, a notice of the Department's proposed determination whether one or more of the regulatory responses specified in sections 69506.5 or 69506.6 is required.

(2) If the Department requires a regulatory response under section 69506.6, the Department shall specify the proposed due date for implementation of the regulatory response. In assigning a due date for completing a regulatory response required by the Department under section 69506.6, the Department shall consider the complexity of implementing the regulatory response.

(d) All notices issued by the Department pursuant to this section shall be issued to the person who submitted the AA Report, and a copy of the notice shall be sent by the Department to all persons identified in the AA Report pursuant to subsections (c)(2) and (c)(3) of section 69505.5.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

Article 6. Regulatory Responses

§ 69506. Applicability.

The requirements of this article apply to any alternative selected pursuant to section 69505.4(c) that is placed into the stream of commerce in California. These requirements also apply to the Maximum Concentration Value of a chemical of concern that is the basis for the Priority Product listing if an alternative is not selected, or if the Priority Product will remain in commerce pending development and distribution of the selected alternative.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

~~**§ 69506.1. AA Report Supplemental Information Requirements.**~~

~~The Department may at any time require the responsible entity to provide any information supplementary to the Final AA Report that the Department determines is necessary to determine and ensure implementation of one or more regulatory responses imposed pursuant to this article. The responsible entity shall provide this information within the time period specified by the Department.~~

~~The Department may at any time require the responsible entity to obtain or develop information to fill one or more of the information gaps identified in the Final AA Report, pursuant to section 69505.5(h)(2), if the Department determines this information is needed to re-evaluate, pursuant to section 69506.6(d), the initial regulatory response(s) imposed for the~~

~~selected alternative or for the Priority Product that remains in commerce. The responsible entity shall provide this information within the time period specified by the Department.~~

~~NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.~~

§ 69506.2. No Additional Regulatory Response Required.

No regulatory response under sections 69506.3 through 69506.6 is required for the selected alternative, if the Department determines, after review of the Final AA Report, that both of the following criteria are met:

(a) The selected alternative does not contain a Chemical of Concern in a concentration exceeding the ~~de minimis~~alternatives assessment ~~level~~threshold. If the selected alternative contains multiple Chemicals of Concern, the total concentration of all Chemicals of Concern exhibiting the same hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed the ~~de minimis~~alternatives assessment ~~level~~threshold.

(b) The selected alternative does not pose significant potential adverse public health or environmental impacts.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69506.3. Product Information for Consumers.

(a)(1) Except as provided in paragraph (2), during the time that a selected alternative product, or a Priority Product for which an alternative is not selected, is offered for sale in California, the responsible entity shall ensure that all of the following information is made available to the consumer prior to any exposure to the Chemical(s) of Concern:

(A) Manufacturer's name and importer's name, if applicable;

(B) Brand name(s) and product name(s) and description of the product;

(C) A list of, and common names for, all Chemicals of Concern known, based on available information, to be in the product;

(D) Identification of any end-of-life management program for this product, and any end-of-life management requirements specified by law;

(E) Any safe handling procedures needed to protect public health or the environment during the useful life of the product and instructions for the proper end-of-life disposal or management; and

(F) The manufacturer's and, if applicable, importer's website address where the consumer can obtain additional information about the product, the potential adverse public health and/or environmental impacts posed by the product, and proper end-of-life disposal or management of the product.

(2) Paragraph (1) does not apply to a selected alternative product that does not contain a Chemical of Concern in a concentration exceeding the level specified in section 69506.2(a).

(b) The requirements of subsection (a) shall be met by making the required information available to consumers, in easily seen, legible, and understandable formats, by both:

(1) Posting the information in a prominent place on the manufacturer's website and the importer's website, if applicable; and

(2) Using one or more of the following means of informing consumers of this information at the point of sale:

(A) Providing the required information on the product packaging or in a manual that is accessible without breaking the product seal; or

(B) Posting the information in a prominent place at the point of retail display.

(c) A responsible entity that has a product subject to the requirements of subsections (a) and (b), shall ensure that these requirements are fully implemented for that product no later than twelve (12) months after the Department issues a notice of compliance for the Final AA Report for the product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69506.4. End-of-Life Management Requirements.

(a) Except as provided in section 69506.2, a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product ~~and~~ unless it is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that both of the following requirements are met:

(1) The information required by section 69506.3 shall be provided for the product. Additionally, the product information must state that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.

(2) Unless the responsible entity is exempt from the requirements of this section, n~~N~~o later than two (2) years after the Department issues a notice of compliance for the Final AA Report for the product, the responsible entity shall fund, establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:

(A) A comprehensive product stewardship plan must be developed and maintained, and shall include all of the following:

1. A list of, and contact information for, participating manufacturers and importers and, if applicable, other participating persons.

2. The scope of products to be covered by the plan.

3. The roles and responsibilities for manufacturers, importers, retailers, consumers and government throughout the life cycle of the product.

4. Identification and description of collection systems that will be used.

5. End-of-life management information, including what steps will be taken to ensure management that complies with all applicable federal and California State and local laws, and addresses any adverse multimedia impacts.

6. Anticipated resource needs and a description of the financing mechanism to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program. The responsible entity for the product shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product. Multiple responsible entities may form a third-party product stewardship organization, funded by participating manufacturers and responsible entities, to provide local services to collect, recycle, or otherwise appropriately manage the designated products.

7. Program performance measures for:

a. Increasing the capture rate of the products covered at the end-of-life; and

b. Increasing recyclability.

8. Public education, outreach, and communications plans.

9. Public and stakeholder consultation activities during preparation, and periodic review and updating, of the plan.

10. Reporting and evaluation procedures.

(B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and potential collection sites. The collection program must include one or both of the following:

1. Collection mechanisms; and

2. Compensation to retailers and other persons who agree to administer or participate in the collection program.

(C) The responsible entity shall post a copy of the product stewardship plan on is website, and provide a link to the posting to the Department for posting on its website.

(D) The responsible entity for a product subject to the requirements of this section shall, every two (2) years from the date the end-of-life management program is required to be implemented, ensure that a report is provided to the Department. The report must include both of the following:

1. The amount of products placed into the stream of commerce in California over the previous two-year period, by total tonnage; and

2. The number of products recovered over the same two-year period, by total tonnage.

(b) Upon request, the responsible entity shall provide to the Department a copy of the product stewardship plan required under this section.

(c) A responsible entity subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A responsible entity may not substitute an alternative end-of-life management plan for the plan specified in this section unless it receives written approval from the Department.

(d) A responsible entity shall be exempt from the requirements to provide a financial guarantee to the extent that there is an established market-based end-of-life management program that recycles the Priority Product that will continue regardless of the potential bankruptcy of a responsible entity.

~~(c)~~(e) A responsible entity subject to the requirements of this section may request an exemption from the requirement to provide an end-of-life management program by demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69506.5. Product Sales Prohibition.

(a) Except as provided in section 69506.2 and subsection (c), the requirements of subsection (b) apply to a selected alternative that contains one or more Chemical(s) of Concern, or a Priority Product for which an alternative is not selected, if the Department notifies the responsible entity and provides all identifying and substantiating information, pursuant to section 69506.8, that the Department has determined that a safer alternative exists that does not contain a Chemical of Concern and that is both functionally acceptable and technologically and economically feasible.

(b) Effective no sooner than one (1) year after the Department issues a notification pursuant to subsection (a), ~~unless the Department specifies a shorter period of time in the notification~~, any responsible entity for the product that is the subject of the notification shall cease to place the product into the stream of commerce in California. The Department shall establish product-specific timeframes based on the complexity of the redesign and reformulation of the product. Longer timeframes of at least three to five years, will be established for products requiring extensive performance and safety testing.~~The responsible entity shall also ensure that an inventory recall program for the product is implemented and completed within three (3) years after the notification is issued by the Department, unless the Department specifies a shorter period of time in the notification.~~

(c) A product that is the subject of a notification issued by the Department pursuant to subsection (a) is not subject to the requirements of subsection (b) if all of the following requirements are met:

(1) Within sixty (60) days after the notification is issued by the Department, the responsible entity notifies the Department of its intent to submit a revised Final AA Report that selects an alternative that does not contain a Chemical of Concern;

(2) Within one (1) year after the notification is issued by the Department, ~~unless the Department specifies a shorter period of time in the notification~~, the Department receives a Final AA Report that selects an alternative that does not contain a Chemical of Concern and that fully meets the requirements of section 69505.5; and

(3) The product containing one or more Chemical(s) of Concern is completely removed from commerce in California, ~~and an inventory recall in California is completed~~, by the date specified by the Department in the notice of compliance or notice of disapproval for the Final AA Report submitted under paragraph (2), or in a separate notice issued by the Department under section 69505.6(c)(1). The due date shall be no longer than three (3) years after the Department issues the notice.

(d)(1) The responsible entity may request a one-time extension to the due date for the Final AA Report to be submitted under subsection (c)(2), pursuant to the procedures specified in section 69505.1(c).

(2) If an extension is granted by the Department, one of the following requirements must be met by the due date specified in the extension approval:

(A) A revised Final AA Report meeting the requirements of subsection (c)(2) shall be submitted to the Department; or

(B) The requirements of subsection (b) shall be implemented.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69506.6. Other Regulatory Responses.

(a) Except as provided in section 69506.2, the Department may impose one or more of the following regulatory responses that it determines are necessary to limit ~~potential~~ direct and significant exposures to, and reduce ~~the level of~~significant ~~potential~~ adverse public health or environmental impacts posed by, a selected alternative, or by a Priority Product for which an alternative is not selected or which will remain in commerce in California pending development and distribution of the selected alternative:

~~(1) The Department may impose one or more of the regulatory responses specified in sections 69506.1 and 69506.3 through 69506.5 to situations other than those situations specified in sections 69506.1 and 69506.3 through 69506.5.~~

~~(2)~~(1) The Department may impose one or more of the following regulatory responses ~~to any situation~~, including those situations specified in sections 69506.1 and 69506.3 through 69506.5:

(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

~~Requiring a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department in a specified time period.~~

(b) In accordance with the process specified in section 69506.8, the Department shall notify known affected responsible entities of regulatory response determinations made pursuant to this section, along with the implementation due date for the regulatory response and the rationales for the regulatory response determination.

(c) In assigning a due date for completing a regulatory response required under this section, the Department shall consider the complexity of implementing the regulatory response.

(d) The Department may periodically re-evaluate each regulatory response imposed under this section to determine if changes are needed based on changes in science or technology, ~~or other relevant information or facts~~ that have accrued since the regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report pursuant to section 69505.5(h)(2).

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69506.7. Exemption from Regulatory Response Requirements.

(a) A selected alternative, or a Priority Product for which an alternative is not selected, is exempt from the requirements of this article, if the responsible entity requests, and the Department grants, an exemption. The responsible entity shall submit exemption request to the Department no later than whichever of the following dates is applicable:

(1) Sixty (60) days after the Department issues a notice to the responsible entity, pursuant to section 69505.6(c); or

(2) Sixty (60) days after the Department issues a notice of compliance for a Final AA Report for a product subject to sections 69506.3 and/or 69506.4.

(b) An exemption request submitted pursuant to subsection (a) must include all of the following:

(1) The name of, and contact information for, the person filing the exemption request;

(2) The name of, and contact information for, the responsible entity(ies) on whose behalf the exemption request is being submitted;

(3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer and, if applicable, importer of the product;

(4) The name of, and contact information for, other responsible entities for the product, to the extent known to the person submitting the exemption request;

(5) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and information specifically identifying the assembled product it is contained in ~~component~~, if applicable; and

(6) Information that demonstrates ~~to the Department's satisfaction~~ that either ~~or both~~ of the following apply:

(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.

(c) Within sixty (60) days of receiving an exemption request, the Department shall issue a notice to the person who submitted the request granting or denying the exemption request. The Department shall send a copy of the notice to known responsible entities for the product.

(d) If the exemption request or the Department's granting of the exemption is based solely on the criteria specified in subsection (b)(6)(A), the Department may require or propose implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.

(e) The Department shall rescind an exemption granted pursuant to this section if the Department determines that the facts and/or assumptions that the Department relied upon in granting the exemption were not, or are no longer, valid. If the Department rescinds an

exemption, the Department shall notify the person who submitted the exemption request and known responsible entities for the product.

(f) The Department shall include in all notices granting, denying, or rescinding an exemption pursuant to this section a statement of basis for its decision.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257.1, Health and Safety Code.

§ 69506.8. Regulatory Response Determination Process.

(a) Prior to issuing a final regulatory response determination notice pursuant to sections 69506.5(a) or 69506.6(b), the Department shall notify all known responsible entities for the product of the proposed regulatory response(s) pursuant to paragraphs (1) through (3) of section 69505.5(c), and make the proposed regulatory response determination notice available on its website, for public review and comment. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed regulatory response determination. The Department shall publish in the CRNR, send to persons on the listserv(s) that the Department establishes related to this chapter, and post on its website a notice regarding the availability of the proposed regulatory response determination. This notice must include:

(1) The last day for the public to submit written comments on the proposed regulatory response determination. The last day for submission of public comments shall be forty-five (45) days from the date the availability of the proposed regulatory response determination notice is published in the CRNR;

(2) The method(s) for submitting comments to the Department; and

(3) The date, time and location of the public workshop(s).

(b) After review and consideration of public comments on the proposed regulatory response determination, the Department shall finalize and send to known responsible entities the final regulatory response determination notice. The Department ~~may~~ shall respond to ~~some or~~ all public comments received.

(c) All proposed and final regulatory response determination notices shall include all of the following:

(1) A description of the required regulatory response;

(2) The Department's determination(s) that is the basis for the required regulatory response;

(3) The rationales, information, and information sources, supporting the Department's determination(s); and

(4) The implementation due date for any regulatory response imposed pursuant to sections 69506.5 and 69506.6.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257, Health and Safety Code.

§ 69506.9. Regulatory Response Report and Notifications.

(a) A responsible entity subject to a regulatory response pursuant to this article, except for the regulatory responses specified in subparagraphs (C) and (D) of section 69506.6(a)(2), shall ensure that a notice is sent to the initial point(s) of sale in ~~retailers who sell the product in California~~, informing ~~the retailers of~~them of the applicability of the regulatory response to the product. ~~The notice shall be sent to the retailers, and A~~a copy should be sent to the Department, no later than whichever of the following dates is applicable:

(1) ~~Thirty~~ Ninety (9~~3~~0) days after receiving a final regulatory response determination notice, pursuant to section 69506.8(b), for a product subject to sections 69506.5(a) and/or 69506.6(b); or

(2) ~~Thirty~~ Ninety (9~~3~~0) days after the Department issues a notice of compliance for a Final AA Report for a product subject to sections 69506.3 and/or 69506.4.

(b) The notice required pursuant to subdivision (a) shall include all of the following:

(1) The name and contact information for the manufacturer and the importer, if applicable;

(2) The responsible entity's name and contact information, if different from the manufacturer or importer;

(3) Information identifying and describing the original Priority Product, and the selected alternative, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and the name(s) of any persons identified as the manufacturer and/or distributor on the product label; and

(4) A description of the required regulatory response(s) and the due date for implementing the regulatory response(s).

(c) The responsible entity shall notify the Department upon completing implementation of the required regulatory response(s) and, if applicable, upon completing development and introduction into the California marketplace of the selected alternative. The notification must include information describing how the regulatory response(s) was/were implemented. If requested by the Department, the responsible entity shall provide periodic implementation status reports regarding the selected regulatory response(s). The information provided to the Department pursuant to this subsection shall also be posted on the website of the responsible entity.

(d)(1) The Department shall prepare and post on its website, and update at least semi-annually, a Regulatory Response Report that identifies the regulatory response(s) for each selected alternative for a Priority Product, or for the Priority Product, whichever is applicable. The Regulatory Response Report must contain all of the following information:

(A) The name and contact information for the manufacturer and the importer, if applicable;

(B) The names of, and contact information for, other known responsible entities;

(C) Information identifying and describing the original Priority Product, and the selected alternative, if any, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;

(D) The due date and actual date for completing development and introduction into the California marketplace of the selected alternative, if any;

(E) The regulatory response(s), if any;

(F) The applicable section in this article specifying the regulatory responses;

(G) The implementation due date, and the actual implementation date, for the regulatory response; and

(H) Other information provided to the Department pursuant to subsections (a) through (b).

(2) The Department shall also include in the Regulatory Response Report the information specified in paragraphs (1)(A) through (1)(D) for each exemption granted by the Department pursuant to section 69506.7.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257, Health and Safety Code.

Article 7. Dispute Resolution Processes

§ 69507. Dispute Resolution.

(a) This article applies to any responsible entity that wishes to dispute a decision made by the Department pursuant to this chapter that applies to the responsible entity.

(b) The procedures set out in this article are required for resolving disputes arising under this chapter. If the responsible entity fails to follow the procedures specified in this article for disputes subject to this article, it shall have waived its right to further contest the disputed issue administratively.

(c) A requirement imposed by the Department pursuant to this chapter on a responsible entity, and any posting on the Failure to Comply list pursuant to section 69501.3(d) concerning the requirement, shall be stayed during the pendency of a dispute concerning the requirement.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

§ 69507.1. Informal Dispute Resolution Procedures.

(a) For a dispute regarding a decision made by the Department pursuant to the provisions of this chapter, other than sections 69506.5, 69506.6, and 69506.7, a responsible entity may, within ~~fifteen~~ ninety (90~~15~~) days following the notice or website posting of the Department's decision that is the basis of the dispute, request that the Department informally resolve the dispute. The Department shall provide the responsible entity with an opportunity to resolve the dispute informally within ~~thirty~~ 180~~(30)~~ days of receiving the request for dispute resolution. If a request for informal dispute resolution is not received within ~~fifteen~~ ninety (~~1~~90~~5~~) days of the notice or website posting of the Department's decision, the Department's decision is final and is not eligible for any dispute resolution procedures under this article.

(b) If the responsible entity disagrees with the Department's decision following completion of the informal dispute resolution process, the responsible entity may appeal to the Director of the Department under section 69507.2.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

§ 69507.2. Appeal to the Director.

(a) A responsible entity appealing the Department's decision following completion of the informal dispute resolution process shall submit information stating the basis for seeking further review, and the reasons why the decision does not comport with the requirements of this chapter or is otherwise unreasonable. The responsible entity shall also provide:

(1) The original statement of dispute;

(2) Supporting documents; and

(3) Copies of responses prepared by Department employees.

(b) The appeal shall be made to the Department's Director within ninety~~thirty~~ (90~~30~~) days after completion of the informal dispute resolution process under section 69507.1.

(c) The Director or designee shall issue a decision granting or denying the relief sought in whole or in part within ~~sixty~~ ninety (90~~60~~) days after receipt of the request under this section. If the relief sought is denied, the decision shall specify the date by which the responsible entity shall comply with the requirements of this chapter that were in dispute. A decision issued pursuant to this subsection is the Department's final decision and is not subject to additional administrative dispute resolution.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257.1, Health and Safety Code.

§ 69507.3. Formal Dispute Resolution.

For all disputes arising under sections 69506.5, 69506.6, or 69506.7, the procedures specified in sections 69507.4 through 69507.7 shall apply in lieu of the procedures set forth in sections 69507.1 and 60507.2.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257.1, Health and Safety Code.

§ 69507.4. Time Lines for Requests for Review.

Within ninety~~thirty~~ (90~~30~~) days of a responsible entity receiving a determination from the Department that section 69506.5, 69506.6, or 69506.7 applies to one or more of its products or selected alternative, the responsible entity may submit a Request for Review to the Department to review such determination. If a Request for Review is not filed within this time period, the Department's determination is final and is not eligible for any dispute resolution procedures under this article.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257.1, Health and Safety Code.

§ 69507.5. Contents of Request for Review.

A Request for Review filed pursuant to section 69507.4 must include a statement of the reasons supporting the Request for Review, and as applicable, a showing that the determination is based on:

(a) Erroneous facts, assumptions, approaches, or conclusions of law; and/or
(b) A policy judgment that the Department should, in its discretion, consider.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257.1, Health and Safety Code.

§ 69507.6. Department Procedures for Requests for Review.

(a) Within sixty (60) days following the filing of a Request for Review under section 69507.4, the Department shall issue an order either granting or denying the Request for Review.

(b) An order denying review shall constitute the Department's final decision and shall not be subject to additional administrative dispute resolution. The decision shall be effective on the date of the order. The order denying review shall specify the date by which the responsible entity shall comply with the requirements of this chapter that were the subject of the Request for Review.

(c) An order granting review shall specify a schedule for briefing of the issues by the responsible entity and the Department.

(d) The Department shall issue an order specifying its decision on the merits of the Request for Review within one hundred and eighty (180) days from the date it grants the Request for Review.

(1) If the final order upholds the Department's decision under this chapter, the order is the Department's final decision and is not eligible for additional administrative dispute resolution. An order upholding the Department's original decision shall specify the date by which the responsible entity shall comply with the applicable requirements of this chapter.

(2) If the final order grants the relief sought by the responsible entity, in whole or in part, the order must remand the decision that is the subject of the Request for Review to the responsible program within the Department for re-evaluation by a specified date. The date for completion of the re-evaluation must be no more than ninety (90) days from the date of the order. The order may also provide guidance or criteria for the re-evaluation.

(e) No Department staff that participated in the decision that is the subject of the Request for Review filed under section 69507.4 may participate in decision-making or review of decisions made under this section.

(f) No Department staff participating in decision-making or review of decisions made under this section may have communications about the Request for Review with the

Department staff that participated in the decision that is the subject of the Request for Review filed under section 69507.4, unless the Department simultaneously communicates with the responsible entity or its representative regarding the issues under discussion with Department staff.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257.1, Health and Safety Code.

Article 8. Accreditation Bodies and Certified Assessors.

§ 69508. Qualification and Certification of Assessors.

(a) ~~On and after January 1, 2015~~Until such time as institutions are accredited by the Department and the sufficient numbers of assessors have been certified, an individual in lead charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, must be certified by an accreditation body, and must meet three ~~all~~ of the following requirements:

(1)Possess a Bachelor's or post-graduate degree ~~with a major~~ in a scientific or engineering field from an accredited college or university.

(2)(A) Have the equivalent of four (4) years of professional experience performing AAs or working in a scientific or engineering field, or both.

(B) Post-graduate work in the performance of AAs or in a scientific or engineering field, or both, may be substituted on a year-for-year basis for the experience required pursuant to subparagraph (A).

(3)(A) Successful completion of an assessor training program that is developed and delivered by an accreditation body, and successful completion of an exit exam that meets the requirements of section 69308.2(c)(5).

(B) Successful completion of an approved challenge test developed by the accreditation body may be used in lieu of the classroom training requirements and written and practical tests for applicants who meet the competency requirements and/or possess on-the-job training equivalent to that specified in section 60508.2(c)(4)(A) through (E).

(4) Receive a "Certified Assessor" certificate, meeting the requirements of section 69308.2(c)(6), and issued by the accreditation body whose training program the assessor successfully completed pursuant to paragraph (3).

(5) Maintain certification by doing all of the following:

(A) Complete at least 20 hours of continuing education during each two-year accreditation period, as required and provided by, or verified by, the accreditation body from which the assessor will seek re-certification upon expiration of their current certification. Continuing education may be education and/or training focused on one or more aspects of performing, conducting and verifying AAs or closely related topics. At least two (2) hours of continuing education must be in professional ethics.

(B) Submit a certificate renewal application to an accreditation body at least thirty (30) days prior to the expiration of the assessor's certification. If the assessor complies with the requirements of this subparagraph and subparagraph (A), the license will remain in effect unless the accreditation body denies the application for renewal.

(C) Receive a renewed "Certified Assessor" certificate that satisfies the requirements of section 69508.2(c)(6) and is issued by the accreditation body who provided or verified the assessor's continuing education pursuant to subparagraph (A).

(6) Possess, and produce when requested, a current "Certified Assessor" certificate meeting the requirements of section 69508.2(c)(6).

(b) If the Department rescinds, pursuant to subsection (g)(2), (g)(3) or (g)(4) of section 69508.3, the designation of the accreditation body from which the assessor obtained accreditation, the assessor shall apply for re-certification from another accreditation body no later than sixty (60) days after information concerning the rescission is posted on the Department's website.

(c) An assessor's certificate shall be subject to rescission by the accreditation body or the Department, or both, for failure to comply with the requirements of this chapter, or if the Department or the accreditation body finds the assessor has engaged in activities governed by this chapter in a manner that is negligent, fraudulent, or otherwise unethical. The accreditation body shall provide to the Department the name and contact information for any assessor whose certification is rescinded by the accreditation body, and an explanation of the reasons for the rescission.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69508.1. Qualifications for Accreditation Bodies

(a) An entity wishing to be designated, or to renew designation, by the Department as an accreditation body to certify assessors, shall have on staff one or more individuals that, in combination, possess all of the following:

(1) A post graduate degree with a major in a scientific or engineering field from an accredited college or university.

(2) The equivalent of four (4) years of professional experience performing AAs and/or working in a scientific or engineering field. Post-graduate work in the performance of AAs and/or in a scientific or engineering field, while attending an accredited college or university, may be substituted on a year-for-year basis for the required experience.

(3) The ability to teach, and experience teaching, the principles and practices of performing AAs as specified in article 5.

(4) The ability to teach, and experience teaching, the application of life cycle assessment tools and methodologies relevant to products.

(5) The ability to teach and experience teaching, or have access to subject matter experts with the ability to teach and experience teaching, in one or more of the following:

(A) Chemistry;
(B) Chemical engineering;
(C) Environmental law;
(D) Toxicology;
(E) Public policy;
(F) Pollution prevention;
(G) Cleaner production methods;

(H) Environmental health;
(I) Public health;
(J) Risk analysis;
(K) Materials science;
(L) Nanotechnology;
(M) Chemical synthesis; and
(N) Maternal and child health.

~~(6) An entity seeking accreditation may not have any economic interest in any~~

~~responsible entity, manufacturer, consortium of manufacturers, or trade association, or any economic interest in any person that manufactures, sells, or distributes any Chemical of Concern or product containing a Chemical of Concern.~~

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Sections 25253 and 25257, Health and Safety Code.

§ 69508.2. Accreditation Body Designation Requirements.

(a) An entity meeting the qualification requirements specified in section 69508.1 may apply to be designated by the Department as an accreditation body to certify assessors.

(b) The application to be a designated as an accreditation body or renew designation as an accreditation body must include all of the following:

(1) The name of, and contact information for, the person(s) submitting the application.

(2) A summary of the qualifications of the individuals, meeting the requirements specified in section 69508.1, including education, experience, and areas of subject matter competency, that are available within, or to, the entity for training and certifying individuals to perform AAs.

(3) Documentation that the entity meets all of the qualification requirements specified in section 69508.1.

(4)(A) A detailed description of the accreditation program demonstrating that the program meets the requirements specified in subsection (c).

(B) The entity's training program for certification of applicants, including for each course the title, content description, hours, and exam plan.

(C) Demonstrated qualifications and areas of expertise of the individuals responsible for developing the entity's training curriculum, as evidenced by education and experience, professional licenses, registrations, or other relevant credentials.

(D) The entity's continuing education curriculum for re-accreditation applicants, including for each course the title, content description, hours, and exam plan.

(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 renewals must be included. Required information includes all of the following:

(A) The applicant's name and contact information;

(B) The applicant's educational experience, which must meet the requirements of section 69508(a)(1) and must be substantiated by submittal of transcripts or other equivalent records;

(C) The applicant's employment and other experience history, which must meet the requirements of section 69508(a)(2) and for which references must be provided;

(D) The professional licenses, registrations, or other relevant credentials that the applicant possesses;

(E) Documentation of completion of continuing education required pursuant to section 69508(a)(5), if the application is for certificate renewal; and

(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 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."

(2) Verification Procedures. Written procedures must be included for verifying an applicant's qualifying education and experience, including verification of fulfillment of continuing education requirements.

(3) Denial Criteria. A summary of the criteria and procedures for denying an applicant for certification or certification renewal must be included. Denial decisions must be provided to the applicant in writing and must state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be certified or re-certified as an assessor.

(4) Training of Assessors. The training program must include classroom and on-the-job assistance and/or training of applicants. The training must incorporate classroom and/or on-the-job training in analysis of information and practical application of principles, at a minimum, in all of the following:

(A) The requirements of this chapter, with an emphasis on the requirements of articles 5, 6, and 10;

(B) Training and case studies on principles and practices of performing AAs as specified in article 5, using life cycle thinking and life cycle assessment tools and methodologies;

(C) Training and case studies on identification of alternatives for consideration in AAs;

(D) Training and case studies on identification of the life cycle segments and exposure pathways for chemicals and products; and

(E) Training needed for the attainment of expertise in specific fields necessary to the performance of AAs.

(5) Evaluation and Examination of Assessors. The program must include:

(A) A Department-approved written and practical test or evaluation that demonstrates the applicant's competence in the training requirements specified in paragraphs (4)(A) through (4)(E); and

(B) A Department-approved challenge test developed by the accreditation body that may be used in lieu of the classroom training requirements and written and practical tests for

applicants that meet the competency requirements and/or possess on-the-job experience that is equivalent to the requirements specified in paragraphs (4)(A) through (4)(E).

(6)(A) Certificate Issuance. A certificate for initial certification and certification renewal that is entitled "Certified Assessor" and includes, at a minimum, all of the following:

1. Assessor's name;
2. Certificate number;
3. Certification issuance date and expiration date;
4. Name and contact information of the accreditation body issuing the certificate;
5. An indication as to whether the certificate is for initial certification or a renewal;
6. The product type(s) and/or industry sector(s) for which the assessor is certified;
7. A statement that the assessor meets the requirements of section 69508(a); and
8. The signature of the owner or an officer of the accreditation body issuing the certification.

(B) The accreditation body's program must include requirements and a process for certification renewal every two (2) years.

(7) Assessor Agreement and Audit Program. The program must require that certified assessors enter into an agreement with the accreditation body under which the assessors agree to:

(A) Provide alternative assessment services only in the areas of expertise in which the individual has demonstrated competence;

(B) Provide true and accurate analysis and verifications where appropriate; and

(C) Random auditing by the accreditation body or its consultants of work completed to ensure the quality of work and proper application of tools by the assessor.

(8) Record Maintenance Program. The accreditation body shall maintain a database of the names of individuals whose applications were accepted or denied, names of individuals certified, their certificate numbers, and their certificate issuance and expiration dates. The database must also include copies of applications, verification information, audit records, and violations, if any. All records shall be maintained for a minimum of five (5) years.

(A) The accreditation body shall submit electronically to the Department the name and contact information for each assessor certified by the accreditation body, their certificate number, their certificate issuance and expiration dates, and the areas of expertise in which the assessor is certified. The accreditation body shall provide an electronic update of this information to the Department at least once a year.

(B) Upon the request of the Department, but not more frequently than annually, an accreditation body shall submit to the Department sufficient information to facilitate audits by the Department pursuant to article 9.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69508.3. Accreditation Bodies Designation Process.

(a) The Department shall review the application submitted pursuant to section 69508.2 and approve or deny the request for designation as an accreditation body, within sixty (60) days of receiving the application. The Department shall notify the person submitting the application of its determination. A notice of denial shall state the grounds for denial and, if applicable, specify the conditions the applicant must fulfill in to order to be designated, or re-designated, as an accreditation body.

(b) If the information submitted pursuant to section 69508.2 changes, the person that submitted the application shall provide updated written information to the Department within thirty (30) days of the change.

(c) A designation as an accreditation body expires after a period of five (5) years, except that it may be renewed upon application by the accreditation body, pursuant to section 69508.2, not later than ninety (90) days before expiration of the existing designation. Applications for renewal of designation meeting the requirements of section 69508.2 shall extend the expiring designation until the Department makes a determination on the renewal application.

(d) If an entity is found to be negligently or willfully in violation of this chapter, the entity shall lose its designation as an accreditation body for a period of at least ten (10) years. After this period, the entity may reapply to be designated as an accreditation body.

(e) An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach.

(f) The Department may annually review the performance of accreditation bodies to determine whether the accreditation bodies comply with the requirements of this chapter. This review may include records review and/or interviews of assessors participating in the training and certification program.

(g) The Department shall rescind its designation of an accreditation body if one or more of the following occurs:

(1) The designation period has lapsed, and the accreditation body has not submitted a renewal application that meets the requirements of section 69508.2;

(2) A substantial number of individuals certified by the accreditation body as assessors are found to be in violation of this chapter;

(3) The Department finds that the accreditation body has significantly deviated from the documentation submitted to the Department pursuant to section 69508.2, or is out of compliance with the applicable requirements of this article; or

(4) The Department finds the accreditation body to have carried out its activities governed by this chapter in a manner that is negligent, fraudulent, or is otherwise unethical.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

§ 69508.4. Filing a Complaint.

(a) A person may file a complaint alleging a violation of this chapter by an accreditation body and/or certified assessor. The complaint must be submitted to the Department in accordance with section 69501.4, and must include all of the following:

(1) Name of, and contact information for, both of the following:

(A) The accreditation body or certified assessor that is the subject of the complaint, hereinafter referred to as the subject; and

(B) The complainant.

(2) Description of the complaint, including the particular requirements that are alleged to have been violated and the facts which the complainant relies upon to support the alleged violation.

(b) Within thirty (30) days of receiving a complaint, the Department shall review the complaint and determine if the complaint contains the items specified in subsection (a). If the Department determines that a complaint is complete, the Department shall notify the complainant that the Department will conduct further review to determine whether a violation has occurred. If the Department determines that the complaint is incomplete, it shall notify the complainant and specify the basis for the determination.

(c) If the complaint substantially complies with the requirements of this section, the Department shall serve a copy to each subject, together with an order requiring that the complaint be answered by the subject within thirty days (30) after the date of service.

(d) The Department shall review the information and documentation in the response from the subject and may refer items to external subject matter experts for review and recommendations.

(e) If the Department determines there is insufficient evidence to determine whether or not a violation has occurred, the Department shall close the complaint.

(f) If the Department determines that a violation has occurred, the department shall:

(1) Warn the subject by issuing a citation, and obtain compliance;

(2) Pursue the violations under the Administrative Procedures Act; or

(3) Refer the matter to the Attorney General or appropriate district attorney.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.

Article 9. Audits

§ 69509. Audit of Alternatives Assessments and Regulatory Responses.

(a) The Department may audit AAs, AA Reports, and regulatory responses. Only Department staff who ~~that~~ have received certification as ~~a~~ certified assessors may be auditors.

(b) The scope of any audit may include an examination of one or more of the following:

(1) Compliance with article 5 requirements;

(2) Information quality and adequacy of analysis;

(3) Implementation of the selected alternative, if applicable; and

(4) Compliance with the regulatory response(s) imposed pursuant to article 6, if any.

(c) Upon completion of an audit, the Department shall:
(1) Notify the responsible entity(ies) of the audit findings; and
(2) Inform the responsible entity(ies) of the process to dispute audit findings.

NOTE: Authority cited: Sections 25253, and 58012, Health and Safety Code. Reference: Article 8 of Division 4.5 of Chapter 20 and Section 25253, Health and Safety Code.

Article 10. Trade Secret Protection

§ 69510. Assertion of a Claim of Trade Secret Protection.

(a) A person who asserts a claim of trade secret protection with respect to documents or information submitted to the Department will receive a written request from the Department to furnish the Department with all of the following supporting information:

(1) The identity of the person asserting the claim;

(2) A brief description of the nature of the information for which trade secret protection is being claimed;

(3) The period of time for which trade secret protection is claimed, and the justification for the period of time specified;

~~(4) The extent to which the information is known by employees or others involved with the facility or business of the person, and whether or not those individuals are bound by nondisclosure agreements;~~

~~(5) The extent to which the information is known outside of the facility or business of the person, and whether or not individuals with such knowledge are bound by non-disclosure agreements;~~

~~(6) The measures taken to restrict access to and safeguard the information, and whether or not the person plans to continue utilizing such measures;~~

~~(7) The estimated value of the information to the person or the person's competitors;~~

~~(8) The estimated amount of effort or money expended by the person in developing the information;~~

~~(9) The estimated ease or difficulty with which the information could be properly acquired or duplicated by others;~~

~~(10)~~(4) Copies of, or references to, any pertinent trade secret or other confidentiality determinations previously made by the Department or other public agencies;

~~(11)~~(5) A description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed;

~~(12)~~(6) The signature of the person's general counsel or other executive with knowledge of the preparation of the substantiating information, certifying under penalty of perjury and subject to the provisions of section 69501.4(b), and also based up on the knowledge and belief of the signatory, that:

(A) The substantiating information is true, accurate, and complete;

(B) The information for which trade secret protection is claimed is not otherwise publicly available; and

(C) There is a reasonable basis to assert trade secret protection for the information so claimed; and

(13) Contact information for the individual to be contacted if part of the claimed information is requested to be disclosed under the California Public Records Act.

(b) The substantiating information required in subsections (a)(1) through (a)(11) shall be provided for each individual trade secret claim, although such information may be incorporated by reference to apply to multiple claims, as appropriate. The requirements of subsections (a)(12) and (a)(13) may be met once for all claims submitted at one time.

(c) A person who asserts a claim of trade secret protection shall also, at the time of submission, provide the Department with both of the following:

(1) A complete copy of the documentation being submitted, which shall include the information for which trade secret protection is claimed; and

(2) A redacted copy of the documentation being submitted, which shall exclude the information for which trade secret protection is claimed, and which the Department may make available to the public at its discretion.

(d) A person who asserts a claim of trade secret protection shall make such assertion at the time of submission by marking the words "Trade Secret", conspicuously on each page containing the information for which trade secret protection is claimed. If no claim of trade secret protection is made at the time of submission, the Department may make the submitted information available in full to the public without further notice.

(e) If the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation shall be separately supplied in both complete and redacted form as required by subsection (c), and marked as required by subsection (d), but shall not itself require further supporting documentation. Such documentation shall be separate from documentation used to comply with other provisions of this chapter.

(f) Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

§ 69510.1. Department Review of Trade Secrecy Claims.

(a) Upon receipt of information submitted pursuant to this chapter that contains information identified as being subject to trade secret protection, or at any time thereafter, the Department may review the trade secret claim and supporting information for compliance with the requirements of this article.

(b) If the Department determines that information provided in support of a request for trade secret protection is incomplete or insufficiently responsive, the Department shall notify the submitter of the Department's finding of deficiency, the specific area(s) of deficiency, an

explanation as to why the Department has determined the information to be deficient, and the date by which the submitter must cure the deficiency. If the submitter fails to cure the deficiency within the timeframe specified, the Department shall notify the submitter by certified mail that the claimant is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief. During this 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.

(c) If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a writ of mandate, injunction, protective order, or other appropriate relief. During this 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.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252, 25253, and 25257, Health and Safety Code.

Article 11. Severability

§ 69511. Severability.

If any provision(s) of this chapter, or the application thereof to any person or circumstances, is held invalid, such invalidity shall not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application, and to that end the provisions of this chapter are severable.

NOTE: Authority cited: Sections 25252, 25253, and 58012, Health and Safety Code. Reference: Sections 25252 and 25253, Health and Safety Code.

Article 12. [Reserved]

§§ 69512 -- 69599. [Reserved]

CNCDA
California New Car Dealers Association

January 13, 2012

Ms. Deborah Raphael
Director
Department of Toxic Substances Control (DTSC)
P.O. Box 806
Sacramento, CA 95812-0806

RE: Informal Draft of Safer Consumer Product Regulation

Dear Director Raphael:

The California New Car Dealers Association (CNCDA) is a statewide trade association which represents the interests of over 1,200 franchised new car and truck dealer members. CNCDA members are primarily engaged in the retail sale of new and used motor vehicles, but also engage in automotive service, repair, and parts sales. We are writing to provide comments and suggested solutions to issues raised by the draft "Safer Consumer Product Alternatives" (Green Chemistry) Regulations.

CNCDA has actively participated in commenting on the Green Chemistry Regulations since the initial draft Regulations were circulated in 2010. We have supported the development of a science-based process to improve the safety and reduce the environmental impact of consumer products in California, but have had significant concerns with previous drafts due to the burdens those proposals placed on California retailers. CNCDA believes that the current draft is much improved, and that the current draft demonstrates that the Department understands of retailer concerns. In particular, the following provisions are appreciated:

- Definition of Manufacture: by excluding from the definition of "manufacture" simple product repair and refurbishment, and installation of standardized components (as long as Chemicals of Concern are not added or replaced) the Department appropriately excludes activities that should not be treated as manufacturing under the regulation. This approach strikes an appropriate balance between commercial reality and consumer safety.

- Duty to Comply: by emphasizing that manufacturers and importers have the primary duty to comply with the substantive requirements of the regulation, the Department appropriately recognizes that businesses that do not manufacturer or import products should not be treated as manufacturers or chemical experts, but instead viewed as an "on/off" switch for product distribution.

- Failure to Comply List Notification: By conditioning a retailer's duty to comply with a substantive regulatory requirement upon the notification on the Failure to Comply list, the Department appropriately places the burden on manufacturers and importers. If a retailer is willing to fulfill the

duties of a manufacturer or importer, however, the retailer will have the option of continuing to sell the consumer product.

- Retailer "Off-Ramp": by allowing retailers to avoid regulatory mandates concerning a product by ceasing the order of the product and providing a notice of this fact, the Department both recognizes that retailers are often unable to fulfill technical requirements, and that the prospect of financial losses stemming from a mass exodus of retail outlets is likely to pressure manufacturers and importers into meeting their regulatory obligations.

While the draft regulation is significantly improved compared to previous drafts, CNCDA still has concerns with several provisions, and appreciates the opportunity to provide comments and suggestions to the Department. Our suggestions are primarily an attempt to clarify the circumstances under which a retailer must comply with substantive requirements of the regulation, and avoid the ability of manufacturers or importers to impose regulatory compliance burdens and costs upon retailers.

General Technical and Grammatical Comments

- Internal Citations: The draft regulation is inconsistent in its internal citation format. Certain provisions of the draft refer to subdivisions as "subsections."[1] The correct citation should be to a "subdivision."

- Redundant Language: Certain portions of the draft regulation refer to "responsible entity or a chemical manufacturer or importer." Since manufacturers and importers are already considered "responsible entities," this duplicative language should be deleted—instead referring collectively to "responsible entities." Alternatively, if the Department seeks to differentiate between "manufacturers" and "chemical manufacturers," and "importers" and "chemical importers" such terms should be defined.

- Historic Products: While the regulation appears intended to apply only to "new" and unsold products, nothing in the regulation specifically exempts "used," "pre-owned," or "historic" products, or the components needed to repair such product. For instance, a vehicle manufactured in 1996 should not be subject to the proposed regulation. Similarly, a replacement part (e.g., an airbag) manufactured for repair of that vehicle should not be subject to the regulation—otherwise, manufacturers of such replacement parts are unlikely to devote the considerable costs in redeveloping alternative replacement parts for such vehicles, and parts necessary for repairing such vehicles will be unavailable in California. As a forward-looking regulatory proposal, items that have been previously sold to consumers should be specifically exempted, and special consideration should be provided regarding components necessary to repair such historic products.

- Typos: We noticed two typos in the draft language, which should be corrected as follows:
    - P. 27, ln. 39: "Potential ~~Chemicals~~ Adverse Impacts from Chemicals of Concern";
    - P. 29, ln. 40: "Safer" instead of "Saver"

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[1] *See*., e.g., Section 69501.3(a)(1).

Specific Comments:

Proposed 22 California Code of Regulations Section 69501.2.
Definitions.

Section 69501.2 provides a large list of definitions used throughout the Green Chemistry Regulations. While most definitions appear appropriately drafted, CNCDA seeks clarifying amendments to the definitions of "Manufacturer" and "Responsible Entity."

(50) "Manufacturer":
Page 12, Line 29

- The Proposed Definition of "Manufacturer" is Overbroad and Lacks Clarity: "Manufacturer," is defined in the draft regulation as "any person who manufacturers a product, or *any person that controls the specifications and design of, or use of materials in, a product*." (emphasis added). While we believe the language of this definition is intended to apply to situations where a retailer provides instructions to a manufacturer on the specifics design and substances to be used in creating a custom-made consumer product to be sold by or through that retailer, we fear that this language is susceptible to a much broader interpretation. Without further context, "control" by a person of the "specifications and design or, or use of materials in, a product" could be interpreted to include ordering a product configured based upon manufacturer-specified available options. Applied to the retail new vehicle industry, our dealers order vehicles from their franchised vehicle manufacturers configured based upon a set number of options which are established and made available by the vehicle manufacturer. If, for instance, a Ford dealer orders a Ford Fusion with a six cylinder engine and leather seats, one could misconstrue the draft language to deem the *dealer* as a manufacturer, since the dealer is exercising limited control over the specifications (engine) and use of materials (leather seats) in the vehicle (product). While we believe that the dealer is merely configuring the vehicle to include manufacturer-established characteristics, and that the vehicle manufacturer is the entity that controlled the specifications, design, and materials, we would appreciate clarification and guidance from the Department on this issue.

- Suggested Fix: Provide clarifying language in the draft definition such that configuring a product from a set number of manufacturer-established options does not render a person as a manufacturer.

> (50) "Manufacturer" means any person who manufactures a product, or any person that controls the specifications and design of, or use of materials in, a product. "*Manufacturer" does not include a person who orders a consumer product from a manufacturer or importer where the product is configured to include optional components, accessories, or characteristics that are generally offered by the manufacturer or importer.*

(68) "Responsible Entity":
Page 15, Line 29

- Definition of "Responsible Entity" Lacks Clarity and Context. Perhaps the most important definition of the proposed regulation for our dealer members, and retailers in general, is the definition of "responsible entity," which lists product manufacturers, importers, and retailers without distinction. This definition is used throughout the draft regulation to denote which party is responsible for compliance with the substantive provisions of the Green Chemistry program. While draft section 69501.3 provides clarification as to which parties have primary responsibility for compliance with the regulation in general, CNCDA strongly urges that contextual language be added to the draft definition, consistent with the language of section 69501.3.

- Suggested Fix: Include language that describes limited circumstances under which a retailer may be considered a responsible entity, in a manner consistent with the "Duty to Comply" provisions of Section 69501.3:

> (68) "Responsible entity" means any of the following:
> (A) The manufacturer of a consumer product.
> (B) The importer of a consumer product.
> (C) The retailer of a consumer product, *if notified by the Department, pursuant to subdivision (a) of section 69501.3, of the failure of the manufacturer and, if applicable, importer of such consumer product to comply with the duty or duties, and the notification includes all of the information provided in paragraph (4) of subdivision (d) of section 69501.3.*

Proposed 22 California Code of Regulations Section 69501.3.
Duty to Comply and Consequences of Non-Compliance
Page 17, Line 5

Section 69501.3 provides the crucial keystone to the entire Green Chemistry Regulatory program: identifying which parties have the responsibility to comply with the substantive provisions of the regulation, the priority of compliance mandates, and procedures under which responsible entities may take action and remove themselves from any potential mandates under the regulation ("offramp" procedures). This section also provides requirements for the Department to establish a list of parties who have failed to comply with the regulatory requirements, and to provide notification to retailers of a duty to comply with regulatory requirements if they wish to continue selling products manufactured or imported by non-compliant entities. While the intent of this draft is clear, and provides a marked improvement over previous drafts of this section, a few minor amendments are needed to provide a clear allocation of responsibility under the regulation.

- The "Offramp" Stop Order and Notice Requirement Have the Same Deadline: Subdivision (c) of Section 69501.3 provides retailers with an "offramp" that they can use to avoid compliance with the substantive requirements of the regulation: within 60 days of notification of a duty under the regulation, the retailer can elect to stop ordering a covered product, and file a notice with the

Department containing certain information. This much-appreciated provision allows unsophisticated retailers with a way to avoid complicated and expensive regulatory mandates, and will likely result in significant pressure on any manufacturers and importers who have failed to comply with their own regulatory requirements.

CNCDA is concerned that a retailer has the same deadline to a) try to convince the manufacturer or importer to comply with their regulatory obligations, b) decide whether to attempt to fulfill the obligations in place of the manufacturer or importer, or to cease ordering the product, c) implement a "stop order" (if appropriate), and d) notify the Department by completing the mandatory filing.

While the 60 day stop order deadline is appropriate, we believe retailers should have an additional 30 days to compile the requested information to file with the Department.

- Deadline to Remedy Manufacturer/Importer Failure to Comply is Too Short: Subdivision (d) of Section 69501.3 establishes a Failure to Comply List to inform the public and retailers of the failure of a manufacturer and/or importer to comply with a regulatory requirement. The same list provides retailers with notice of their obligation to comply in place of the manufacturer and/or importer, and provides for the establishment of a deadline of at least 60 days. As discussed in the previous comment, retailers are provided with the same 60 days to decide whether to take advantage of the regulation's "offramp" provisions. Retailers may need to spend a large portion, if not all, of the 60 day period to determine whether to fulfill the regulatory requirement or to utilize the regulatory "offramp." Any deadline to comply with a regulatory requirement should be at least 60 days *after* the expiration of the "offramp" rights, for a minimum of 120 days after publication of a duty to comply on the Failure to Comply List.

- Failure to Comply Notice Should Inform Retailer of Compliance "Offramp": The importance of the Department's inclusion of the "offramp" provisions for retailers—particularly less-sophisticated retailers—cannot be overstated. A notification of a retailer's duty to comply with a regulatory requirement should also include a description of a retailer's "offramp" rights under the regulation.

- List of Non-Compliant Retailers Should be Regularly Updated: The regulation provides that the identity of known retailers of a product who have not submitted an "offramp" notification shall be posted on the Failure to Comply List. The proposal should be amended to the effect that the Department regularly update this list, on at least a weekly basis.

- Regulation Should Provide for Coordination of Compliance Efforts for Multiple Retailers: With several hundred thousand retailers in California, a situation may arise where several retailers who have been notified of a duty to comply may attempt to remedy the non-compliance independently. Although we do not have language to provide, the Department should attempt to assist in coordination of such efforts to avoid unnecessary expense and conflicting or duplicative efforts. We are happy to discuss potential coordination procedures with the Department.

Suggested Fix: Pursuant to the abovementioned discussion, the draft regulation should be amended to read as follows:

(a) Duty to Comply.
(1) A manufacturer has the principal duty to comply with requirements applicable to a responsible entity. In the event a manufacturer does not comply, it shall be the duty of the importer, if any, to comply. A retailer is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer, if applicable, have failed to comply and the Department notifies the retailer of the manufacturer's and the importer's, if applicable, non-compliance by posting the information on the Failure to Comply List, pursuant to ~~subsection~~ *subdivision* (d)(4)(C).
(2) 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 the responsible entity.

(b)(1) Manufacturer or Importer Option.
A responsible entity that is the manufacturer or importer of a product shall not be held responsible for complying with requirements of this chapter applicable to a responsible entity if the manufacturer or importer provides a notice to the Department containing information demonstrating to the Department's satisfaction that the product is no longer placed into the stream of commerce in California. The notice shall include all of the following:
(A) The manufacturer's or importer's name and contact information;
(B) The name of, and contact information, for all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;
(C) 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, if applicable; and
(D) Information describing the product, including the brand name(s) and product name(s) under which the product was placed into the stream of commerce in California.
(2) If the manufacturer or importer places into the stream of commerce in California a product that replaces, in terms of use and customer bases, the removed Priority Product and that contains the same or different Chemical(s) of Concern, the manufacturer or importer shall provide a notice to the Department at the same time as the notice required pursuant to paragraph (1) or within thirty (30) days after the replacement product is first placed into the stream of commerce in California, whichever is later. The notice shall include all of the following information:
(A) The manufacturer's or importer's name and contact information;
(B) The name of, and contact information, for all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months;

(C) 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, if applicable;

(D) Information describing the Priority Product that is replaced by the new product, including the brand name(s) and product name(s) under which the Priority Product was placed into the stream of commerce in California; and

(E) Information describing the new product that replaces the Priority Product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California, and the Chemical(s) of Concern in the new product. (3) Paragraph (2) does not apply to a replacement product first placed into the stream of commerce in California prior to the issuance of the applicable proposed Priority Product list, unless there is a two-fold or greater increase in the sales of the replacement product in California within one year after the date of the notice required pursuant to paragraph (1).

(c) Retailer Option.

A retailer of a consumer product for which the Department has provided notice pursuant to ~~subsection~~ *subdivision* (a), shall not be held responsible for complying with the requirements specified in the notice if:

(1) The manufacturer or importer complies with the requirement specified in the Department's notice, or fulfills the requirements of ~~subsection~~ *subdivision* (b), within sixty (60) days after the Department issues the notice; or

(2) The retailer complies with both of the following requirements:

(A) The retailer ceases ordering the product no later than sixty (60) days after the Department has provided notice pursuant to ~~subsection~~ *subdivision* (a)(1); and

(B) No later than ~~sixty (60)~~ *ninety (90)* days after the Department has provided notice pursuant to ~~subsection~~ *subdivision* (a)(1), the retailer notifies the Department that it has ceased ordering the product, and provides the following information to the Department:

1. The retailer's name and contact information;
2. The manufacturer's and importer's name and contact information;
3. Identification and location of the retailer's sales outlets where the product is sold, supplied or offered for sale in California;
4. Name of, and contact information for, the person immediately upstream from the retailer in the supply chain for the product;
5. Information describing the product, including the brand name(s) and product name(s) under which the retailer placed the product into the stream of commerce in California; and
6. A statement certifying that the retailer will not re-initiate ordering the product unless and until information posted on the Department's website indicates that the non-compliance has been remedied.

(d) Failure to Comply List.

(1)(A) If the Department determines that one or more requirements of this chapter have not been complied with for a specific chemical or product, the Department shall issue a notice of non-compliance to the manufacturer and the importers, if applicable, for the product.

(B) A notice of non-compliance shall describe the nature of the non-compliance and the Department's intent to place information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4).

(2) If the non-compliance has not been remedied to the satisfaction of the Department, the Department shall post information concerning the determination of non-compliance on the Failure to Comply List on its website pursuant to paragraph (4). The Department shall post the information on the Failure to Comply List not less than 45 days and not later than 90 days after issuing the notice of non-compliance. The non-compliance shall be deemed to be remedied if the Department determines that the requirements of ~~subsection~~ *subdivision* (b)(1) have been fulfilled, or that the condition of non-compliance has been fully remedied.

(3) Paragraph (2) does not apply if there is pending dispute under article 7 concerning the notice of non-compliance.

(4) The Department shall post and maintain on its website a Failure to Comply List that includes all of the following information for each product covered by a notice of non-compliance:

(A) Information identifying and describing the product, including the brand name(s) and product name(s) under which the product is placed into the stream of commerce in California;

(B) The requirement(s) of this chapter, and the applicable due date(s), that are the basis for the notice of non-compliance;

(C) A statement placing retailers of the product on notice of the Failure to Comply by the manufacturer and, if applicable, importers, pursuant to ~~subsection~~ *subdivision* (a)(1), including identification of the requirement with which the retailer shall comply and the timeframe for compliance, which shall be no less than ~~sixty (60)~~ *one hundred twenty (120)* days after the notice is posted on the Department's website*, and a statement informing retailers of the ability to avoid any duty under this Chapter by fulfilling the requirements of subdivision (c) of this Section*;

(D) The Chemical(s) of Concern known to be in the product;

(E) The name of and, if known, the contact information for the person listed on the product label as the manufacturer and the person, if any, listed as the distributor;

(F) The name of and contact information for any manufacturer or importer that has been notified by the Department, pursuant to paragraph (1);

(G) The name of, and contact information for, retailers of the product known to the Department who have not fully complied with the requirements of ~~subsection~~ *subdivision* (c), *which shall be updated by the Department on at least a weekly basis*; and

(H) The date the product is first listed on the Failure to Comply List.

(5) The Department shall remove a product, and the associated information, from the Failure to Comply List if the Department determines that the condition of non-compliance has been fully remedied, or that the requirements of ~~subsection~~ *subdivision* (b)(1) have been fulfilled.

(6) The Department shall remove information concerning a retailer who is a responsible entity from the Failure to Comply List if the Department determines that the retailer has complied with the applicable requirements of ~~subsection~~ *subdivision* (c).

Proposed 22 California Code of Regulations Section 69501.5.
Chemical and Product Information.
Page 20, Line 29

Section 69501.5 provides procedures whereby the Department may request information concerning a product or chemical from a responsible entity, which would be required to provide such information or be named on the Department's publicized Failure to Respond List.

- Chemical and Product Information Requirements Should Only Apply to Manufacturers and Importers: While retailers are considered "responsible entities" in certain circumstances, and may be subject to requirements under the regulations, this should not apply to requests for chemical or product information: such information is held closely by chemical and product manufacturers and importers, and would not be released to retailers. Accordingly, Section 69501.5 should be amended to apply only to product manufacturers and importers.

  Suggested Fix: Section 69501.5 should be amended to refer to "manufacturer or importer" rather than "responsible entity." Furthermore, since chemical manufacturers and chemical importers are not defined by regulation, and likely would be included in the broad definition of "manufacturer" or "importer," these descriptors should also be removed. The amendments would be as follows:

  (a) The Department shall seek to obtain and/or review information that it determines is necessary to implement this chapter using one or more of the following approaches:
  (1) Obtain and/or review information in the public domain that is readily available in a usable format, without a subscription or other charge;
  (2) Obtain and/or review information in the public domain that is readily available in a usable format, with a subscription or other charge, to the extent resources are available to pay the required costs;
  (3) Request a *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~ to make existing information available to the Department, in accordance with a schedule specified by the Department; and
  (4) Request a *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~ to generate new information and provide it to the Department, in accordance with a schedule specified by the Department.
  (b) The Department may request that information be made available to it pursuant to this section by either or both of the following methods:
  (1) Correspondence sent to an individual *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~ electronically or by United States mail. Copies of the correspondence shall be posted on the Department's website; and/or
  (2) Information call-ins that, unless otherwise specified, apply to all *manufacturers or importers* ~~responsible entities and/or all chemical manufacturers and importers~~ of a specific chemical or product or group of chemicals or products. The Department shall post information call-ins on its website, provide notice to individuals on the listservs established by the Department related to this chapter, and provide notice in the CRNR.

(c) The Department shall post on its website on the Failure to Respond List a notice that the *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~ has not made the requested information available to the Department, if that person, or person acting on behalf of or in lieu of that person, does not make the requested information available by the date specified by the Department, unless the *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~ demonstrates to the Department's satisfaction that is does not have and is unable to produce the requested information. The Department shall also post information identifying the *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~, and the chemical or product that is the subject of the request. The Department shall remove this information from its website upon determining that the *manufacturer or importer* ~~responsible entity or a chemical manufacturer or importer~~, ~~or~~ another person has fulfilled the request for information*, or that the responsible entity does not have and is unable to produce the requested information*.

Proposed 22 California Code of Regulations Section 69503.2.
Priority Products Prioritization.
Page 29, Line 40

Section 69503.2 provides the process by which the Department decides which products containing a Chemical of Concern are to be deemed Priority Products.

- The Department Should be *Required* to Consider Whether a Functionally-Acceptable and Technologically and Economically Viable Safer Alternative Exists: When a product is named a Priority Product, the sale, use, and availability of that product is likely to decrease drastically. If a readily available alternative is economically feasible, industry and consumers will merely begin using the alternative product. If no readily available replacement for that product may be used, unanticipated consequences may result. For instance, if a brake-cleaning product were named a Priority Product, and no replacement brake cleaner is readily available, both automotive repair shops and the driving public could find themselves in a situation where their brakes could not be cleaned effectively. Were this the case, the effectiveness of affected customers' braking systems would be reduced and public safety could be affected.

While the abovementioned example is drastic, the consideration of whether alternative products are readily-available should be necessary as part of sound public policy making. While the Department may decide to list the product as a Priority Product despite the lack of available alternatives, consideration should be among the other important factors discussed in making such a determination.

Suggested Fix: Rather than having the discretion to consider the availability of replacement products when considering whether to name a product a Priority Product, the Department should be *required* to do so. Section 69503.2(c)(4) should be amended to read as follows:

(4) ~~Saver~~ *Safer* Alternative. The Department *shall* ~~may, at its discretion,~~ consider whether there is a readily available safer alternative, that is functionally acceptable and technologically

and economically viable~~, to further adjust the prioritization~~ prior to listing a product as a Priority Product.

Proposed 22 California Code of Regulations Section 69503.6.
Priority Product Notifications
Page 33, Line 29

Section 69503.6 provides that each responsible entity for a Priority Product, including retailers, must send a notice to the Department containing specified information.

- Department Should Clarify That the Priority Product Notification Requirement Applies Only to Manufacturers and Importers: With several hundred thousand retailers in California, the number of Priority Product notices required for almost any named product would be enormous, and the notices themselves likely of little value to the Department. The information sought by the Department through the Priority Product Notification requirement would be more-appropriately provided by manufacturers and importers. Furthermore, since much of the information sought by the Department relates to product information that will not be known to a retailer, the possibility for retailer non-compliance will be high.

  Suggested Fix: To avoid several thousand unnecessary filings for each Priority Product, Section 69503.6 should be amended to apply only to manufacturers and importers, as follows:

  (a) Within sixty (60) days after a product is listed as a Priority Product, each ~~responsible entity~~ *manufacturer and importer* for such a Priority Product shall notify the Department that its product is a Priority Product, unless ~~the responsible entity has submitted~~ a De Minimis Exemption Notification *is submitted* pursuant to section 69503.5. For a Priority Product that is first manufactured or first placed into the stream of commerce in California after the date the product is listed as a Priority Product, the ~~responsible entity~~ *manufacturer and importer* shall provide the notice within sixty (60) days after the product is first placed into the stream of commerce in California. The notification shall include all of the following:
  (1) The ~~responsible entity's~~ name and contact information *for the manufacturer or importer*, and a statement indicating whether the responsible entity is the product manufacturer~~,~~ *or* importer~~, or retailer~~;
  (2) The type, brand name(s), and product name(s) of the Priority Product and, if applicable, information specifically identifying the component(s) triggering the product's listed as a Priority Product; and
  (3) The name of, and contact information for, the person that will be complying with the requirements of article 5 on behalf of or in lieu of the ~~responsible entity~~ *manufacturer or importer*, if someone other than the ~~responsible entity~~ *manufacturer or importer*.
  (b) If the Department determines that the notice requirements specified in ~~subsection~~ *subdivision* (a) have not been complied with for a particular product that is a Priority Product, the Department shall post this information on the Failure to Comply List pursuant to section 69501.3(d).

Proposed 22 California Code of Regulations Section 69506.3.
Product Information for Consumers
Page 48, Line 22

Section 69506.3 of the draft regulation provides procedures by which the Department may, as part of its regulatory response program, order product information disclosures concerning a Priority Product or Selected Alternative.

- The Product Information Mandate Should Apply to Manufacturers and Importers. The required disclosure content provided for in Section 69506.3 is information that will not be known by the vast majority of retailers. The regulation should be amended to clarify that the mandate applies to manufacturers and importers of products.

- Manufacturers and Importers Should Not Be Permitted to Mandate Point of Sale Disclosures Unless Required By Law. The current draft language allows manufacturers with the option to provide mandatory point of sale disclosures either by providing the information on the product packaging or on an accessible manual, or to shift the product disclosure burden to retailers by requiring the posting of signs at the point of retail display. To ensure that the disclosures are appropriately made, the regulation should be amended to *require* that the disclosure be provided on the product's packaging or on an attached manual, *and* that the signage requirement apply only if mandated by law.

Suggested Fix: To appropriately place the product information disclosure requirement on the entity familiar with the product, Section 69506.3 should be amended as follows:

> (a)(1) Except as provided in paragraph (2), during the time that a selected alternative product, or a Priority Product for which an alternative is not selected, is offered for sale in California, the ~~responsible entity~~ *manufacturer and, if applicable, importer* shall ensure that all of the following information is made available to the consumer prior to any exposure to the Chemical(s) of Concern:
> (A) Manufacturer's name and importer's name, if applicable;
> (B) Brand name(s) and product name(s) and description of the product;
> (C) A list of, and common names for, all Chemicals of Concern known, based on available information, to be in the product;
> (D) Identification of any end-of-life management program for this product, and any end of-life management requirements specified by law;
> (E) Any safe handling procedures needed to protect public health or the environment during the useful life of the product and instructions for the proper end-of-life disposal or management; and
> (F) The manufacturer's and, if applicable, importer's website address where the consumer can obtain additional information about the product, the potential adverse public health and/or environmental impacts posed by the product, and proper end-of-life disposal or management of the product.

(2) Paragraph (1) does not apply to a selected alternative product that does not contain a Chemical of Concern in a concentration exceeding the level specified in section 69506.2(a).

(b) The requirements of *subdivision* (a) shall be met by making the required information available to consumers, in easily seen, legible, and understandable formats, by both:

(1) Posting the information in a prominent place on the manufacturer's website and the importer's website, if applicable; and

(2) Using ~~one or more of~~ the following means of informing consumers of this information at the point of sale:

(A) Providing the required information on the product packaging or in a manual that is accessible without breaking the product seal; ~~or~~ *and, if required by applicable law*

(B) Posting the information in a prominent place at the point of retail display.

(c) A ~~responsible entity~~ *manufacturer and, if applicable, importer* that has a product subject to the requirements of ~~subsections~~ *subdivisions* (a) and (b), shall ensure that these requirements are fully implemented for that product no later than twelve (12) months after the Department issues a notice of compliance for the Final AA Report for the product.

Proposed 22 California Code of Regulations Section 69506.4.
End-of-Life Management Requirements.
Page 49, Line 18

Section 69506.4 of the draft regulation provides a requirement under which responsible entities must implement End-of-Life Management programs for Priority Products or Selected Alternatives that must be managed as Hazardous Waste in California.

- Responsible Entities Should Not Be Permitted to Impose End-of-Life Management Requirements Upon Third Parties without Consent. The proposed language of Section 69506.4 requires that the responsible entity for a covered product establish a product stewardship program meeting certain requirements. The draft appears to allow responsible entities to create product stewardship programs and establish roles without consulting or receiving consent of third parties in the supply chain—including product retailers. The language should be amended to ensure that any program created by a responsible entity pursuant to Section 69506.4 only describe roles of third parties if the third parties have contractually agreed to perform those roles.

- Collection Plans Under Product Stewardship Programs Should Provide for *Both* Collection Mechanisms and Compensation to Third Parties: While Section 69506.4(a)(2)(B) appropriately requires that collection and recycling plans under a product stewardship program be created in consultation with retailers and potential collection sites, it requires that the plan only contain *either* collection mechanisms *or* compensation to third parties who administer the program. The language should be amended to include *both* collection mechanisms, *and* compensation, and that the compensation be agreed to by the third parties who agree to administer the program.

Suggested Fix: To avoid the ability of a responsible entity to create a product stewardship plan that does not include contractual arrangements with third parties named in the plan, Section 69506.4 should be amended as follows:

(a) Except as provided in section 69506.2, a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that both of the following requirements are met:

(1) The information required by section 69506.3 shall be provided for the product. Additionally, the product information must state that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.

(2) No later than two (2) years after the Department issues a notice of compliance for the Final AA Report for the product, the responsible entity shall fund, establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:

(A) A comprehensive product stewardship plan must be developed and maintained, and shall include all of the following:

1. A list of, and contact information for, participating manufacturers and importers and, if applicable, other participating persons.
2. The scope of products to be covered by the plan.
3. The roles and responsibilities ~~for~~ manufacturers, importers, retailers, consumers and government *are contractually obligated to perform* throughout the life cycle of the product.
4. Identification and description of collection systems that *have been established by contract* ~~will be used~~.
5. End-of-life management information, including what steps will be taken to ensure management that complies with all applicable federal and California State and local laws, and addresses any adverse multimedia impacts.
6. Anticipated resource needs and a description of the financing mechanism to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program. The responsible entity for the product shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product. Multiple responsible entities may form a third-party product stewardship organization, funded by participating manufacturers and responsible entities, to provide local services to collect, recycle, or otherwise appropriately manage the designated products.
7. Program performance measures for:
a. Increasing the capture rate of the products covered at the end-of-life; and
b. Increasing recyclability.
8. Public education, outreach, and communications plans.
9. Public and stakeholder consultation activities during preparation, and periodic review and updating, of the plan.
10. Reporting and evaluation procedures.

(B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and potential collection sites. The collection program must include ~~one or~~ both of the following:

1. Collection mechanisms; and
2. Compensation *agreed* to *by* retailers and other persons who agree to administer or participate in the collection program.

(C) The responsible entity shall post a copy of the product stewardship plan on is website, and provide a link to the posting to the Department for posting on its website.

(D) The responsible entity for a product subject to the requirements of this section shall, every two (2) years from the date the end-of-life management program is required to be implemented, ensure that a report is provided to the Department. The report must include both of the following:

1. The amount of products placed into the stream of commerce in California over the previous two-year period, by total tonnage; and
2. The number of products recovered over the same two-year period, by total tonnage.

(b) Upon request, the responsible entity shall provide to the Department a copy of the product stewardship plan required under this section.

(c) A responsible entity subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A responsible entity may not substitute an alternative end-of-life management plan for the plan specified in this section unless it receives written approval from the Department.

(d) A responsible entity subject to the requirements of this section may request an exemption from the requirement to provide an end-of-life management program by demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product.

Conclusion:

CNCDA appreciates this opportunity to comment on the informal draft regulation language outside of the normal regulatory process. We look forward to working with DTSC to address our concerns in the near future. If you have any questions or comments concerning this letter or Green Chemistry issues in general, please feel free to contact me at (916) 441-2599, or at jmorrison@cncda.org.

Sincerely,

Jonathan Morrison
Staff Counsel

January 13, 2012

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
VIA EMAIL: cgregs@dtsc.ca.gov

Re: DIVISION 4.5, TITLE 22, CALIFORNIA CODE OF REGULATIONS CHAPTER 55. SAFER CONSUMER PRODUCTS – INFORMAL DRAFT REGULATIONS R-2011-02 (October 31, 2011)

Dear Ms. Jones:

On behalf of the California Grocers Association (CGA) and its member companies, we respectfully submit the following comments relative to the Safer Consumer Products (Chapter 55 of Division 4.5 of Title 22, California Code of Regulations) October 31, Informal Draft Regulations (Green Chemistry).

CGA is a non-profit, statewide trade association representing the food industry since 1898. CGA represents approximately 500 retail members including chain and independent supermarkets, convenience stores and mass merchandisers operating over 6,000 food stores in California and Nevada, and approximately 300 grocery supplier companies.

We applaud the Department's efforts in drafting regulations that seek to accomplish the goals outlined by statute and are in accordance with much of the Informal Draft Regulations. These regulations take substantial steps towards ensuring hazardous chemicals in products and the environment are reduced or eliminated. However, we are concerned that without further clarification and revisions, the average retail operation will either not understand how to comply with the requirements of the revised Informal Draft Regulations or compliance will not be possible. We recommend additional modest revisions and clarifications which we feel will make the draft more concise.

In reviewing the revised content of the Informal Draft Regulations, we have limited our specific comments to eight areas for which we seek further clarification: **Definitions, Duty to Comply, Chemicals of Concern Identification, Priority Products List, Applicability and Petition Contents, Product Information for Consumers, End-of-Life Management and Product Sales Prohibition.** We appreciate your consideration on the issues we have identified as well as our suggested alternatives where we deem them to be appropriate.

§ 69501.2 - Definitions

Manufacturer:
The definition of "Manufacturer" is broad in its current form and unclear to us how it would be applied. CGA is concerned that the current definition would have the potential to capture many items in our stores by virtue of the fact that in choosing items we order, we are potentially choosing the specifications, design or materials. For example, a retailer may direct a manufacturer to order a liquid household cleaner that has an antibacterial and smells like lemon. In this case, the retailer has provided the manufacturer with specification and design information but does not have actual knowledge of materials and/or chemicals used to meet the retailer's request. For this reason, CGA believes that the definition needs more clarity.

Responsible Entity:
CGA believes the definition of "Responsible Entity" must be clarified to create a tiered level of responsibility. A retailer should only be responsible in the event that both a manufacturer and an importer have failed to comply with their responsibilities under the Safer Consumer Products regulations. By clarifying this tiered approach in the definition, some of our other concerns with the current reading of the Informal Draft Regulations will be mitigated.

§ 69501.3 – Duty to Comply

Reporting Timeline:
In the event a manufacture fails to comply, and the department notifies the retailer of the manufacturer's non-compliance by posting the information on the Failure to Comply List, the retailer is not responsible for complying with the requirements if they exercise the following two options: 1) cease ordering the product no later than sixty (60) days after the Department has provided notice and 2) no later than sixty (60) days after the Department has provided notice the retailer notifies the Department that it has ceased ordering the product and provides specific information requested by the Department. Given that retailers must cease ordering within sixty (60) days, which may prove difficult depending on their purchase agreements; CGA believes that the reporting timeline should be extended to ninety (90) days. If the retailer is given sixty (60) days to make and act upon a decision, they need additional time to submit a report for that action.

§ 69502.2 Chemicals of Concern Identification

Exemptions:
CGA believes that clarification is needed to ensure that exempted products are not listed and then subsequently removed. Listing chemicals that are knowingly exempted could cause unnecessary public concern. We believe the following amendment would clarify that exempted items are never listed:

California Grocers Association |1215 K Street, Ste. 700 | Sacramento, CA 95814 | P: 916-448-3545 | F: 916-448-2793

> *§ 69502.2 (a)(1) The chemical is identified as exhibiting hazard trait on one or more of the following lists unless exempted by section 69501(b).*

§ 69503.3 Priority Products List

Responsibility:
As discussed earlier in our comments, we believe the responsible entity shall be clarified as a tiered system. Retailers must have clarity in their responsibility, which should not be equal with that of a manufacturer or an importer. Additionally, CGA believes further amendments are needed to remove the responsibility for "each" responsible entity as shown below, and in other sections where it is used:

> *§ 69503.3 (f)* ***Each*** *responsible entity for a product listed on the Priority Products list shall provide to the Department a Priority Product Notification as specified in section 695036 or a De Minimis Exemption Notification as specified in section 69503.5 within sixty (60) days after the product is listed as a Priority Product.*

This highlights the challenges with the inclusion of retailers in the responsible entity definition. Because retailers do not manufacture products, there is no way for them to have the information necessary regarding chemicals and formulations to be able to determine whether they are selling a priority product in order to provide the Department with the required notifications.

§ 69504 Applicability and Petition Contents

Petitions:
While we understand the value in having a petition process for adding chemicals to the list, we believe that same petition process should also be available for removing chemicals from the list.

§ 69506.3 Product Information for Consumers

Posting Information for Consumers:
This section requires manufacturers to inform consumers at the point of sale by either providing information on the product packaging that can be accessed without breaking the product seal, or by posting information in a prominent place at the point of retail display (§69506.3(b)(2)). CGA has significant concerns with the manufacturer having the option to place the notification burden on the retailer rather than on their packaging design. We understand the reason for this language is twofold: to ensure the consumer has product information *prior* to purchase, and to allow for signage where product labeling cannot be mandated. We believe that this section must be changed to clarify that the burden of providing any signage and/or labeling is on the manufacturer. Additionally, CGA believes this section should be tiered to set the priority for notification on product package labeling, followed by signage only in the instance where labeling cannot be legally or safely accomplished.

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Sections 69506.4 – End-of-Life Management

End-of-Life Management Programs:
This section requires manufacturers to develop and maintain a comprehensive end-of-life management plan, which includes listing the roles and responsibilities for retailers, among others, throughout the life cycle of a product. As drafted, this would allow a manufacturer to dictate to a retailer an end-of-life management program, without regard for the retailer. Furthermore, this section places no burden on the manufacturer for financing the end-of-life management program they dictate. These two aspects of the end-of-life management program are simply unworkable. Retailers must be involved in the development of the end-of-life management program if they are to have any roles and responsibilities. We believe this section needs to be amended to specify that nothing in these regulations requires a retailer to participate in an end-of-life management program (whether through take-back or otherwise). The draft should specifically state, that it shall be the manufacturer's responsibility to negotiate with the retailer and obtain their consent if the manufacturer wishes to utilize their services in order to fulfill the take-back/end-of-life management required of the manufacturer in the regulations.

Sections 69506.5 – Product Sales Prohibition

Recalls:
This section requires the responsible entity to ensure that an inventory recall program for the product is implemented and completed within three (3) years after the notification by the Department. CGA believes that if the Department is requiring a recall program, the regulation should specify that the manufacturer is responsible for that recall program. Manufacturers are equipped to implement recall programs for their products, but retailers are not similarly equipped. The existing manufacturer recall infrastructure and responsibility for consumer products should be continued in these regulations.

While we appreciate the work DTSC and other interested stakeholders have put into the process thus far, we believe the outlined areas must be addressed to clarify the intent and direction of the regulations. Thank you again for your efforts in improving the Informal Draft Regulations.

Sincerely,

Kara Bush
Manager, Government Relations

CC: Debbie Rafael, Director, DTSC
Odette Madriago, Chief Deputy Director, DTSC

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January 13, 2012

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
VIA EMAIL: cgregs@dtsc.ca.gov

Dear Ms. Jones:

The California Retailers Association respectfully submits these comments in response to the October 31, 2011 release of **Informal Draft Regulations for Safer Consumer Products**, also referred to as the Green Chemistry regulations.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, fast food restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware, furniture and home improvement stores. California's retail industry currently operates over 164,200 stores with sales in excess of $571 billion annually and employs 2,776,000 people—nearly *one fifth of California's total employment.*

Progress Made

CRA greatly appreciates the openness of the Department of Toxic Substances Control's ("DTSC" or "Department") process of development of this ambitious and unprecedented regulation, and the availability and accessibility of its staff. We commend the Department for several changes that have been made in the most recent informal draft. In particular, CRA acknowledges and supports the following:

- Clarification in the Duty to Comply section that the principal responsibility for compliance with the regulation's requirements rests with product manufacturers and in the event of a manufacturer's noncompliance, the responsibility falls on the importer before it becomes a retailer's duty to comply.

- Inclusion of a regulatory "retailer off-ramp" when retailers have been advised of a manufacturer's noncompliance via DTSC's website listing, which allows retailers to

decide whether to fulfill the responsibilities of the manufacturer or stop ordering that manufacturer's product.

- The Director's expressed intention to initially limit the number of Priority Products to 2-5 products. We believe this is the best way to begin a new program, so that we can undergo a rational phase-in without massive disruption in the marketplace.

- The ability to consider *de minimus* percentages within a product, although we are aware there is still controversy over what those percentages should be.

- The elimination of mandatory independent third party review of Alternative Analyses, replaced with a certified assessor requirement.

Concerns Remain

There remain sections in the draft where we urge clarifications be made to ensure ease of compliance. Definitions of "manufacturer" and "responsible entity" remain problematic and need further revision to make retailers' responsibilities less confusing under different sections of the regulation. We also have strong objections to some portions of the new language in the Regulatory Response section, particularly those that relate to product information for consumers and end-of-life management requirements.

The amendments we propose in these comments, if accepted by the Department, will streamline and provide clarity of responsibilities without hampering DTSC's ability to meet its statutory mandate under AB 1879. Our comments are organized by issue and, where appropriate, reference the relevant Section numbers and pages in the draft regulation, and propose a recommendation. CRA is committed to spending as much time as is needed to work with DTSC staff to develop a workable regulation.

1. ISSUE: "RESPONSIBLE ENTITY" DEFINITION NEEDS CLARITY
Section 69501.2(a)(68), page 15

The definition of "responsible entity" includes the manufacturer, importer **and** retailer of a consumer product. This definition causes confusion throughout the regulation except in the Duty to Comply section (§ 69501.3), which specifically details retailers' responsibilities. The language in the Duty to Comply section specifies that manufacturers are the first responsible entity, importers the second, and only if and when a responsible manufacturer and a subsequently-responsible importer have failed to respond would a retailer have responsibility for compliance. In our December 20, 2011 meeting with departmental representatives, the Department agreed that the Duty to Comply section IS intended to apply to ALL provisions in the regulation where "responsible entity" is referenced. If and when a responsible manufacturer or importer fails to comply and the burden then becomes the retailer's, the retailer would become aware of this responsibility through the Failure to Comply list.

Additionally, the draft contains references to "*each* responsible entity" in Sections 69503.3(f) and 69503.6 (a), which may be simple drafting errors, but which, if left uncorrected, will require duplicative actions. If the regulations create parallel obligations on manufacturers, importers and retailers, then the regulations essentially impose joint and severable liability on all parties, which we know is not the intent of the Department.

Recommendation:

The same clarity provided in Section 69501.3 (a)(1) should be included in the definition of "responsible entity" and stated as to its applicability to all sections of the regulation, so that it is very clear from a compliance and enforcement standpoint what retailers' responsibilities are. The revised definition would read:

(68) "Responsible entity" means any of the following:
(A) The manufacturer of a consumer product.
(B) The importer of a consumer product.
(C) The retailer of a consumer product.
A retailer is required to comply with the requirements applicable to a responsible entity only if the manufacturer and the importer, if applicable, have failed to comply and the Department notifies the retailer of the manufacturer's and the importer's, if applicable, non-compliance by posting the information on the Failure to Comply List.

2. ISSUE: CHANGE TO "MANUFACTURER" DEFINITION
Section 69501.2(a)(50), page 12

The definition of "manufacturer" has been expanded from prior versions of the proposed regulations. The proposed definition now reads: "Manufacturer" means any person who manufacturers a product, *or any person that controls the specifications and design of, or use of materials in, a product."*

The expansion of the definition of "manufacturer" to include retailers who "spec and design" was apparently made by the Department to cover private label products where a retailer provides specs regarding use of specified chemicals or chemical processes. However, this phrase is of concern to retailers because its broadness signals an opportunity for future confusion; it is so broad as to be unclear what is specifically intended.

Retailers, particularly apparel retailers, may specify design elements to their private label manufacturers. Examples of design specs include: fabric; color; fuller or sleeker cut; cuffs or no cuffs; colors; flocking; glitter, stone, beading, sequins or button embellishments; material type; thread color, pant cut (boot cut, skinny leg, straight, etc.). For example, an apparel retailer may direct a clothing manufacturer to make a women's boot cut jean in a dark wash with embroidery on the back pockets and slanted front pockets. Or, a general merchandise retailer may direct a product manufacturer to make a body cream with a lavender scent in a pump bottle of 11 ounces in size. In either case, the retailer has provided the manufacturer with some general specification and design information, but does not have knowledge of, nor control over, the materials, chemicals and/or chemical

processes used to meet those specifications. The bottom line is that the manufacturer still has the responsibility for the chemical composition decisions for the product. The change in the definition of "manufacturer" subjects the retailer to requirements that are within the control of the product manufacturer, which contradicts the intent and statements made in the Duty to Comply section.

Recommendation:

Amend the language to read:

"Manufacturer" means any person who controls the manufacturing processes and chemical ingredients or formulation used to produce the finished product. The use of quality or performance specifications alone, such as color, size or material, does not constitute control.

This clarification assigns the appropriate level of responsibility to the top of the supply chain where the manufacturer has the most knowledge and control of the product's actual creation. In the event of manufacturer or, if applicable, importer noncompliance, the retailer, under the Duty to Comply section (§ 69501.3) would be required to fulfill the manufacturer's responsibilities under the regulation, or cease ordering the noncompliant product.

3. ISSUE: "IMPORTER" DEFINITION NEEDS CLARITY
Section 65901.2(a)(41) and (42), page 11

To provide further clarity to the definitions of "import" and "importer", we suggest the following change to the existing definitions:

Recommendation:

(41) "Import" means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce *in the State of California....*
(42) "Importer" means a person who imports a consumer product into the United States *for ultimate sale in the State of California.*

4. ISSUE: DEFINITION OF HISTORICAL PRODUCTS WAS DELETED
Section 69501.2(a)(21), page 9

The current consumer products definition does not include an exemption for historical products. Previous versions of the regulation included an exception for products that are no longer being placed in to the stream of commerce before the regulation was enacted.

Recommendation:

CRA suggests that the following language from the November 2010 version of the draft regulation be added to the consumer products definition, as Section 69501.2 (a) (21), new (D):

"Consumer product does not include a product that is no longer being placed into the stream of commerce by a person in California as of the date that it would have otherwise become subject to one or more requirements of this chapter."

5. ISSUE: RETAILER OFFRAMP: TIME EXTENSION
Section 69501.3 (c), page 18

This section specifies the retailer "offramp" from compliance if: 1) the retailer ceases to order the product within **60** days after the Department posts its notice, and 2) the retailer notifies the Department within those **60** days of the cessation of ordering the product. The decision to stop carrying a product will require analysis to identify possible alternatives to the product, accessibility and cost of alternatives (if any), customer demand, relationship with the manufacturer or importer, market share, distribution and advertising issues. The decision will likely take at least 90 days.

Recommendation:

We request that an additional 30 days be added to fulfill the notification process to the Department. The proposed language would be amended to read:

69501.3(c)(2)(B) "No later than ***90*** days after the Department has provided notice pursuant to subsection (a)(1), the retailer notifies the Department that it has ceased ordering the product, and provides the following information to the Department:"

69501.3 (c)(4)(C) : "A statement placing retailers of the product on notice of the Failure to Comply by the manufacturer and, if applicable, importers, pursuant to subsection (a)(1), including identification of the requirement with which the retailer shall comply and the timeframe for compliance, which shall be no less than ***90*** days after the notice is posted on the Department's website, and a statement informing retailers of the ability to avoid any duty under this Chapter by fulfilling the requirements of Section 69501.3(c)."

6. ISSUE: PRIORITY PRODUCTS NOTIFICATION NEEDS CLARIFICATION
Sections 69503.3(f), page 31 and 69503.6(a), page 33

Under these sections, "**each**" responsible entity, including retailers, must provide DTSC with either a Priority Products or De Minimis Exemption Notification. We don't believe it is the intent of the Department to receive multiple duplicate Notifications from all responsible entities.

Recommendation:

It is our understanding that the Department will clarify this section to make it clear that the Priority Product notifications are the responsibility of the manufacturer, not "each" responsible entity, unless and until the manufacturer and importer, if applicable, fail to comply. CRA supports this clarification.

7. ISSUE: CLARIFICATION RE INTERNAL BUSINESS APPLICABILITY

It is not clear in the draft regulations whether businesses would have responsibilities for chemical products used internally in conducting business, when those products are *not themselves made available to the public.* An example would be the use of various solvents and adhesives as well as the solder used in the repair of electronic equipment used to support a retail business, but not directly sold to consumers. Another example would be wiring or cable used for electronic transmission in the conduct of a retail business, where that wiring and/or cable is not sold directly to consumers. We assume that Section 69501 (B)(1) ("...this chapter applies to all consumer products placed in the stream of commerce in California") means the regulations would not apply to chemical products or processes used internally within a business, because these "products" are not placed into the stream of commerce in California; we request confirmation of this assumption.

8. ISSUE: INFORMATION PROVISION

Section 69501.5, page 20

Under this section, the Department grants itself the authority to request a responsible entity or a chemical manufacturer or importer to provide existing or generate new information and provide it to the Department, in accordance with a schedule specified by the Department. Our concern is that the breadth and scope of the information DTSC could request of responsible entities is unlimited. This section could be deemed impermissibly vague as to the Department's enforcement discretion.

Recommendation

DTSC should be more specific about the kind of information it will request industry to disclose or generate.

9. ISSUE: PRIORITY PRODUCTS LIST: WHAT MIGHT IT LOOK LIKE?

Section 69503.3 (a), page 30

CRA does not believe there has been adequate attention paid to the practical issue of how the actual List of Priority Products will be constructed. It's important to begin thinking about the desired level of specificity *vs* generality of the Priority Product information that will appear on the PP List, from a manufacturer's perspective and from a retailer's perspective.

The responsible entity, i.e., the manufacturer, will have to deal with all the "versions" or "permutations" of their Priority Product. Manufacturers produce hundreds of similar styles of a given product "type", such as apparel, each season, often with only minor

variations to distinguish them (e.g. fit, construction, color, etc). Products are typically sourced from multiple manufacturers. Manufacturers will have a regulatory duty to report to the Department if they sell a Priority Product. If the Department requires manufacturers to report individual SKUs, it would result in the notification of potentially thousands of products, depending on the product type. See mock-up example below, of three possible reporting options. If "Chemical X in Denim Jeans" was established as a Priority Product, here are examples of how the Priority Products List might be organized:

Reporting by SKU
SKU – 1234S – Denim Jeans Boot Cut containing chemical X
SKU – 12346 – Denim Jeans Straight Cut containing chemical X
SKU – 12347 – Denim Jeans Carpenter Style containing chemical X
SKU – 12348 – Denim Jeans Boot Cut with Wrinkle Resistant Finish containing chemical X
SKU – 12349 – Denim Jeans Straight Cut with Wrinkle Resistant Finish containing chemical X
SKU – 12350 – Denim Jeans Carpenter Style with Wrinkle Resistant Finish containing chemical X

Reporting by Manufacturer Supplying Retailer
Manufacturer A – Denim Jeans (multiple SKUs) containing chemical X
Manufacturer B – Denim Jeans with Wrinkle Resistant Finish (multiple SKUs) containing chemical X

Reporting by Product Category
Denim Jeans – multiple denim jean styles (6 styles), from Manufacturers A & B, containing chemical X

Recommendation:

DTSC can reduce the significant administrative burden facing it and the manufacturing industry under this regulation by allowing "grouping" of individual products within the Priority Product type for the purpose of providing § 69503.4 notifications, AA reports, § 69503.5 *de minimis* exemption notifications and other associated documentation. Although grouping may not be relevant to all obligations, the principle that it may be used should be established

Conversely, industry needs further discussion with the Department as to how retailers viewing the Priority Products List will be able to indentify whether or not an individual retailer sells that product. For example, if "Nail Polish Containing Toluene" is established as a Priority Product, how will retailers know which nail polishes they sell, if any, contain toluene? Or toluene above a permitted *de minimus* level? If the product category is small, the burden is not significant, but if the product category contains many product variations and numerous manufacturers, it becomes problematic. CRA would like to have further discussion with the Department as to how it envisions compliance in this area.

Regulatory Responses

Note that the issues discussed in these comments have centered primarily on clarification and definitional issues. However, in the Regulatory Response section of the draft, our concerns are focused on the policy and implementation challenges posed by much of the

new language in this section. The end-of-life section in particular has serious adverse consequences to our industry if adopted as currently drafted.

Retailer involvement in the Green Chemistry process will be most active in the Priority Product area, where retailers will be making decisions regarding continued sale of a priority product or choice of the "offramp" of ceasing to order the product, and in the Regulatory Response area. Following are our comments on the Regulatory Response provisions in the draft regulation.

10. Regulatory Response: PRODUCT INFORMATION TO CONSUMERS
Section 69506.3, page 48

This section requires the responsible entity "to ensure" that specific information is provided to consumers. Section 69506.3 (a)(1)(D) requires "identification of any end-of-life management program for this product..." and (a)(1)(F) requires a website address "where the consumer can obtain additional information about the product...and proper end-of-life disposal or management of the product." Both these sentences *could* be interpreted to permit manufacturers to independently advise consumers to return the products in-store.

Recommendation:

Both 69506.3(a)(1)(D) and (a)(1)(F) should be amended to reference *only* any end-of-life management requirements specified by law.

69506.3(a)(1)(D): Delete "Identification of any end-of-life management program for this product and". The new subsection would read: "Identification of any end-of-life management requirements specified by law."

69506.3(a)(1)(F): Amend the subsection to read: "The manufacturer's, and if applicable, importer's website address where the consumer can obtain additional information about the product, the potential adverse public health and/or environmental impacts posed by the product, and, *if applicable, any end-of life management requirements specified by law.*"

Additionally, we oppose providing manufacturers with the option (Section 69506.3(a)(2)(b)) to provide a sign to retailers to post near the Priority Product, thus shifting the information-provision burden to the retailer. There are already dozens of signage requirements for retail stores. As the number of Priority Products grows there will be more signage requirements, and studies have shown the majority of customers pay no attention to signs. A sign that has fallen down, is removed or is not the most recent updated version triggers an action against a retailer under California's Unfair Business Practices Act, Section 17200 of the Business & Professions Code.

Recommendation:

We recommend the Department not require product information signage as a Regulatory Response when the hazard is implicit with use of the product, and safe handling instructions are communicated on the product. The Department has indicated it wants consumers to have the required information prior to purchase, so posting of the information on the manufacturer's website or including it in the packaging for the consumer to read after purchase is not preferred by the Department. However, OEHHA has dealt with a similar issue for Proposition 65 warnings to consumers for decades, and still has not found a completely workable means of communication prior to purchase. CRA recommends that the Department shift its goal to the provision of information to consumer prior to use. For the rare consumer who will read the warning post-purchase and decide against keeping the product, the item can always be returned to the point of purchase. The majority of consumers will read the use instructions, the optimal point for communication of any warning.

The Department could also consider how the Federal Hazardous Substances Act specifies required warnings and utilize its process. As a last resort, the Department could consider "tiering" the information provision requirements. For example, manufacturers would be required to post the information on their website, provide an 800 number for consumers to access for further information, and provide the specified information on the product packaging or label (such as an accordion label). If the labeling cannot be legally accomplished, manufacturers would provide signage for posting in a retail location reasonably viewable by the average customer.

11. Regulatory Response: END-OF-LIFE MANAGEMENT REQUIREMENTS
Section 69506.4, pages 49-50

As currently drafted, this section requires a manufacturer to establish and fund an end-of-life/product stewardship program for a product, within 2 years after the Department approves the Final Alternative Assessment. CRA has serious concerns about several provisions within this section.

Under the product stewardship policy adopted by the State of California, the manufacturer is responsible for the cost of establishing and operating a comprehensive end-of-life management program. Retailers are not mandated to participate as collection sites, but may do so depending on their business model, and are reimbursed by manufacturers (i.e. the product stewardship organization) for the cost of participating in the program.

69506.4 (a)(2)(A)3: Manufacturer's EOL Program must delineate the "roles and responsibilities for manufacturers, importers, retailers, consumers and government throughout the lifecycle of the product". One entity (manufacturers) should not have the ability to dictate the roles of other entities in a product stewardship program. Retailers cannot support open-ended cost, liability, transport or other mandates imposed by another entity in the supply chain.

69506.4 (a)(1)(A)4: Manufacturer's EOL Program must contain "identification and description of collection systems that will be used". Retailers oppose the ability of

manufacturers to decide on collection systems that mandate retailer participation, without reimbursement, without regard to the retailer's tradestyle, and without the approval of the retailers who will become the operational arm of the stewardship program. Once again manufacturers are permitted the option to offload responsibility for their products onto retailers, which we absolutely oppose.

69506.4(a)(1)(A)6: "The responsible entity shall provide a financial guarantee mechanism for a sustainable end-of-life management program for the product." We question whether this would permit manufacturers to unilaterally impose a fee at POS as the funding device for the manufacturer's program. If so, we again object to the ability of one segment of the supply chain to impose mandates on another. Any financial mechanism to finance a product stewardship program, as well as the consumer's interface and experience with the mechanism, should only be decided in conjunction with the retail industry.

69506.4(a)(1)(B) On line 18, strike "one or". The sentence in its entirety should read: "The collection program must include **both** of the following: 1. Collection mechanisms; and 2. Compensation to retailers and other persons who agree to administer or participate in the collection program." The "one or both of the following" is apparently a drafting error.

69506.9 (b)4: Retailers are required to receive, from a manufacturer subject to a regulatory response, the "due date for implementing the regulatory response". If the regulatory response involves a stewardship program, a sales restriction or ban, new labeling requirements or signage, we want to be sure the retail industry has sufficient notice and time to comply. There is no time provision set in this section, so the concern is that the information provided to retailers could include the announcement that the regulatory response takes effect in 14 days, or 30 days, or any other timeframe that would be insufficient. We request that the section be amended accordingly: "A description of the required regulatory response(s) and the due date for implementing the regulatory response(s), which in no case shall be less than 90 days from the date of the notification."

69506.4 (b) " Upon request, the responsible entity shall provide to the Department a copy of the product stewardship plan required under this section." This sentence summarizes our overarching concern that the development of product stewardship programs could be developed independently of retailer involvement, DTSC involvement, and public input.

Recommendation:

In addition to the specific recommendations proposed in the subdivisions enumerated above, CRA urges the Department to significantly revise the entire Regulatory Response section of the draft regulations, to assure coordination and approval of stewardship programs among all affected entities.

We also recommend that DTSC partner with the Department of Resources Recovery and Recycling and utilize its expertise and experience with product stewardship models for mercury thermostats, beverage containers, carpet and paint.

To ensure the overall goal of the regulation, specifically the reduction and/or elimination of hazardous products, and ensure that retailers are not adversely impacted by manufacturers' product stewardship plans for priority products, we request that DTSC adopt the Extended Producer Responsibility Framework managed by the California Department of Resources, Recycling and Recovery (accessible at http://www.calrecycle.ca.gov/epr/).

Lastly, we propose that language be added to clarify, as delineated in the Duty to Comply section, that a retailer can opt to fulfill the EOL requirements on behalf of a manufacturer, and a that retailer which ceases to sell a product covered by an EOL program no longer has EOL responsibility.

12. Regulatory Response: RECALL
Section 69506.5(b), page 51, and Section 69501.2 (44), page 12

The purpose of the enabling legislation was to produce new "greener" products, using fewer toxic chemicals in the future manufacture of new and existing products, not to look back and remove existing products from the marketplace. DTSC has no experience with handling product recalls. The recall provision is also contradictory to the retail "off ramp" in the bill that allows sell through of products in the stream of commerce while prohibiting future ordering of product.

Recommendation:

We urge the Department to remove Section 69506.5 allowing for product recalls as a regulatory response. The definition of "inventory recall program" in Section 69501.2 (44) should also be deleted.

Conclusion

Again, CRA acknowledges DTSC's hard work in crafting this groundbreaking regulation. Our intent is to continue to provide the Department with reasonable solutions to address the specifics of the regulation from the viewpoint of creating an operationally workable program.

On behalf of all our member companies, thank you for consideration of our comments. If you have any specific questions regarding them, please contact me at (916) 443-1975.

Sincerely,

Pamela B Williams

Pamela Boyd Williams
Senior Vice President

cc: Ms. Debbie Rafael, Director, DTSC
Ms. Odette Madriago

Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

Alliance of Automobile Manufacturers

American Chemistry Council

American Cleaning Institute

American Forest & Paper Association

California Chamber of Commerce

California League of Food Processors

California Manufacturers & Technology Association

California Paint Council

California Restaurant Association

California Retailers Association

Can Manufacturers Institute

Chemical Industry Council of California

Citizens for Fire Safety Institute

Consumer Healthcare Products Association

Consumer Specialty Products Association

Grocery Manufacturers Association

Industrial Environmental Association

Metal Finishing Associations of Northern and Southern CA

National Paint and Coatings Association

Personal Care Products Council

Plumbing Manufacturers Institute

TechAmerica

Toy Industry Association

Western Plant Health Association

Western States Petroleum Association

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 ("Department") draft Safer Consumer Products Regulation ("draft 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 "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
- Compliance Challenges & Regulatory Treadmill

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

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[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 ~~"~~chemical 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 ~~"~~economic 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 ~~"~~functionally 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.

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[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* ―reliable" is scientifically bankrupt and has the potential to drive controversy into a program that is intended to be science-based. In particular, (C) ―Published in scientifically peer reviewed reports or other literature" is problematic. First, ―other 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) ―Reliable 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 ―reliable 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 ―Information Sources" to include the diverse sources listed in (66) and (67) and then to determine reliability by subjecting those studies to this definition for ―Reliable 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 "Responsible Entity," GCA suggests that the Department adopt a definition of "manufacturer" 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 "manufactured for" or "distributed 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 "safer 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 "safer 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 "sensitive 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 "including, but not limited to…" inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of "sensitive 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 ~~"~~technologically 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 ~~"~~reasonable 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 ~~"~~responsible 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 identification and location of the manufacturers or the importers, 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 todays global marketplace.

It is unclear whether the term replacement product" found in §69501.3(b)(3), refers to an alternative. If so, it we suggest using the term alternative," rather than replacement 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 responsible 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 that 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 necessary" 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~~ecessary 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 "candidate 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.*

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[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 ~~-lis~~t", 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~~trong 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 "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 "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 "reviewed 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 ~~-~~strong 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 ~~"~~pick 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 <u>gradual</u> and <u>measured</u> 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 "flame 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 "potential" 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 ~~-s~~**ignificant**". 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 ~~-fu~~nctionally 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~~xternalized" 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~~A") 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~~efinitive 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 ―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 ―legally 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 "qualification" 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 "necessary 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~~(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 ~~t~~he requirements of the statute." The statute specifies in section 25253(a) that the purpose is ~~t~~o 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 ~~t~~hat 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 ~~t~~o 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 ~~"i~~ndirect 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~~fforts 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: · Carcinogenicity · Reproductive Toxicity · 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: · Carcinogenicity · Reproductive Toxicity · 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: · Bioaccumulation · Persistence	**√ Use. Previously recommended by GMA. In 2009, GMA recommended using the <u>393 priority PBiT chemicals</u>, 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: · 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: · Bioaccumulation/Persistence · 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: · 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: · Carcinogenicity · Reproductive/Developmental Toxicity · 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: · 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: · Toxicological Hazard Traits · Environmental Hazard Traits · 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: · Toxicological Hazard Traits · Environmental Hazard Traits · 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: · Bioaccumulation/Persistence · 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: · Bioaccumulation/Persistence · 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: · 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: · Bioaccumulation · Persistence · 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: · 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: · Reproductive Toxicity · 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: · 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.**

Western States Petroleum Association
Credible Solutions • Responsive Service • Since 1907

Catherine H. Reheis-Boyd
President

January 13, 2012

Via email: hjones@dtsc.ca.gov

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

RE: Comments on Safer Consumer Products (SCP) Informal Regulations

Dear Ms. Jones:

The Western States Petroleum Association (WSPA) is a trade association representing twenty-seven companies that explore for, produce, refine, transport, and market petroleum and petroleum products and natural gas in California, Arizona, Nevada, Hawaii, Oregon and Washington. Our companies have extensive operations within California and are significantly affected by the regulations currently proposed by the Department of Toxic Substances Control (DTSC). Because of the substantial impact on WSPA members, the economy, and likely potential impact on energy supplies, WSPA has been an active participant in the public policy discussions about the implementation of DTSC's Safer Consumer Product Alternatives Regulations (Safer Consumer Product regulations) and submitted comments to you in October, 2010 and again in November, 2010.

We recognize that the primary goals of this regulation, set forth in AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008) are to protect human health and the environment, in part by avoiding regrettable substitutions of one chemical in a consumer product for a more deleterious one. Throughout the process to develop these regulations, the DTSC has stated the regulations must be practical, meaningful and legally defensible to achieve these goals.

WSPA members support policies that protect environmental and public health, such as those underlying AB 1879 and SB 509. We agree with the DTSC that if the regulations are not practical, meaningful and legally defensible, they will not achieve the objectives of AB 1879 and SB 509. Instead, it will likely have the opposite and unintended effect of impairing innovation

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and improvement by creating needless uncertainty and adding unnecessary barriers to market entry of safer and "greener" products.

To assure that the regulations do not result in unintended adverse impacts upon human health and the environment, we suggest that the DTSC focus on products where significant regulatory gaps are present that truly warrant more stringent regulation by the DTSC. This will limit the potential for negative unintended consequences associated with unwarranted over-regulation while preserving limited financial resources for all stakeholders, including consumers and the DTSC.

Below, we summarize the major concerns and identify where the informal regulations may be modified to better achieve the objectives of AB 1879 and SB 509. The order of our concerns below is not based upon the relative importance of each, but upon the sequence of the relevant sections of the informal regulation. In addition, WSPA also concurs with a number of other comments raised by the Green Chemistry Alliance (GCA) and other trade groups regarding the draft informal regulations.

Summary of WSPA's Major Concerns with the Informal Draft Regulations

1. A Simpler More Flexible De Minimis Process is Warranted

   Section 69503.4(a) eliminates the requirement to perform an Alternative Analysis (AA) and any further regulatory action if the Chemical(s) of Concern (COC) that is the basis for listing the consumer product as a Priority Product does not exceed a "de minimis level". The DTSC has also proposed the use of up to three de-minimis values as part of this process. [1] However, two of the three values are generic default values (0.01% by weight[2] and 0.1% by weight[3]) which are applicable to every Priority Product unless the DTSC derives a unique COC/product-specific de minimis value. The third method, a unique COC/product-specific de minimis value, may be larger or smaller than the generic default values and is permissible only if multiple criteria are satisfied.[4]

   We agree with the use of a generic default de minimis value of 0.1% as it is harmonized with other international standards used for similar purposes, while the other default de minimis value of 0.01% does not achieve harmonization and is unreasonably low. We also agree that it is critical to have the ability to derive unique alternative COC/product specific de minimis values based upon potential adverse impacts to human health or the environment. However, the criteria permitting the use of alternative COC/product specific de minimis values are too constrained, complex, and confusing. To simplify the process, we believe that only one of these criteria merits consideration and, suggest the sole criterion be, "*the maximum concentration of the COC identified as the basis of listing the product as a Priority Product that the DTSC determines does not pose significant potential adverse public health or environmental impacts*". No other requirement is needed.

[1] Three de minimis levels are identified at §69501.2(a)(25)
[2] §69501.2(a)(25(A)
[3] §69501.2(a)(25(B)
[4] §69501.2(a)(25(C) and §69503.4(c)

We show our proposed changes to text in our detailed comments (Attached).

2. Only One Criterion is Warranted to Justify No Regulatory Action Determination

   Section 69506.2 of the informal regulations identifies two criteria, that when satisfied, obviate the need for regulatory response. The first criterion is that the selected alternative does not exceed the de minimis level[5] and the second criterion is that the "selected alternative does not pose significant potential adverse public health or environmental impacts."[6] We believe that only one criterion is needed to achieve the objectives AB 1879 and SB 509 and that is, "*the selected alternative does not pose significant potential adverse public health or environmental impacts*". We note that use of the criterion in this manner is consistent with the basis for identifying a COC/product-specific de minimis level and for determining when no action is warranted. It would seem clear that the application of consistent criteria assures protection of public health and the environment with consistent regulatory outcomes. The simplified approach defined above is shown in our detailed comments (Attached).

3. Focus Alternatives Analysis by Using Consistent Terms.

   DTSC staff at recent workshops and Green Ribbon Science Panel meetings have indicated that the DTSC intends to apply the Safer Consumer Product regulations in a manner focusing upon the potential impacts posed by the Chemical(s) of Concern identified as the basis for listing the consumer product as a Priority Product. However, the text in several sections of the informal regulations uses similar terminology that could be interpreted to expand the scope of the AA beyond that indicated by DTSC staff. For example, the term "*Chemical(s) of Concern*" is used in several sections in Articles 3, 5, and 6, while another term, "Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product", is used elsewhere. We request the DTSC to use the latter term consistently in this section and throughout these Articles as shown in our Attachment.

4. The Safer Consumer Product Regulation Must Provide Adequate Protection of Confidential Business Information and Intellectual Property (CBI/IP)

   It is essential to provide adequate legal safeguards to protect confidential business information (CBI) and intellectual property (IP) created in the product development and improvement process. Such protection ensures that product innovation and advancement occurs as part of the Safer Consumer Product development process. Failure to do so will likely have the unintended consequence of stifling product improvement and "green" innovation while causing avoidable litigation between the DTSC and regulated entities. We suggest the DTSC carefully consider the comments in our Attachment.

5. Certified Assessors are Unnecessary

[5] §69506.2 (a)
[6] §69506.2 (b)

We believe the shift away from an additional mandatory third-party review of Alternative Assessments (AAs) proposed in prior versions of the regulations is a positive change. However, we believe that the shift to use of certified assessors is unfounded as the DTSC has failed to substantiate the need for certified assessors. We do not believe 3rd party review nor certified assessors are necessary to assure the accuracy and adequacy of AA reports. Instead, we suggest that the DTSC become the principal reviewing authority for the regulations. Should a manufacturer (or other entity) dispute the findings of the agency, then some provision should be made for resolution of the dispute, including, perhaps, qualified impartial 3rd party verification. However, such 3rd party review should be the exception rather than the rule. In any event, any DTSC review of AAs, through whatever process is eventually chosen, must ensure that CBI/IP is protected in perpetuity.

WSPA appreciates the opportunity to comment on the informal regulations. Should you have any questions, feel free to contact me or Mike Wang (mike@wspa.org or 626-590-4905).

Sincerely,

Cc: Ms. Debbie Rapahel (DRaphael@dtsc.ca.gov)
Mike Wang
Jeff Sickenger

Attachment: Discussion of WSPA Comments and Proposed Changes to Informal Regulations

Attachment: Discussion of WSPA Comments and Proposed Changes to Informal Regulations

1. A Simpler More Flexible De Minimis Process is Warranted

Section 69503.4(a) eliminates the requirement to perform an AA and ultimately any further regulatory action provided the COC(s) that were the basis for listing the consumer product as a Priority Product do not exceed a "de minimis level". Three de minimis levels are identified at §69501.2(a)(25). Two of the three values are generic default values applicable to every Priority Product unless the DTSC states otherwise, 0.01% by weight[7] (100 parts per million [ppm]) for COCs identified as exhibiting specific "environmental or toxicological endpoints" and 0.1% (1,000 ppm) for all other chemicals.[8] The third value is an alternative COC/product-specific de minimis value that the DTSC may establish on an ad hoc basis that can be larger or smaller than the generic default values provided multiple criteria are satisfied.[9]

It is our understanding that the purpose of the de minimis exemption[10] is to provide administrative convenience to both the DTSC and regulated entities by reducing unnecessary regulatory burden on those products because they are presumed to not pose significant potential adverse public health or environmental impacts. Unlike chemical-specific MADLs, NSRLs, or PRGs which are science-based values derived using a number of exposure assumptions and the inherent toxicological properties of the chemical, the default de minimis values of 0.01% and 0.1% appear to be purely arbitrary policy decisions as there is no justification, scientific or otherwise, provided by the DTSC for the derivation and selection of the default values.

We agree with the use of a generic default de minimis value of 0.1% as it is consistent with other international standards used for similar purposes. Conversely, the arbitrary generic default value of 0.01% for Priority Products containing COCs exhibiting specific "environmental or toxicological endpoints" is inconsistent with international standards, such as the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program, and is unreasonably low based upon the considerations discussed

[7] §69501.2(a)(25(A)
[8] §69501.2(a)(25(B)
[9] §69501.2(a)(25(C) and §69503.4(c)
[10] Presumably the concept of the de minimis exemption is based in part upon the legal principle of *de minimis non curat lex* – "the law does not concern itself with trifles"; e.g., a fact so insignificant that a court will overlook it in deciding an issue or case. Other regulatory programs incorporate a similar principle in the context of "acceptable risk" based upon a specific quantitative value for risk, such as the Maximum Acceptable Daily Level (MADL) and No Significant Risk Levels (NSRLs) to determine if potential exposure is "significant" (greater than 1/100,000 for carcinogens or 1/1000th the No Observed Effect Level) for Proposition 65, Preliminary Remediation Goals (PRGs; target cancer risk for carcinogens = 10^{-6} and target Hazard Quotient for non-carcinogens = 1) used to identify chemicals of concern present at remediation sites under the federal Superfund program and state remediation programs (target cancer risk for carcinogens = 10^{-6} and target Hazard Quotient for non-carcinogens = 1) , the contained-in policy for listed hazardous waste constituents to identify hazardous waste in the federal Resource Conservation and Recovery Act program, etc. We believe that the objectives of these programs are consistent with those of AB 1879 and SB 509. Thus, these programs may offer guidance to the DTSC as it develops unique COC/product-specific de minimis values.

in the GCA comment letter. At minimum, an explanation by the DTSC of the policy and technical considerations supporting the generic default de minimis values is warranted to enhance the transparency of the regulatory basis for these values because no justification is provided by the DTSC. As a result, both values appear to be arbitrary.

We also agree that it is critical to have the ability to derive unique alternative COC/product specific de minimis values based upon potential adverse impacts to human health or the environment. However, the criteria permitting the use of alternative COC/product specific de minimis values are too constrained, complex, and confusing. To simplify the process, we believe that only one of these criteria merits consideration and, suggest the sole criterion be, "*the maximum concentration of the COC identified as the basis of listing the product as a Priority Product that the DTSC determines does not pose significant potential adverse public health or environmental impacts*". No other requirement is needed.

We can find no rational reason to require the performance of an AA if the Priority Product can be demonstrated to not pose significant potential adverse public health or environmental impacts. Consequently, all the other conditions and criteria for decreasing or increasing the de minimis level set forth in §69503.4(c) are irrelevant for attaining the objectives of AB 1879 and SB 509 in a cost-effective manner while avoiding unnecessary duplicative regulation. Moreover, this single simple criterion is consistent with the criterion set forth at §69506.2(b) that specifies the condition warranting no additional regulatory response while providing a practical, meaningful and legally defensible means to achieve the objectives of AB 1879 and SB 509.

We also suggest that the DTSC develop guidance for deriving alternative COC/product-specific de minimis values in conjunction and consistent with the AA guidance documents identified in §69505. This will enhance regulatory transparency and allow stakeholders to provide input to the DTSC in developing and identifying alternative COC/product-specific de minimis values for prospective Priority Products containing specific COCs that are anticipated to be the basis for listing. Assuming the DTSC develops and promulgates alternative COC/product-specific de minimis values for Priority Products in the future, it is appropriate and necessary for the DTSC to include an explanation of the basis and scientific rationale for the alternative COC/product-specific de minimis value.

We suggest the following changes to the proposed informal regulation to reduce the complexity and potential ambiguity,[11] and apply symmetrical conditions to either decrease or increase the alternative COC/product-specific de minimis level:

§ 69503.4. De Minimis Exemption

(a) *All references in this section to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.*

[11] "See Point 3 below requesting changes to clarify potential ambiguity created by the use of similar terms "Chemical(s) of Concern" and "Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product" in various sections of the informal regulation.

(~~c~~ *d*)(1) The Department may specify a de minimis level that is lower or higher than the level specified in subparagraph (A) or (B) of section 69501.2(a)(25) for the Chemical of Concern in the Priority Product, if the Department determines based on available information that a lower or higher de minimis level is warranted. *The specified de minimis level shall be the maximum concentration of the COC identified as the basis of listing the product as a Priority Product that the Department determines does not pose significant potential adverse public health or environmental impacts.*

(2) ~~The Department may specify a lower de minimis level if one or both of the following criteria apply:~~

~~(A) The Chemical of Concern is found in concentrations at or below the level specified in subparagraph (A) or (B) of section 69501.2(a)(25), whichever is applicable, in products that are common and are frequently used, and reliable information shows that, even when individual product concentrations of the Chemical of Concern are below the de minimis level,there is the potential for adverse impacts from potential exposures to the Chemical of Concern, or releases of the Chemical of Concern, due to one or more of the following:~~

~~1. Potential aggregate or cumulative exposures;~~

~~2. The inherent potency of the Chemical of Concern;~~

~~3. Potential bioaccumulation; or~~

~~4. The unintended presence of the Chemical of Concern in organs, tissues, or fluids.~~

~~(B) Reliable information shows the Chemical of Concern poses, or potentially poses, adverse impacts in concentrations at or below the level specified in subparagraph (A) or (B) of section 69501.2(a)(25), whichever is applicable.~~

~~(3)(A) The Department may specify a higher de minimis level if all of the following criteria apply:~~

~~1. The source of the Chemical of Concern is one of the following:~~

~~a. A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product;~~

~~b. Air or water frequently used as a processing agent or an ingredient to manufacture the product;~~

~~c. A contaminant in recycled materials that are common and are frequently used to manufacture the product; or~~

~~d. A processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended;~~

~~2. The concentration of the Chemical of Concern in the Priority Product does not exceed the concentration of the Chemical of Concern in the source; and~~

~~3. The Chemical of Concern cannot reasonably be removed from the product.~~

~~(B) The Department may not specify a higher de minimis level if this would result in increased adverse public health or environmental impacts.~~

2. Only One Criterion is Warranted to Justify No Regulatory Action Determination

Section 69506.2 states that no regulatory response is required for the selected alternative if two criteria are both satisfied. The first criterion set forth at §69506.2 (a) is that the

> "selected alternative does not contain a Chemical of Concern in a concentration exceeding the de minimis level. If the selected alternative contains multiple Chemicals of Concern, the total concentration of all Chemicals of Concern exhibiting the same hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed the de minimis level."

The second criterion set forth at §69506.2(b) is that the "selected alternative does not pose significant potential adverse public health or environmental impacts."

We agree that the regulations must identify the criteria for determining no regulatory response is justified for the selected alternative; however, only a single criterion is necessary to achieve the objectives of AB 1879 and SB 509. We feel that the single criterion should be **"***that the selected alternative does not pose significant potential adverse public health or environmental impacts* "– which is the same criterion used as the basis for identifying a COC/product-specific de minimis level.

Using the same criteria for both identifying COC/product-specific de minimis values and determining when no regulatory response is required for the selected alternative is logically consistent and results in an internally coherent Safer Consumer Product program. Failing to properly integrate the criteria for both identifying COC/product-specific de minimis values and when no regulatory response is required for the selected alternative will likely result in many inconsistent regulatory outcomes that will require the use of limited DTSC resources to redress the inconsistencies and other associated problems created.

In our view, §69506.2(a) is unnecessary if the selected alternative does not pose significant potential adverse public health or environmental impacts as it is irrelevant whether the selected alternative contains a COC or the sum of multiple COCs at a concentration exceeding an arbitrary generic default de minimis level. By requiring satisfaction of both §69506.2(a) and (b), the DTSC is regulating consumer products beyond the point that the DTSC itself has concluded do not pose significant potential adverse public health or environmental impacts. We can find no rational reason for the DTSC to impose additional and unwarranted regulation to such products.

As discussed above, no scientific basis was identified as demonstrating that any one chemical (let alone the tens of thousands of COCs present on the various lists specified in §69502.2), does in fact pose significant potential adverse public health or environmental impacts if

present at 0.01% or 0.1% in any (or everyone) of the tens of millions of consumer products potentially subject to this regulation. It does not seem reasonable or prudent for the DTSC to establish a permanent ceiling concentration for all COCs in every consumer product at the very inception of the Safer Consumer Product program based upon arbitrary and non-scientifically derived generic default de minimis values.

However, basing the ceiling level of a particular COC upon a product-specific de minimis value derived through a scientifically-based exposure/risk assessment process is reasonable provided that that the de minimis value for the same COC in the same product was, itself, based upon the criterion that the concentration of the COC(s) does not pose significant potential adverse public health or environmental impacts. Regardless, we suggest the DTSC consider the proposed changes to §69506.2 below to avoid limiting the discretion of the DTSC to implement the Safer Consumer Product program:

§ 69506.2. No Additional Regulatory Response Required

No regulatory response under sections 69506.3 through 69506.6 is required for the selected alternative, if the Department determines, after review of the Final AA Report, that *the selected alternative does not pose significant potential adverse public health or environmental impacts*. ~~both of the following criteria are met:~~

~~(a) The selected alternative does not contain a Chemical of Concern in a concentration exceeding the de minimis level; and, if the selected alternative contains multiple Chemicals of Concern, the total concentration of all Chemicals of Concern exhibiting the same hazard trait, or environmental or toxicological endpoint, and mode of action does not exceed the de minimis level.~~

~~(b) The selected alternative does not pose significant potential adverse public health or environmental impacts.~~

If this suggestion is rejected, at a minimum, we request the DTSC clarify §69506.2 to assure the evaluation is upon the COC(s) identified as the basis of listing the Priority Product at issue, rather than possibly all COCs present in the Priority Product. We propose the following minor clarifications to §69506.2(a) to focus the AA upon the COC(s) identified as the basis of listing the Priority Product at issue:

§ 69506.2. No Additional Regulatory Response Required

No regulatory response under sections 69506.3 through 69506.6 is required for the selected alternative, if the Department determines, after review of the Final AA Report, that both of the following criteria are met:

(a) The selected alternative does not contain a Chemical of Concern *identified as the basis of listing the Priority Product* in a concentration exceeding the de minimis level; If the selected alternative contains multiple Chemicals of Concern *identified as the basis of listing the Priority Product*, the total concentration of all Chemicals of Concern *identified as the basis of listing the Priority Product* exhibiting the same hazard trait, or

environmental or toxicological endpoint, and mode of action does not exceed the de minimis level.

3. Focus Alternatives Analysis by Using Consistent Terms

The communications by various DTSC staff at recent workshops and Green Ribbon Science Panel meetings indicates the DTSC intends to apply the Safer Consumer Product regulations in a manner focusing upon the potential impacts posed by the Chemical(s) of Concern identified as the basis of listing the consumer product as a Priority Product, rather than all potential adverse impacts associated with the product in general. The DTSC has stated that they intend to identify the "worst" product categories in the initial set of Priority Products based upon product use patterns coupled with the presence of specific COCs, e.g., the aim is to target the "worst-first". The means used to focus upon the potential adverse impacts attributable to the presence of the COC(s) identified as the basis of the listing of the Priority Product is by requiring performance of an AA followed by a logically consistent regulatory action selected to mitigate the potential adverse impacts attributable to that COC(s) in the Priority Product that were identified in the AA. We agree with this approach.

However, the text of the informal regulation could be interpreted to mandate a much broader evaluation and AA resulting in potentially more burdensome, time-consuming, and costly regulatory actions than indicated in communications from the DTSC. As a result of this apparent disparity between communications by DTSC and the text of the informal regulation, we offer comments on two primary topics in an effort to reconcile the apparent disparity. The first concern is the potential ambiguity introduced by the use of two similar terms, "Chemical(s) of Concern" and "Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product", a more limited qualified term. The second concern is the unnecessarily broad scope of the AA.

a. Minimize Potential Ambiguity Introduced by the Use of Similar Terms

In several sections in Articles 3, 5, and 6 the term "Chemical(s) of Concern" is used, while another similar term, "Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product" is used elsewhere in these sections. Based upon communications by various DTSC staff at recent workshops and Green Ribbon Science Panel meetings, the DTSC is directing regulated entities to focus analysis, alternative development, and its subsequent regulatory actions upon the specific COC(s) that was the basis of identifying specific products as Priority Products. For example, if nail polish was identified as a priority product because of the presence of formaldehyde (a carcinogen) other chemicals that are on the COC list may be used in lieu of formaldehyde, such as toluene, provided the formaldehyde is removed and the alternative poses no greater cancer risk than the baseline product.

To eliminate the potential ambiguity associated with the use of these two similar terms, we request the DTSC make the following changes:

§ 69503.3. Priority Products List

(a)(1) The Department shall use the procedures specified in this section and the factors specified in section 69503.2 to identify and list products as Priority Products.
(2) The Department shall specify in the proposed and final Priority Products lists the following for each listed product:
(A) The Chemical(s) of Concern that is/are the basis for the product being listed as a Priority Product.
(B) The de minimis level for the Chemical(s) of Concern *that is/are the basis for the product being listed as a Priority Product*.

§ 69503.4. De Minimis Exemption[12]
(a) All references in this section to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.
(~~a~~ *b*) A responsible entity is exempt from the requirements of article 5 with respect to a product that is listed as a Priority Product and that meets the criteria for a de minimis exemption specified in subsection (b), if one of the responsible entities for the product submits a complete and timely De Minimis Exemption Notification to the Department pursuant to section 69503.5, unless subsection (d) or (e) of section 69503.5 applies.

§ 69505.3. Alternatives Assessment: First Stage
(a) All references in this *article* ~~section~~ to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.

§ 69506. Applicability
(a) The requirements of this article apply to any alternative selected pursuant to section 69505.4(c) that is placed into the stream of commerce in California. These requirements also apply to the Priority Product if an alternative is not selected, or if the Priority Product will remain in commerce pending development and distribution of the selected alternative.
(b) All references in this article to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.

b. Require Only Relevant Information Necessary to Mitigate Potential Adverse Impacts Attributable to the COC Identified as the Basis for Listing as a Priority Product

The DTSC's intent of the AA is limited to identifying the potential adverse impacts not subject to regulation by other agencies that are attributable to the presence of the COC(s) identified as the basis of the listing of the Priority Product (baseline condition). In the AA, the identified impacts of the baseline condition are compared to those impacts identified for the various alternatives considered, and the most appropriate alternative is

[12] Assuming the request to use a single criterion for the de minimis exemption discussed in Point 1 above is denied by the DTSC.

selected. We also understand that the DTSC does not intend to require the AA to evaluate other potential adverse impacts attributable to characteristics of the product other than the COC identified as the basis of listing, such as potential adverse impacts attributable to other ingredients in a product, the methods of production of the product, its packaging, its means of transport through the supply chain, etc.

Based on our understanding above, a number of provisions in §§ 69505.3, 69505.4, and 69505.5 request information that we believe is irrelevant and unnecessary to perform a focused AA. We have identified proposed modifications to the text of §§ 69505.3, 69505.4, and 69505.5 below consistent with our concerns.

§ 69505.3. Alternatives Assessment: First Stage

(a) All references in this *article* ~~section~~ to "Chemical(s) of Concern" mean the Chemical(s) of Concern that is/are the basis for the product being identified as a Priority Product.

§ 69505.4. Alternatives Assessment: Second Stage

The second stage of the AA shall include all of the following steps:

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.

(2) The responsible entity shall collect and use available quantitative information.

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

§ 69505.5. Alternatives Assessment Reports

(a)(1) The Preliminary and Final AA Reports must include, as applicable, all of the information specified in subsections (b) through (~~n~~ *m*).

~~(d) Supply Chain Information.~~

~~(1) The name of, contact information for, and headquarters location of the manufacturer(s) and the importer, if applicable, and, if the AA Report is prepared on behalf of a consortium of manufacturers or other persons in the Priority Product's supply chain, a list of the participants along with their corresponding contact information;~~

~~(2) The name of, and contact information for, the person identified on the product label as the manufacturer, and the person, if any, identified as the distributor, if different from paragraph (1);~~

~~(3) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months; and~~

~~(4) Identification and location of the manufacturer's and/or importer's retail sales outlets where the manufacturer and/or importer sold, supplied, or offered for sale the product in California, if applicable.~~
~~(e) Facility Description and Location. A description and location of the facility(ies) where the Priority Product is produced. This description must also indicate the proximity to raw or recycled materials that directly or indirectly influences the type and amount of Chemical(s) of Concern in the Priority Product~~

(~~h~~ *g*) Supporting Information

(2) The Final AA Report must include the identification of unavailable reliable information *known to the preparer of the AA* that, if available, could be used to:

(B) Address any *significant outcome determinative* uncertainties in the analyses conducted pursuant to sections 69505.3(b) and 69505.4; and

(C) Ensure that the list of chemical ingredients *that differ from the chemical ingredients in the Priority Product or that are present in the selected alternative at a higher concentration than in the Priority Product* required to be identified for the Priority Product and its alternatives during the conduct of the AA and the preparation of the AA Reports is complete.

(~~i~~ *k*) Selected Alternative. The Final AA Report must identify and describe …

(3) A demonstration that the manufacture, use, and disposal of the selected alternative, in conjunction with any regulatory response(s) proposed pursuant to subsection (n), will have no greater significant adverse public health or environmental impacts *that are not addressed by other federal and California State regulatory programs that were considered in the AA* than *such* ~~the~~ impacts associated with the Priority Product. For purposes of this paragraph only, "environment", as it pertains to California's environment, means "environment" as defined in section 21060.5 of the Public Resources Code.

4. The Safer Consumer Product Regulation Must Provide Adequate Protection of Confidential Business Information and Intellectual Property (CBI/IP)

In order to advance the principles of the Safer Consumer Product regulations associated with product improvement, including "green" technological innovations, it is essential to provide adequate legally enforceable safeguards to protect the confidential business information and intellectual property (CBI/IP) inherent in product improvement and innovation as one of several critical incentives.

As nearly all the regulated entities are for-profit businesses, product improvement and "green" technological innovation will be hindered without these safeguards to effectively protect CBI/IP because the economic risk and costs of developing improvements and innovation will likely exceed the future downstream financial benefits of such improvements or innovation. Consequently, failure of the Safer Consumer Product regulations to effectively protect CBI/IP will likely produce the unintended consequence of stifling product improvement and "green" innovation.

We are concerned that the informal regulations fail to adequately protect CBI/IP for several reasons. First, § 69501.6 requires the DTSC to post a much information contained a variety of documents on its website, including de minimis notifications[13], preliminary and final AA reports[14], and notices from manufacturers, importers, and retailers that they no longer place the product into the stream of commerce in California.[15] The information contained in these documents that will be posted on the DTSC website will likely contain CBI/IP. Considering the lack of both procedural and predictable substantive protection accorded to CBI/IP for the reasons described below, it seems likely that CBI/IP may be disclosed via the DTSC website – something that must be avoided.

Second, in order to assert a claim to trade secret protection, the regulated entity must provide a vast amount of disparate information and documents to satisfy the many detailed requirements contained in the two pages of text that make up §69510. Satisfying every requirement in §69510 will require a great deal of time, effort, and resources by regulated entities; it may ultimately be infeasible to do so for some businesses given resource constraints. The DTSC has provided no basis indicating all of the information and documentation required in §69510 is necessary to assert a claim of trade secret protection. Moreover, the scope of what qualifies for trade secret protection appears to be unjustifiably narrow. Therefore, we believe the hurdles necessary to assert a successful claim of trade secrecy per §69510 is unduly burdensome.

We also have serious concerns about the uncertainty associated with the criteria to be applied by the DTSC in its review of trade secrecy claims as described in §69510.1, including the opportunity to cure deficiencies, timing to complete review, predictability in outcome, and appeal. Furthermore, it is unclear how inappropriate disclosure of CBI/IP would be remedied by the DTSC. Considering the lack of procedural and substantive predictable protection of CBI/IP in conjunction with the requirement to post documents which are likely to contain CBI/IP on the DTSC website, we are not confident that the informal regulations will adequately protect CBI/IP.

We suggest the DTSC carefully consider the comments above and those from others that have many years of experience in product development that can provide information on the importance of effectively protecting CBI/IP. Failure to do so will likely have the unintended consequence of stifling product improvement and "green" innovation while causing

[13] §69501(a)(5)(D)(1)
[14] §69501(b) (4) and (5)
[15] §69501(b) (1) referring to notices provided by such entities at §69501.3(b)(c)

avoidable litigation between the DTSC and regulated entities. We look forward to working with the DTSC to address our concerns regarding adequately protecting CBI/IP.

5. The Certified Assessors Requirement Should be Eliminated

We believe the shift from an additional mandatory third-party review of AAs included in prior proposed versions of the regulations is a positive change. However, we believe that the certified assessor requirement is fraught with many problems and should be eliminated. Certified assessors are unnecessary, particularly considering the numerous expert professionals that have decades of experience working in product development and innovation already demonstrated by the regulated entities. In fact, DTSC has not provided any data demonstrating certified assessors are necessary to assure the accuracy and adequacy of AA reports.

This seems even more apparent because even DTSC itself has concluded that certified assessors are not needed at the inception of this program when experience is lowest – and will not be needed until January 1, 2015.[16] Then, in an even more paradoxical shift, the TSC concludes that certified assessors are warranted starting January 1, 2015 – after experience with the AA process may have made the need for certified assessors moot.

In other words, by including the certified assessor requirements in Article 8, the DTSC implicitly acknowledges it is incapable of adequately administering the Safer Consumer Product regulations. Yet, by its own proposal, prior to January 1, 2015, the DTSC alone will be reviewing and approving all AA reports and related documents. Even more problematic, to date the DTSC has not provided any information that it is incapable of implementing the Safer Product regulations. Consequently, there appears to be more than adequate ability for the DTSC to assure the accuracy and adequacy of AA reports without the imposing the unduly burdensome certified assessor requirement.

Apart from the lack of necessity for this certified assessor program, the informal regulation fails to provide adequate safeguards for both prospective certified assessors as well as the CBI/IP contained in the AA reports and related documents prepared by and accessible to the certified assessors. One such problem is the mandatory waiver of the rights of prospective certified assessors to provide access to potentially confidential information to the accreditation body and accompanying lack of procedural protections for the assessors. Section 69508.2(c)(1)(F) requires among other things, for prospective certified assessors to authorize educational institutions and all employers identified in the certified assessor enrollment application to release any information that the educational institutions and employers possess to the certified assessor accreditation body to which the prospective certified assessor is applying, and to the State of California.

Another flaw in the certified assessor program is the lack of adequate safeguards for CBI/IP. The accreditation body designation requirements[17] mandate that it audit all the assessors it

[17] §69508.2(c)(7)(C)

certifies. This mandate has the possibility of requiring disclosure of protected CBI/IP to accreditation bodies and their agents. This is problematic for the following reasons:

- The information for review is likely to be the property of the regulated entity for which the assessor drafted the AA report; therefore, the accreditation body does not have the right to review the report even with the waiver.
- The assessor may have executed confidentiality and non-disclosure agreements with the regulated entity, thereby preventing the voluntary release of the information by the assessor to the accreditation body without prior approval of the regulated entity even if the regulated entity doesn't "own" the information.
- The regulation fails to identify any procedural safeguards governing notification to the regulated entity that in all likelihood actually "owns" the report and information contained therein that is sought by the accreditation body, and the process by which the "owner" of the report can contest its release to the accreditation body.
- The regulation also fails to identify any substantive protections and penalties to be imposed upon the accreditation body and its agents for the improper use, dissemination, and disclosure of the CBI/IP and related sensitive information.

The certified assessor requirement is fraught with many problems and should be eliminated. Should DTSC nonetheless disagree, we urge the DTSC to:

- Provide the information describing why the certified assessor program is essential to the implementation of the Safer Consumer Product program in order to promote transparency;
- Require all DTSC staff reviewing the AAs to also be certified; and
- Delay implementation of the Safer Consumer Product regulations until a sufficient number certified assessors are available to support both the DTSC and the regulated community to implement the Safer Consumer Product regulations.

CPSC
California Product Stewardship Council SM

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916-706-3420

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(IC)89-California Product Stewardship Council

January 23, 2012

Debbie Raphael, Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814-2828

Subject: Comments on Green Chemistry Regulations and Take It Back Program Status

Dear Director Raphael:

I am writing to provide input on the Department of Toxics Substances Control's (DTSC) Take it Back (TIB) Program to you in your new role as Director of DTSC, and, in particular, how Californians can benefit from the lessons provided by this voluntary program. We feel that the results of the TIB program make the case to have strong Extended Producer Responsibility authority maintained in the Green Chemistry Regulations.

I know you are familiar with the California Product Stewardship Council (CPSC) but as general background, CPSC is a California based non-profit comprised of businesses, local governments and their associations, individuals and others working with product manufacturers and partnering with them to encourage a stewardship approach to product management. Product stewardship is when the producer designs, funds, and operates collection and end-of-life management systems for their products or implements design changes to reduce the lifecycle impacts of that product or package. CPSC has supported the adoption of 125 local government resolutions in support of product stewardship and is the leader in California education and outreach efforts on Extended Producer Responsibility (EPR). A complete listing of our partners is attached.

The TIB program was developed in 2006 to help increase the visibility of new locations collecting universal waste in California and to encourage voluntary collection of universal waste by business and other entities in addition to local government. A website was created at CalRecycle http://www.calrecycle.ca.gov/HomeHazWaste/Collection/Intake.asp with a form for businesses who wanted to sign up to accept universal waste, which helped populate the "Electronic Products Management Directory" database at this website. While CalRecycle hosted the site, DTSC was to verify the information provided by businesses and send it to CalRecycle for inclusion in the database.

However, we and others have found that DTSC has not effectively verified or updated the location information submitted by businesses and, as a result, CalRecycle decided not to maintain the site's link to the TIB Program. It also seems that there is no activity with this partnership on DTSC's end, while some entities are still using the TIB logo. We have experienced this first-hand as we have tried to get information from DTSC staff on how to use the program to promote our battery and lamp collection projects in Del Norte County, San Gabriel Valley in Los Angeles, and Napa County.

Given that the DTSC website http://www.dtsc.ca.gov/TIB/index.cfm has a bad link for this program, and that DTSC staff are unable to answer questions about the program and who is responsible for it, we respectfully suggest that if the TIB network is no longer actively maintained, the program description be removed from the DTSC website.

We also request that DTSC work with CalRecycle staff to develop a final report outlining the goals and costs to setup and manage this voluntary take-back program, the results from the program in terms of new universal waste collection locations in California and public education to support them, and lessons learned from this program so the entire state can benefit from the program's experience.

As supporters of EPR, we are very grateful to the state for establishing a voluntary take-back program for universal waste and know that the results will provide solid data to use in determining what the cost/benefits are for future programs be they voluntary or mandatory. We need to summarize and publicize the findings of this publicly funded program so all stakeholders can benefit from the program results. **We also believe the findings will support the EPR portion of the Green Chemistry regulations and the need for a mandatory approach to take-back for some product types.**

Which leads us to our second issue; comments on the Green Chemistry regulations.

CPSC has met with the two previous directors of DTSC a total of four times to express our interest in preserving DTSC's authority to require a meaningful producer responsibility collection program for products banned from disposal. We have sent four letters dating back to July 2009 on our concerns and testified at hearings on subject, yet many of our comments are still not addressed in the latest version of the Informal Draft Regulations dated October 31, 2012.

The following are our key issues with the current draft regulations:

1) Section 69506.4 (a) (2) - Providing two years for the products to develop and implement a product stewardship program is too long and we recommend that be reduced to one year.

2) Section 69506.4 (a)(2)(A)(7) – Currently reads that the producers will outline their program performance measures but in a true EPR program the government sets the performance goals and the producers state how they will meet those goals.

3) Section 69506.4 (a)(2)(D). The current language required a report by the producers on the program only every two years, and typically, they are required annually and called "annual reports". We believe it is reasonable and necessary to require annual reports as is required all over the world in EPR systems, especially for toxic products banned from disposal.

4) Section 69506.4 (a)(2)(D)(2)(d) – This section should be removed. There is not a single instance in the world that we are aware of that when a company that makes and distributes a product into the chain of commerce has no possibility of recovering it. That assumes that local governments and others could not possibly recover that product either which means that toxic products that cannot find safer substitutes are being sold knowing they will result in pollution.

I am happy to discuss any of these comments with you and we are very glad that EPR is a part of the green chemistry regulations in light of all the industry opposition even though the same companies operate in these systems all over the world. We are well aware of the many challenges in developing these regulations and greatly appreciate the efforts of the department to complete them in 2012. Thank you very much for your consideration.

Sincerely,

Heidi Sanborn, Executive Director

CPSC
California Product Stewardship Council SM

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www.CalPSC.org

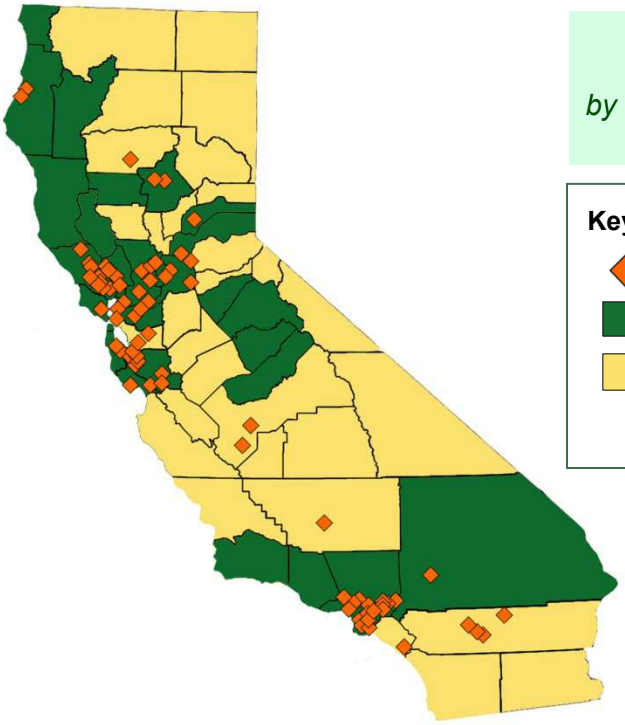
Who is CPSC?

The California Product Stewardship Council (CPSC) is a coalition of local governments and their associations related to solid waste, recycling, resource conservation, environmental protection, water quality, and other cross-media issues (Associates).

In Partnership with non-government organizations (NGOs), businesses, and individuals (Partners) across California, CPSC has created a powerful network of people supporting product stewardship and extended producer responsibility (EPR).

CPSC Associates

Map of CPSC Associated Counties and Cities with EPR Resolutions



As of October 24, 2011
122 resolutions have been passed
by California local jurisdictions and organizations supporting product stewardship!

Key to Map:

- City has passed an EPR resolution
- County has individually passed an EPR resolution
- County is a member of an association[1] that has passed an EPR resolution or policy statement, but has not individually passed an EPR resolution

[1] California State Association of Counties (CSAC) or Regional Council of Rural Counties' Environmental Services Joint Powers Authority (ESJPA)

Local Government Agencies Participating by Pledge, Resolution or Funding

35 Counties: Board of Supervisors or Countywide Agencies

- Alameda*
- Amador*
- Butte
- Calaveras
- Contra Costa
- Del Norte*
- Glenn
- Humboldt
- Kern*
- Lake
- Los Angeles
- Madera
- Marin*
- Mariposa
- Mendocino*
- Monterey*
- Napa
- Nevada
- Placer
- Sacramento
- San Bernardino
- San Diego*
- San Francisco
- San Joaquin*
- San Mateo
- Santa Barbara*
- Santa Clara
- Santa Cruz
- Solano
- Sonoma
- Tehama
- Trinity
- Tuolumne
- Ventura
- Yolo

** Countywide agency other than Board of Supervisors*

Mission: To shift California's product waste management system from one focused on government funded and ratepayer financed waste diversion to one that relies on producer responsibility in order to reduce public costs and drive improvements in product design that promote environmental sustainability.

96 City & Town Councils

- Albany
- Amador City
- Apple Valley
- Arcata
- Arvin
- Belmont
- Burbank
- Calabasas
- Calistoga
- Carson
- Chico
- Chula Vista
- Claremont
- Cloverdale
- Corning
- Cotati
- Covina
- Cupertino
- Davis
- Diamond Bar
- Dixon
- Duarte
- Dublin
- El Cerrito
- Elk Grove
- Eureka
- Fairfield
- Folsom
- Fort Bragg
- Fortuna
- Fresno
- Glendale
- Healdsburg
- Hillsborough
- Huntington Park
- Indian Wells
- Larkspur
- La Puente
- La Quinta
- La Verne
- Lemon Grove
- Lincoln
- Los Altos Hills
- Los Angeles
- Los Gatos
- Lynwood
- Millbrae
- Monrovia
- Monte Sereno
- Morgan Hill
- Mountain View
- Napa
- Nevada City
- Oakland
- Palm Desert
- Palm Springs
- Palo Alto
- Paradise
- Pasadena
- Petaluma
- Pittsburg
- Rio Vista
- Rohnert Park
- Rosemead
- Roseville
- Sacramento
- San Dimas
- San Joaquin
- San Jose
- San Juan Capistrano
- Santa Clara
- Santa Cruz
- Santa Monica
- Santa Rosa
- Sebastopol
- Sierra Madre
- Signal Hill
- Sonoma
- South Gate
- St. Helena
- Stockton
- Sunnyvale
- Thousand Oaks
- Torrance
- Union City
- Vacaville
- Vallejo
- Ventura
- Vernon
- Walnut Creek
- West Hollywood
- West Sacramento
- Windsor
- Winters
- Woodland
- Yountville

36 Local Government Associations

- Association of Bay Area Governments (ABAG)
  - Bay Area Hazardous Waste Management Facility Allocation Committee
  - San Francisco Estuary Project
- Bay Area Clean Water Agencies
- Bay Area Stormwater Mgmt. Agencies
- California Council of Directors of Environmental Health (CCDEH)
- California State Association of Counties
- California Stormwater Quality Association
- Central Contra Costa County Solid Waste Authority
- Central Contra Costa Sanitation District
- Coachella Valley Association of Governments
- Contra Costa Clean Water Program
- Delta Diablo Sanitation District
- East Bay Municipal Utility District
- Fresno Council of Governments
- League of California Cities
- Los Angeles County Integrated Waste Mgmt. Task Force
- Mojave Desert and Mountain Recycling Authority
- Napa County Upper Valley Waste Mgmt. Agency
- Rural Counties' Environmental Services JPA (ESJPA)
- Sacramento Business Environmental Resource Center
- Sacramento County Dept. of Waste Mgmt. and Recycling
- Sacramento County Dept. of Water Resources
- Sacramento County Stormwater Quality Program
- Sacramento Regional County Sanitation District
- San Gabriel Valley Council of Governments
- Santa Clara County Recycling and Waste Reduction Commission
- Santa Clara Valley, CLEAN South Bay
- Santa Clara Valley Urban Runoff Pollution Prevention Program
- Santa Clara Valley Water District
- South Bayside Waste Management Authority
- Southern California Association of Governments
- Solid Waste Association of North America (SWANA)
- Tamalpais Community Services District
- West Contra Costa Integrated Waste Mgmt. Authority
- Western Placer Waste Mgmt. Authority
- West Valley Clean Water (Campbell, Los Gatos, Monte Sereno, Saratoga)

CPSC Business Partners

Platinum Partners
$10,000 or more

- Recology
- Republic Services

Gold Partners
$5,000 - $9,999

- California Resource Recovery Association
- Product Policy Institute

Silver Partners
$2,500 - $4,999

- Amazon Environmental, Inc.
- CalRecycle*
- F&H Office Systems
- Marin Sanitary Service
- Nortech Waste LLC
- Waste Management Inc.

Bronze Partners
$500 - $2,499

- Acrylatex Coatings and Paint
- California Paint Recycling, Inc.
- California Waste Solutions
- Clean Harbors Environmental Services, Inc.
- Ecology Action
- Johnson's Environmental Products
- Peninsula Packaging Company
- PerfPower Corporation
- PSC Environmental Services
- Rinauro Consulting
- SEI Solid Waste
- Visions Paint Recycling, Inc.
- Zanker Disposal and Recycling

** CalRecycle has not signed the CPSC Pledge, since this would be inappropriate for a State agency, but is a partner of CPSC.*

Green Partners
$1 - $499

- Business Waste Mgmt. Consulting
- Edgar & Associates
- I2I Innovation To Industry
- MKM Environmental
- Pinerworks Architecture & Building Group
- Sierra Club - Solano
- SLV Recycling Redemption Centers
- TDC Environmental
- The Carpet Recyclers

Supporters

- A Green Plan
- Abbey Flooring
- Aces Waste Services
- Ag Plastics & Innovations
- Allied Waste, Daly City
- B&J Towing
- Buda*Star
- Burbank Green Alliance
- BuyGreen
- California Dream Week
- California Resource Connections Inc.
- Capital Ideas Development Corp., Inc.
- Capitol City Automotive, Inc.
- Center for Environmental Health
- Clean Water Action
- Concord Disposal Service
- Condor Earth Technologies
- CR&R Waste and Recycling Services
- Davis Farmer's Market
- Discovery Bay Disposal Service
- Ecology Center
- EcoMom Alliance
- Eco-Stream Sustainability Consulting
- Electronics Take Back Coalition
- Environmental Alternatives Consulting
- Environmental Defense Fund
- Environmental Innovations
- Executive Communications
- Folsom EcoHousing
- General Environmental Management, Inc.
- Gill's Onions
- Going Green Radio Program
- Good News Reuse
- Grassroots Recycling Network
- Greenleaf Project Management
- Green Party of Los Angeles County
- Green Purchasing Institute
- Green Sangha
- GreenWaste Recovery, Inc.
- Hollinger & Associates, Inc.
- Interagan Technology Group
- Jason Grant Consulting
- Kaiser Chemical Dependency
- Keep California Beautiful
- L2 Environmental
- Leadership Institute for Ecology & the Economy
- Long Beach Coalition for a Safe Environment
- Main Street Moms
- Mediaplanet
- Mt. Diablo Recycling
- Napa Recycling & Waste Services
- NBI Sustainable Work Environments
- NewLevel Group, LLC
- North Bay Corp./Redwood Empire Disposal
- Northern Recycling & Waste Services
- Oakley Disposal Service
- Pacific Ag Commodities Corporation
- Pacific Recycling Solutions
- Pegasus Building Services
- Pena's Disposal Incorporated
- Pittsburg Disposal Service
- Plastic Pollution Coalition
- Reel Green Media
- Remediation Earth
- Rent-A-Green Box
- Reusable Packaging Association
- Reuse Alliance, California Chapter
- ReUse Arizona
- Reverse Logistics Association
- Rick Mauck and Associates
- Rio Vista Sanitation Service
- S. Groner Associates (SGA)
- San Diego Convention & Visitors Bureau
- Science for Environmental Excellence Dedicated to Sustainability (SEEDS)
- Sempiterno Solutions LLC
- Sierra Club - Bay Area
- Sierra Club - Canada
- Sierra Club - Napa
- Sierra Club - Zero Waste Committee
- Sierra Cost Management
- Silicon Valley Toxics Coalition
- Special Waste Associates
- State Agency Recycling Coordinator's Comm
- Supply Brothers, Inc.
- Sustain LA
- Sustainable Napa County
- Sustainable San Rafael
- Takayama Consulting
- Teleosis Institute
- TerraCycle
- The Altum Group
- The Future 500
- The JBC Groups, LLC
- The Watershed Project
- Total Recycling Associates
- Waste Management of Orange County
- YCC International
- Yuba Environmental Science Charter Academy

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California Council for Environmental and Economic Balance

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January 27, 2012

Director Debbie Rafael
California Department of Toxic Substances Control
State of California
1001 I Street
Sacramento, CA 95812

(via email)

Re: Revisions to Informal Draft Regulations for Safer Consumer Products

Dear Ms. Rafael:

The California Council for Environmental and Economic Balance (CCEEB) is a coalition of business, labor, and public leaders that advances strategies for a strong economy and a healthy environment. On behalf of CCEEB, we want to thank the California Department of Toxic Substances Control (DTSC) for this opportunity to comment on the Informal Draft Regulations for Safer Consumer Products. Additionally, CCEEB appreciates the assurance by staff and the Director that there will be a 45-day notice in the future to amend this regulation and hopefully address CCEEB's concerns.

Our primary concerns at this stage of the regulatory development process are based on the wide scope of the "Informal Draft Regulation" released on 10/31/11. CCEEB urges DTSC to narrow the scope of the regulation prior to release of the formal draft regulations including specific chemical-product combinations DTSC has identified for initial regulation and including the reasoning behind those choices. We have been verbally assured that DTSC will limit its approach in this regulation however; the informal draft regulation is open ended.

We have two questions/comments at this point, both regarding the status within the proposed regulations of chemical products which a company may *use internally* to conduct their operations but which are not themselves part of any product made available to the company's customers i.e. the public.

- It is not clear in the informal draft regulations whether businesses would have any responsibilities for *chemical products which are used internally or production intermediates* in conducting manufacturing, but which are not themselves sold or made available to the public. There are a number of chemical products a business may use internally as necessary intermediaries in the eventual delivery of services or products to its customers. A few simple examples of these include various solvents and adhesives as well as the solder used in the repair of electronic equipment or products used during the manufacture of a product but are not part of the product. CCEEB is troubled at the notion of reaching up into the manufacturing chain and regulating these intermediary chemical from a workers safety perspective, as OSHA already does. DTSC has said if you purchase and use a consumer product, it can be regulated under this statute. That includes railcar and tank car quantities. **Will a company's internal use of these products place any regulatory compliance burden on it under these proposed regulations?**

- It is not clear in the informal draft regulations what factors the DTSC will consider when evaluating chemical product combinations and what process will be used to determine acceptable alternatives. It is essential that any "alternatives assessment" or prioritization process designed to identify "greener and safer" consumer products also very carefully consider a number of factors that provide the context in which the products are used. Although the intent of the regulations is to reduce toxicity, the alternatives may result in unintended tradeoffs including resource depletion, end-of-life considerations, and energy efficiency. (Two examples include the replacement of lead solder to tin alloy. The tin alloy is less abundant than lead and has complications in recycling. Lead acid battery alternatives that include lithium have additional safety consequences, particularly if wet.) Factors that we believe need to be taken into consideration are:

    1. The effectiveness of any product in achieving its intended purpose. The collateral impact on businesses and consumers of the *potentially reduced efficacy* of consumer products in general, or of those consumer products used internally in conducting business operations, as a result of their elimination or reformulation by product manufacturers must be considered. Moreover, such an efficacy evaluation must consider all of the potential uses for a product. For example, all consumer products must function at optimal efficiency just like those used as part of the delivery of health care or public safety. And finally, the life cycle impacts of the product must be part of the evaluation as well.

    2. The continued availability of various chemical products used internally to conduct essential company operations. For example, in some processes, tin may be an alternative to lead, but tin is more scarce and could be difficult to obtain as a substitute without significant impact on the company and the cost of the products being sold.

    3. Conflicting Agency Requirements It is important that companies not be put in a position of having to meet conflicting agency requirements. For example, the CEC is in the midst of an Appliance Energy Efficiency proceeding that will

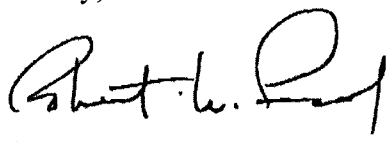
impose energy efficiency requirements on certain products in order to meet California's energy savings goals. The CEC requirements could be conflicting with the green chemistry regulations. Additionally, components in an aircraft must meet Federal Aviation Administration (FAA) standards in order to get initial flight certification and to maintain flight certification. It is not appropriate for DTSC to require industries to change components or constituents unless the material has gone through, and received qualification by the FAA or other regulatory bodies. By not explicitly establishing exemption provisions and priorities this regulation could create a great deal of regulatory uncertainty which will negatively affect the policy.

Many companies invest considerable expense and effort in identifying, choosing, sourcing and purchasing the tools and materials necessary to provide products and services to their public customers. We believe it is essential that DTSC also consider the possible unintended impacts of the loss of consumer products deemed essential, or superior in performance to any possible alternative products, on the effective conduct of a company's operations and service delivery.

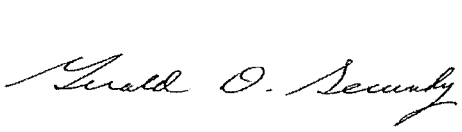
- The draft informal regulations continue to incorporate an apparent 'joint and several' liability approach to compliance among "responsible entities" that invites confusion and redundancy of effort among manufacturers, importers, retailers and others in the supply chain. Despite DTSC's articulation of a hierarchical approach that places the "principal duty" of compliance on manufacturers, the regulations nonetheless appear to place parallel obligations on non-manufacturers in the event that manufacturers fail to comply. The regulations should be revised throughout to ensure that manufacturers (and/or importers) bear the sole obligation for compliance for those aspects of the regulations that are within the control of manufacturers, and that any obligations of retailers and others within the supply chain (e.g., suppliers, distributors, wholesalers) be limited to compliance with any appropriately tailored regulatory response after completion of the Alternatives Assessment phase of the evaluation process.

CCEEB would like to thank DTSC for considering its comments on the revisions to informal draft regulations for safer consumer products and looks forward to additional changes in the draft regulation in the future. CCEEB is a unique organization that represents a broad cross-section of the entities in California. As such, CCEEB is in a position to represent diverse industry sectors and would like to assist DTSC in developing these ideas further. CCEEB looks forward to playing a role in the future development of the safer consumer products regulations. If there are any questions please call Robert Lucas at (916) 444-7337.

Sincerely,



Robert W. Lucas
Waste and Water Quality Project Manager



Gerald D. Secundy
President

cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency
Odette Madriago, Chief Deputy Director Department of Toxic Substances Control