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

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September 12, 2011

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

RE: Revised Proposed Regulation for Green Chemistry Hazard Traits (7/29/11)

Dear Ms. Kammerer:

On behalf of the Green Chemistry Alliance (GCA) and its stakeholders, http:/www.greenchemistryalliance.org, GCA respectfully submits the following comments and concerns relative to the Office of Environmental Health Hazard Assessment's (OEHHA) Revised Proposed Regulation for Green Chemistry Hazard Traits ("regulation") released July 29, 2011.

The enacting legislation, SB 509 (Simitian, 2008), requires OEHHA "to evaluate and specify the hazard traits and environmental and toxicological endpoints and any other relevant data that are to be included in the clearinghouse." This directive is simple and clear.

The Green Chemistry Alliance (GCA) is extremely concerned that the novel approach OEHHA has proposed for hazard trait determination amounts to a California-specific process of classifying chemicals. Not only are major aspects of OEHHA's approach unauthorized by the implementing statute, but in many instances as discussed below represents scientifically questionable deviations from well established, internationally agreed upon, systems and principles for determining chemical hazards.

Of all of GCA's concerns or questions, the overarching and recurring issue continues to revolve around how the information in the regulation will be applied. The proposed Green Chemistry Hazard Traits regulation is generally unclear and disconnected from the Department of Toxics Substances Control's (DTSC) AB 1879 approach and DTSC's own vision for the Toxics Information Clearinghouse (TIC) – both of which have yet to be proposed by the Brown Administration.

It is also unclear whether the peer reviewers, chosen to conduct an independent scientific peer review, received adequate

background information, reiterating the significance of the OEHHA hazard traits and the Green Chemistry Initiative's safer consumer product alternatives process[1]. A thorough understanding or a lack thereof regarding the nexus of these two activities might well result in different evaluations by the same reviewer. Furthermore, in cases where reviewers pointed out technical weakness in the hazard trait framework, OEHHA made no attempt to address any of these points in their revised draft. Since the OEHHA regulations will be a critical touchstone for DTSC's AB 1879 process, scrutiny needs to be employed in the development of applicable, definable and scientifically sound hazard traits and endpoints in order to inform the prioritization process. The proposed Green Chemistry Hazard Traits regulation does not accomplish this critical task.

The underlying statutes clearly envision a coordinated approach between DTSC and OEHHA and with the change in Administration it is important that incoming leaders at both DTSC and OEHHA have the opportunity to provide the Brown Administration input regarding the approach envisioned by OEHHA's proposed Green Chemistry Hazard Trait regulation. The OEHHA regulation will define content for the TIC and identify considerations for "Chemicals of Concern" listings. Without clarity of the regulatory structure into which the hazard traits must fit, there is significant uncertainty regarding both their operative impact and sufficiency.

Given DTSC has yet to adopt and implement regulation for AB 1879 GCA urges OEHHA to withdraw their Green Chemistry Hazard Traits revised proposed regulation until the regulatory approach that DTSC is charged with undertaking becomes clearer. In order to help ensure clarity and consistency, it is critical that OEHHA coordinate more closely with DTSC as the overall regulatory development process moves forward. GCA strongly urges OEHHA to first undertake the necessary coordination with DTSC and the CalEPA Secretary and then to revise the proposed regulation to adopt a structure that allows existing chemical toxicity information and hazard trait determinations to be utilized in a scientifically rigorous and cost effective manner to fulfill its mandate under SB 509.

Beyond the issue of Agency coordination and consistency, the system of hazard traits envisioned by OEHHA is unlike any adopted by major countries and global cooperatives regarding chemical management. Why would California seek to implement a unique chemical management data system which will require significant time and resources, while simultaneously ignoring international chemical management precedent and immediate access to extensive chemical data from around the world? The information contained on over 2100 chemical datasets that are publicly available under the OECD and US HPV program databases, over 3900 chemicals already available in the European Union's REACH database, and the 680,000 chemical data records contained in the OECD's eChemPortal provided by the 30 OECD member countries will be unusable in OEHHA's proposed Hazard Trait system unless and until it is laboriously converted from the global standard into OEHHA's unique approach.

Requirements for data accessibility, storage, management, analysis and interoperability are becoming increasingly critical for regulatory decision making. Many organizations are already actively pursuing how to effectively harness increasingly larger and more complex datasets to more accurately predict and identify safer, sustainable alternatives. For example, the US EPA has launched a multi-stakeholder program to discuss how to design such an integrated, interoperable system that OEHHA could immediately engage and leverage for the TIC[2].

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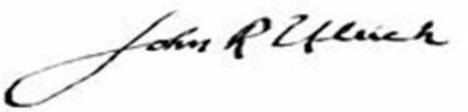
[1] George V. Alexeef, Ph.D., D.A.B.T. Deputy Director for Scientific Affairs, Draft Memorandum to Gerald W. Bowes, Ph.D. Manager, Cal/EPA Scientific Peer Review Program, Re: Peer Review of Green Chemistry Hazard Traits Regulation, and Initial Statement of Reasons, January 7, 2011.

[2] <http://yosemite.epa.gov/opa/admpress.nsf/0/f7b2e8162ff521b4852578b0005c7edb?OpenDocument>

Implementation of OEHHA's proposed regulation without exploring opportunities to incorporate the recommendations from aforementioned national and international efforts is a wasteful and scientifically indefensible exercise which will significantly and unnecessarily delay the use of the information in advancing Green Chemistry in California.

For questions or further information regarding the Green Chemistry Alliance, its members, or comments please contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. Thank you!

Sincerely,



John Ulrich
Co-Chair
Chemical Industry Council of California

Dawn Sanders Koepke
Co-Chair
McHugh & Associates

Cc: The Honorable Matt Rodriguez, Secretary, CalEPA
The Honorable Debbie Raphael, Director, DTSC
Office of the Governor

Green Chemistry Alliance Signatories

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Cleaning Institute
American Forest & Paper Association
Amway
Association of Global Automakers, Inc
Association of Home Appliance Manufacturers
BASF
The Boeing Company
California Aerospace Technology Association
California Chamber Commerce
California Grocers Association
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
California New Car Dealers Association
California Paint Council
California Restaurant Association
California Retailers 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
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Florida Chemical Company, Inc.
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Independent Lubricant Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Fragrance Association of North America
International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Industries, Inc.
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National Association of Chemical Distributors (NACD)
National Paint & Coatings Association
National Shooting Sports Foundation (NSSF)
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Rio Tinto
Rubber Manufacturers Association
SABIC Innovative Plastics
Silicones Environmental Health and Safety Council
Society of Chemical Manufacturers and Affiliates (SOCMA)
Solar Turbines
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
Synthetic Amorphous Silica & Silicate Industry Association
TechAmerica
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

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Guide to GCA Comments regarding
The Proposed Green Chemistry Hazard Traits Regulation

(September 12, 2011)

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2) GCA Talking Points re: OEHHA Proposed Hazard Trait Regulation Concerns – August 31, 2011

INDEPENDENT EXTERNAL SCIENTIFIC PEER REVIEW

California Health and Safety Code § 57004 (HSC 57004), requires all California Environmental Protection Agency (CalEPA) organizations, including OEHHA to conduct an external scientific peer review of the scientific basis for adoption. A final regulation cannot be issued until such a peer review has been completed. OEHHA's proposed regulation would create a novel, California-only method of hazard classification or designation. Therefore, it is imperative that the scientific basis of the regulation is thoroughly and comprehensively peer reviewed by external scientific experts to establish that the proposed rule is based upon sound scientific knowledge, methods, and practices.

On June 17, 2011, OEHHA posted peer review comments submitted by three peer review scientists – Dr. Pertti Hakkinen with the National Institutes of Health, Dr. Bette Meek with the University of Ottawa, and Dr. Errol Zeiger with Errol Zeiger Consulting – who indicated they lacked expertise to comment on all aspects of the proposed regulation (see statements by the peer reviewers). In lacking such expertise, they failed to comment on all of the Articles of the regulation. As such, GCA feels strongly that the peer review process should be expanded to ensure that all aspects of the proposed regulation have been subjected to a rigorous peer review process.

GCA noted and supported the February 2011 recommendation made by the American Chemistry Council (ACC) to have the National Academy of Sciences (NAS), the most appropriate body for conducting external scientific peer, conduct the peer review as required by HSC 57004. GCA continues to support peer review by the NAS because "the proposed regulation represents scientifically questionable deviations from well established, internationally agreed upon systems for evaluating and describing chemical hazards."[3] Additionally, GCA noted that the NAS is best suited to conduct the required external scientific peer review because of its global stature and proven track record for tackling complex toxicology and risk assessment issues. Moreover, adoption of a novel California-specific method of hazard trait identification could have global ramifications, since the California economy represents 13-14% of the US GDP and is the eighth largest in the world. For all of these reasons and the lack of expertise among the three peer reviewers who provided comment per HSC 57004, **GCA urges a more rigorous peer review by a body such as the NAS**.

LACK OF POTENCY & EXPOSURE CONSIDERATIONS

GCA strongly believes the proposed regulations are also critically flawed in that they fail to consider dose or potency or exposure as an initial step in the DTSC evaluation of hazard traits that would be required under HSC 25252(b). As written, the proposed regulation would impose burdens to review and evaluate each substance for every toxic effect documented in scientific literature, regardless of the dose or concentration that caused an effect. In this regard, it is important to note that **all** natural and synthetic substances can produce toxicity at some dose level and therefore, any safer chemical alternative could be potentially eliminated from further consideration based on one or more of the hazard traits proposed by OEHHA. The proposed regulation should focus the hazard trait analyses for alternatives on those chemicals that pose a real risk to human health.

Specific to dose, scientists test substances at very high doses in order to be sure that the full spectrum of potential toxic effects is known during hazard profiling for safe use determinations.

[3] American Chemistry Council, OEHHA Hazard Trait Regulation comments, February 15, 2011, pg. 5.

Scientists integrate exposure potential with hazard to determine what levels would be levels of concern and what levels would be expected to be safe, often using realistic, conservatively high exposure scenarios to anchor the assessment. A fundamental principle in the field of toxicology is that it is impossible to prove that a substance is not toxic. The best one can strive for is to know the probability that an adverse effect will occur to a living organism under well defined exposure conditions, in other words, to assess the risk. Failure to include realistic exposure scenarios as well as potential toxic effects in the risk assessment process ignores this fundamental principle of risk assessment and instead promotes a fatally flawed process that will be of highly questionable value to the people of the state of California.

With all of these points in mind, GCA raises a number of questions regarding the lack of clarity with how this information will be used. Specifically,

- How will the TIC address the very real issue of potency before declaring that substance possesses a toxicity trait?

- Without information about the dose at which a substance causes acute toxicity, will everything in the TIC be marked as acutely toxic?

OEHHA has established a framework that will undoubtedly be misunderstood and certainly misused. **GCA recommends that OEHHA apply existing systems, particularly OECD's Harmonized Templates for Reporting Chemical Test Summaries (see comments above) to understand how other authoritative and respected bodies have handled this critical issue**.

ARTICLE 1 GENERAL

Section 69401.1 – Conduct of the Evaluation

In the revised proposed regulation, OEHHA has altered the language to provide that DTSC shall "…develop criteria for chemical evaluations…" as compared to the prior version of the regulations (December 13, 2010) that provided DTSC would "…evaluate chemicals by developing criteria…" GCA believes this proposed change lacks clarity in that it doesn't specify which entity in California government, if any, would be conducting the chemical evaluations and under what authority. This raises additional questions around issues of consistency in evaluation of chemicals and more that require clarification.

Additionally, GCA argues that an "authoritative organization" should utilize processes that guarantee comprehensive, deliberative, and fully documented evaluations undertaken to reach conclusions regarding chemical hazards. Peer reviewer Dr. Bette Meek echoed this comment stating, ". . . *there is no clear delineation of criteria for acceptability of products of authoritative organizations*" in the proposed regulation.[4] While many of the entities listed by OEHHA use processes that are transparent and involve a sound scientific review process to come to conclusions that are subsequently made public, this is not the case for all of the entities listed. GCA and Dr. Meek, per her written comments, suggest greater consideration for this issue to ensure that those utilizing the OEHHA database will have assurance that the authoritative body noted has used a deliberative and transparent review process.

The amendments made to this definition continue to raise the concern that the definition fails to account for the concept of "deliberative review" in coming up with scientific findings versus

[4] From Bette Meek, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 2

creation of derivative lists. Continuing to reference "other states" is concerning since there is relatively no authoritative process in place in these jurisdictions. Further, the list does not include an explanation of which entity would take precedent or be more authoritative. OEHHA's list suggests that all entities would be equally authoritative, rather than including acknowledgement that some are more authoritative than others based on the process for review and technical expertise.

Section 69401.2 – Definitions

(b) "Authoritative organization" – This definition fails to account for the concept of "deliberative review" in coming up with scientific findings versus creation of derivative lists. Referencing "other states" is particularly concerning, where there are generally no authoritative processes in place. However, on page 4 the wording suggests that "authoritative organizations" are limited to those listed.

Furthermore, the revised proposed regulation contains significant references to an "authoritative organization" as defined in this section. This definition, rather than a listing of examples of organizations, needs to include criteria for the acceptability of these organizations as "authoritative." These could include, for example, transparency of the scientific process, transparency and inclusiveness of identification of relevant data, nature of peer engagement including peer input, consultation and review in addition to public availability of products. Specification of these criteria would increase transparency of prioritization of classifications of difference agencies considered in the context of strong and suggestive evidence for various endpoints.[5]

(g) "Other relevant data" – GCA shares the concerns and echoes the important questions raised by Dr. Meek in her peer review regarding the failure of OEHHA to include consideration of exposure and use data for chemicals in the revised proposed regulation[6]. Recall, GCA's prior comments of February 2011 (Incorporated herein by reference and attached below as Exhibit 1) raised the concern that this definition failed to include exposure or use data. Continued failure to include this data in the proposed regulation remains a critical flaw, as noted by Dr. Meek. Most internationally recognized hazard classification systems combine toxicity information with anticipated use and/or exposure information, something that could be accomplished in this proposed regulation under the concept of "other relevant data." The revised text of the proposed regulation fails, however, to include any mention of use and exposure data as part of this definition. As noted by Dr. Meek, failure to include these considerations will undoubtedly lead to a database that is biased towards chemicals with large toxicity findings, regardless of whether human exposure potential is an issue.

GCA feels strongly that the failure to include the concept of exposure as an important consideration in the assessment of hazard is not scientifically defensible and will likely create tremendous confusion and misinformation among those who might review and mistakenly rely on such information for making decisions about consumer products that utilize these chemicals.

(i) "Well-conducted scientific study" – this definition lacks clarity and consistency in that it might arbitrarily exclude any study which is not published in the open literature, or submitted to a government agency. Furthermore, this definition is different and inconsistent with DTSC's "reliable information" definition, which attempts to address the critical need of understanding

[5] From Bette Meek, PhD, peer review of OEHHA Hazard Trait Regulation
[6] From Bette Meek, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 3

the quality and reliability of a study. GCA recommends that OEHHA withdraw the "well-conducted scientific studies" terminology and replace it with the following definition:

> *"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."*

Please refer to related comments below in Article 2 under the heading *Data Quality and Reliability Indicators.*

ARTICLE 2 TOXICOLOGICAL HAZARD TRAITS

While GCA acknowledges that carcinogenicity, developmental toxicity, and reproductive toxicity are commonly used hazard traits in current hazard classification systems, we share the concerns noted by Dr. Meek and Dr. Zeiger in their peer reviews regarding the failure of OEHHA to fully develop a few of the key scientific principles in the proposed regulation. Specifically, OEHHA fails to adequately address weight-of-the-evidence in the assessment as well as exposure and use information. The peer reviewers also spoke to the lack of some measure of data reliability in the hazard identification process.

Data Quality and Reliability Indicators

In GCA's 2/15/2011 comments (incorporated herein by reference) OEHHA's definition of "well conducted studies" was deemed insufficient and GCA cited methodology used by the Organization for Economic Cooperation and Development (OECD) as an alternative. GCA made similar comments with regard to DTSC companion definition for "reliable information," and also recommended OECD methodology as an alternative definition – **It is critical that the DTSC and OEHHA employ the same definition**. Meek and Zeiger comments support GCA's recommendation that reliability needs to be built in.

Dr. Meek and Dr. Zeiger both commented on the need to include some measure of data reliability in the hazard trait identification process, as well as the use of weight-of-the-scientific evidence being a critically important consideration. GCA provided comment on this issue in its February 2011 submittal (Incorporated herein by reference) and would again stress the importance of data included in a hazard classification process being judged for reliability and quality in order to ensure that a hazard trait has sound scientific basis. Poor quality data or data from unvalidated study methods should not be used to assign a hazard trait when reliable, quality data are available that do not support the assignment. Furthermore, poor quality data alone should not be the basis for assigning any hazard trait even if good quality studies are lacking.

The proposed OEHHA regulations are void of any data quality or data flags to help the user of the data understand the value of the information being provided. The TIC is supposed to be a tool for consumers, but the way the system is being designed will only allow consumers with

scientific backgrounds to understand and use the information presented. **GCA recommends that for the determination of reliable studies OEHHA adopt 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)**[7]

Weight-of–the-Evidence Assessment

Yet another critical flaw in the revised OEHHA proposed regulation is the misguided perception that OEHHA (or any other instrument of the California government) is authorized to classify chemicals. Moreover, if it were, the approach chosen is flawed by virtue of the failure to include any guidance or mention of applying a weight-of-the-evidence (WOE) process when assigning toxicity hazard traits. As GCA previously noted, it is a general principle of hazard assessment that all available data must be considered and all of the relevant and reliable information integrated in order to develop a scientifically valid decision regarding chemical hazard. With so many varying studies available for any given chemical, it is critical to consider the weight-of-the-evidence to ensure the appropriate, science-based decision is reached. Without such an approach, the proposed regulation could ultimately result in a single study being incorrectly used, despite the quality of the study, to conclude that a particular chemical exhibits "suggestive evidence" that matches with a specific hazard trait.

The proposed regulations only consider positive data, not the negative or contrary data that may be available. The weight-of-the-evidence relied upon for any decision making clearly depends on consideration of all evidence- positive and negative- that may be available regarding a hazard trait or chemical. Additionally, if a chemical substance is determined not to have a hazard trait because it does not have a certain toxic or hazard characteristic – such information is important and should be reflected in the data set. If OEHHA's directive is to designate when a chemical has a hazard trait, the effort should also indicate when a substance does not have a hazard trait. The format considered by OEHHA is therefore distorted and biased.

Specifically, § 69401.1 of the proposed regulations must be clarified since the structure of this chapter provides a circular definition for its method of classifying chemicals. OEHHA must clarify how the proposed regulations will make the initial determination of categorizing a chemical of interest – whether it will be based on professional judgment, exposure rates, production volumes or a combination of all factors.

OEHHA needs to implement a WOE approach considering all credible evidence – positive and negative – that may be available about substances included in the Toxics Information Clearinghouse (TIC). A WOE approach would examine information available from reliable studies that are based on scientifically accepted methodologies. This approach will allow the evaluators to make a reasonable scientific determination of a chemical's hazard based on the best available science. Such an approached is described in a recent paper entitled, "Toxicology and Epidemiology: Improving the Science with a Framework for Combining Toxicological and Epidemiological Evidence to Establish Causal Inference" by Adami at the Harvard School of Public Health Department of Epidemiology, et al. 2011 (Tox Sci, 122(2), 223-234). Additionally, this approach would eliminate "false positives" in hazard assessment evaluations by eliminating studies that had severe limitations. OEHHA should strike any and all of the unauthorized provisions of the regulation that would dictate California government classification of chemicals (See Exhibit 2, Attachment 1)

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

These comments are consistent with those raised by Dr. Meek and Dr. Zeiger who both spoke to the need to provide guidance on the extent and quality of evidence needed to determine toxicity hazard traits for any given chemical.[8] Dr. Zeiger went so far as to specifically mention the need to apply a weight-of-the-evidence approach to such efforts.[9] Both peer reviewers were clear that equal weight should not be given to all types of data in the assessment – particularly when distinguishing between strong and suggestive evidence. The bottom line – the weight-of-the-evidence provides valuable information that should be taken into consideration.

Exposure and Use Information

Dr. Meek, in particular, notes in her review the failure of OEHHA to include consideration of exposure and use information for hazard assessment. She points out that the failure to use exposure and use information as an initial step in hazard identification directly conflicts with other hazard identification systems used around the world, and by which manufacturers must already operate. Since toxic effects of a chemical are a function of inherent toxicity and the route, magnitude, frequency and duration of exposure, production processes and use patterns that influence exposure will ultimately influence the level of hazard and risk posed by any chemical. This is the main reason that hazard identification programs throughout the world have production, use, or exposure triggers for toxicity study data requirements. In this regard and as mentioned by Dr. Meek, the hazard trait discussion needs to incorporate the concept of exposure and use as well as the route of exposure. Although briefly mentioned in Article 7 under "Additional Relevant Data," it is not sufficient based on the importance of exposure and use information when both ranking chemicals for inclusion in a database of hazard traits and when assessing the validity of assigning certain hazard traits to a chemical.

Further clarification is also required for how to measure degree of adverse effect and biological response. OEHHA must clarify whether threshold data will be disclosed in an exposure-response relationship or if all data will be disclosed.

<u>ARTICLE 3</u> OTHER TOXICOLOGICAL HAZARD TRAITS

Regarding Article 3, GCA shares a number of scientific concerns also noted by the peer reviewers. Concerns include the following:

- The list of "other toxicological hazard traits in Article 3 is lengthy and as a result of the numerous delineations of specific traits the list will likely bias the system to chemicals with a lot of data and is not necessarily indicative of hazard, the primary goal of the proposed process.[10]

- The process is inconsistent with globally standardized approaches to testing chemicals where the generally accepted method for hazard identification describes hazards in terms of either durations of exposure or systemic toxicity. The OEHHA process is also inconsistent with other widely recognized and implemented international systems and associated categories. GCA agrees with Dr. Meek that there is no need to break out systemic toxicity or target organ toxicity by specific systems when the goal is hazard identification.

[8] Dr. Bette Meek, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 5-7
[9] Dr. Errol Zeiger, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 6, 11
[10] Dr. Bette Meek, PhD, peer review of the OEHHA Hazard Trait Regulation, pg. 3

- Failure to include consideration of the critical scientific principles of potency, exposure and use, data reliability, and weight-of-the-evidence is a continuing problem and significant flaw throughout the entire proposed regulation, including this section on "other toxicological hazard traits." This Article also fails to consider other key principles such as distinguishing adverse changes from adaptive changes, use of invalidated *in vitro* studies and/or structure-activity data alone as a basis for identifying hazard traits, and use of emerging concepts in toxicology as a basis for hazard trait regulatory decision.

- Endocrine toxicity should not be viewed as a distinct toxicological hazard, but instead a measure of a compound's ability to interact with components of the endocrine system. This is consistent with comments the GCA included in its February 2011 comments (Incorporated herein by reference) and with those made by Dr. Zeiger's peer review.[11] As echoed by EPA, ". . . the fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems."[12]

Section 69403.4 – "Epigenetic Toxicity"

GCA agrees with Dr. Zeiger's point concerning the inclusion of epigenetic toxicity. Specifically, he notes that "*there are, as of now, no standard tests to measure such effects and no clear consensus on what changes or level of changes, and at what life stage of the organism, would constitute an adverse effect*…"[13] He goes on to note that based on this fact OEHHA should reconsider listing epigenetic effects as a hazard trait as it is premature to do so.

As GCA noted in its February 2011 comments (Incorporated herein by reference) comments, epigenetic toxicity, as continuing to be defined by OEHHA, is overly broad as it could include adaptive as well as adverse effects on organisms. This concern is consistent with the comments made by Dr. Zeiger in his peer review. Omission of a discussion of adaptive changes versus adverse effects of chemicals is a flaw in that affects all steps in the process of identifying hazard traits. The changes listed in HSC 69403.4 would likely be manifested in standard toxicity testing as endpoints of systemic toxicity and would include changes in either biological function or tissue structure (pathological or histopathological changes). If such changes do not manifest in acute or repeat dose toxicity studies, they may be adaptive changes only and not relevant for chemical hazard assessment. OEHHA fails to provide any scientific basis for including "epigenetic toxicity" as a separate discrete hazard trait apart from systemic toxicity. As such, this hazard trait should be removed from the modified text of the proposed regulation.

This field is an emerging area of study including the technology used to measure effects. Since the field is in preliminary stages caution should be exercised when using epigenetics as a toxicity characteristic or providing information in this area. One of the concerns with using this data is that mutation rates vary from species to species. Also mutation rates may be adaptive because it is advantageous to produce more genetically variable offspring, producing a better "fit." Mutation rates over long periods can influence the long-term genetic diversity of a population. It is unclear how OEHHA intends to utilize this information and what variety of molecular genetic markers will be reported. Emphasis should be placed on somatic or germ line if epigenetics continue to be included in the Proposed Regulations.

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[11] Dr. Errol Zeiger, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 6

[12] EPA, 2009, Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening; Fed. Reg. Vol. 74, Wednesday, April 15, 2009, pg. 70248-70254.

[13] Dr. Errol Zeiger, PhD, peer review of OEHHA Hazard Trait Regulation, pg. 6-7

Section 69403.11 – "Neurodevelopmental Toxicity"

Part C considers "structural similarity" to other chemicals that have this hazard trait. However, these structural analyses need to be properly weighted and considered in context. As written, it seems these data are given equal weight and relevance to other data, when structural analysis is typically used as a screen for identifying plausibility of other mechanisms.

Section 69403.17 – "Evidence for Toxicological Hazard Traits"

As previously noted here and in GCA's February 2011 comments (Incorporated herein by reference), OEHHA proposes, contrary to the authority of the statute to classify chemicals (See Exhibit 2, Attachment 1), and to establish an inappropriate framework for evaluating scientific results which fails to explicitly include a weight-of-the-evidence approach. OEHHA's framework fails to consider all the relevant information and falls short of the scientific standard of practice for data quality/reliability and weight-of-the-evidence evaluation in toxicity determinations. More specifically, the proposed regulation, as revised, fails to include – or even mention – the evaluation of negative studies; evaluation of the consistency of results across different studies and over time; and evaluation of biological plausibility. These issues are also raised by Dr. Meek and Dr. Zieger in their reviews. The World Health Organization's definition of an endocrine disruptor is very similar to that of EPA and also makes the case for not using endocrine toxicity as a specific hazard trait, but instead use it as a factor only in assessing other hazard traits.[14]

<u>ARTICLE 4 & 5</u> ENVIRONMENTAL HAZARD TRAITS & EXPOSURE POTENTIAL HAZARD TRAITS

GCA is highly concerned that Article 4 and 5 of the proposed regulation have not received sufficient and comprehensive peer review. Each of the three peer reviewers noted they lacked expertise to apply to these sections of the proposed regulation. As such, GCA believes OEHHA has failed to fulfill its obligation to have the entire proposed regulation fully reviewed by external scientific peers. OEHHA needs to seek reviewers with specific expertise in the areas of environmental risk and exposure assessment before finalizing the proposed regulation. As noted in GCA's comments of February 2011, OEHHA's proposed regulation is attempting to establish a California-specific designation in the area of exposure potential. Specifically, "exposure potential hazard trait" is a novel construct that is not used by any other regulatory body around the world and is ultimately unnecessary. Without adequate peer review, this approach is not assured to be based on sound scientific principles for hazard identification.

GCA strongly suggests the adoption of the internationally harmonized approach developed by the OECD for reporting of Physical-Chemical Properties and Environmental Fate data elements.[15] As an alternative to utilizing OECD's approach, OEHHA could eliminate the proposed trait altogether.

[14] WHO/IPCS Global Assessment of the State of the Science of Endocrine Disruptors. www.who.int/ipcs/publications/en/ch1.pdf

[15] www.oecd.org/dataoecd/13/18/36045056.pdf

Section 69405.3 – "Environmental Persistence"

(a) The phrase *"for a long time period"* is overly subjective and vague. **GCA, as an alternative, suggests using language from the Stockholm Convention Annex D[16]:**

(i) Evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months; or

(ii) Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of this Convention;

Section 69405.3 – 69405.5

These sections now list a part (b) which "includes but is not limited to" types of data being considered. This provides far too much subjective authority to OEHHA and DTSC. Hazard traits should be more clearly delineated, listing the types of data or criteria that will be considered. As written, almost any data point can be almost any hazard trait. **GCA recommends removing this phrase from these sections and other parts of the regulation.**

# # # # #

[16] Annex D of the Stockholm Treaty < http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-COP-CONVTEXT.En.pdf > p.53

EXHIBITS

1) **GCA OEHHA Proposed Hazard Trait Regulation Comment Letter – February 15, 2011**

2) **GCA Talking Points re: OEHHA Proposed Hazard Trait Regulation Concerns – August 31, 2011**

EXHIBIT 1

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

February 15, 2011

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

RE: Proposed Regulation for Green Chemistry Hazard Traits (12/17/10)

Dear Ms. Kammerer:

On behalf of the Green Chemistry Alliance (GCA) and its stakeholders, we respectfully submit the following comments and concerns relative to the Office of Environmental Health Hazard Assessment's (OEHHA) Proposed Regulation for Green Chemistry Hazard Traits ("regulation") released on December 17, 2010.

While GCA and its members appreciate the additional background OEHHA has provided for the proposed regulation since the August draft regulation was released, GCA remains highly concerned over the breadth and direction of the regulation.

The enacting legislation, SB 509 (Simitian, 2008), requires OEHHA "to evaluate and specify the hazard traits and environmental and toxicological endpoints and any other relevant data that are to be included in the clearinghouse." This directive is simple and clear. However, the proposed regulation goes beyond the authority provided for in statute, by establishing a chemical classification system that is not only unique to California but also inconsistent with some of the key principles of chemical hazard assessment that are employed worldwide. It would also establish a unique California system of hazard trait nomenclature that will substantially increase the cost and timing of populating and deploying the Toxics Information Clearinghouse, and make it unnecessarily difficult to leverage existing information on chemicals.

Of all of GCA's concerns or questions, the overarching and recurring issue seems to revolve around how the information in the regulation will be applied. The proposed Green Chemistry Hazard Traits regulation is generally unclear and disconnected from the Department of Toxics Substances Control's (DTSC) proposed regulations for safer products, and DTSC's own vision for the Toxics Information Clearinghouse (TIC). Since the OEHHA regulations will be a critical touchstone for DTSC's safer alternatives process, scrutiny needs to be employed in the development of

applicable, definable and scientifically sound hazard traits and endpoints in order to inform the prioritization process. The proposed Green Chemistry Hazard Traits regulation does not accomplish this critical task.

The underlying statutes clearly envision a coordinated approach between DTSC and OEHHA and with the change in Administration it is important that incoming leaders at both DTSC and OEHHA have the opportunity to provide the Brown Administration's input regarding the approach envisioned by OEHHA's proposed Green Chemistry Hazard Trait regulation. The OEHHA regulation will define content for the Toxics Information Clearinghouse (TIC) and identify considerations for "Chemicals of Concern" listings. Without clarity on the regulatory structure into which the hazard traits must fit, there is too much uncertainty regarding both their operative impact and sufficiency.

Given DTSC's Revised Proposed Safer Consumer Products Alternatives Regulation has not been submitted to the Office of Administrative Law (OAL) and all indications are the proposed regulations will be the subject of further review and amendments, GCA urges OEHHA to withdraw their Green Chemistry Hazard Traits proposed regulation until the regulatory approach that DTSC is charged with undertaking becomes more clear. In order to help ensure clarity and consistency, it is critical that OEHHA coordinate more closely with DTSC as the overall regulatory development process moves forward.

In the meantime, GCA respectfully submits the attached comments and concerns regarding the Proposed Green Chemistry Hazard Trait Regulation (December 17, 2010). For questions or further information or questions regarding the Green Chemistry Alliance, its members, or our comments please contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. Thank you!

Sincerely,

John Ulrich
Co-Chair
Chemical Industry Council of California

Dawn Sanders Koepke
Co-Chair
McHugh & Associates

Cc: The Honorable Linda Adams, Secretary, CalEPA
The Honorable Joan Denton, Director, OEHHA
The Honorable Leonard Robinson, Acting Director, DTSC
Office of the Governor

**** The Green Chemistry Alliance*** *(GCA) has its roots in a group of business trade associations and companies that lobbied effectively during the closing weeks, days and hours of the 2008 California legislative session in support of bi-partisan measures to create a new science based framework for chemicals management. The driving force behind the legislation was a broad based desire for state regulators, rather than the legislators alone, to exercise their expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting chemicals of concern in consumer products. In the wake of this groundbreaking legislation, the GCA was formalized for the purpose of constructively informing the implementation effort such that the promulgated regulations remain true to the objective and scientific ideals of the authorizing legislation. GCA has strongly advocated for crafting regulations to enable the full and successful implementation AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008), which will enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development.*

Green Chemistry Alliance Signatories

Alliance of Automobile Manufacturers
American Apparel & Footwear Association
American Chemistry Council
American Cleaning Institute
American Forest & Paper Association
Amway
Association of Global Automakers, Inc.
Association of Home Appliance Manufacturers
BASF
The Boeing Company
California Aerospace Technology Association
California Chamber Commerce
California Grocers Association
California Healthcare Institute
California League of Food Processors
California Manufacturers & Technology Assoc
California New Car Dealers Association
California Paint Council
California Restaurant Association
Can Manufacturers Institute
Chemical Industry Council of California
Chevron
Citizens for Fire Safety Institute
Consumer Healthcare Products Association
Consumer Specialty Products Association
Dart Container Corporation
Defoamer Industry Trade Association
Del Monte
Dow Chemical Company
DuPont
Ecolab
Ellis Paint
ExxonMobil
Fashion Accessories Shippers Assoc
Florida Chemical Company, Inc.
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Independent Lubricant Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Fragrance Association of North America
International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Companies Public Sector
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National Paint & Coatings Association
National Shooting Sports Foundation (NSSF)
Northrop Grumman
OPI Products Inc.
Personal Care Products Council
Phoenix Brands
Plumbing Manufacturers Institute
Procter & Gamble
Reckitt Benckiser
Rio Tinto
Rubber Manufacturers Association
SABIC Innovative Plastics
Silicones Environmental Health and Safety Council
Solar Turbines
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
Synthetic Amorphous Silica & Silicate Industry Association
TechAmerica
Toy Industry Association
Travel Goods Association
United Technologies
Western Growers
Western Plant Health Association
Western States Petroleum Association
Western Wood Preservers Institute

# # # # #

Guide to GCA Comments regarding
The Proposed Green Chemistry Hazard Traits Regulation

(December 17, 2010)

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1) GCA OEHHA Pre-Draft Hazard Trait Regulation Comment Letter – September 13, 2010

EXECUTIVE SUMMARY

The Green Chemistry Alliance (GCA) is highly concerned about the novel approach OEHHA has proposed for hazard trait determination, which amounts to a California-specific process of classifying chemicals. Not only are major aspects of OEHHA's ~~is this~~ approach unauthorized by the implementing statute, in many instances it represents scientifically questionable deviations from well established, internationally agreed upon systems and principles for determining chemical hazards.

Additionally, OEHHA's Notice of Proposed Regulation suggests that the Proposed Regulations will "not impose new duties on OEHHA or any other state agency other than the need to periodically review and update the regulation to keep up with changing scientific knowledge and methodologies" (page 5). Even evaluating the information to put in to the Toxics Information Clearinghouse (TIC) will require resources. OEHHA should not underestimate the costs associated with this Proposed Regulation.

Attachment 1 will discuss the legal and technical issues associated with the regulation. This will include consideration of the following overarching issues:

Independent Scientific Peer Review – The scientific portions of the proposed regulation have not yet been subjected to independent external scientific peer review. Although public comments have been solicited by OEHHA, the public comment process is not equivalent to independent external scientific peer review. Under California Health and Safety Code Section 57004, all CalEPA organizations, including OEHHA, are required to conduct an external scientific peer review of the scientific basis for any rule proposed for adoption, and a final regulation cannot be issued until such a scientific peer review has been completed. Given that this proposed regulation would create a create a novel, California-only method of hazard classification or designation, it is imperative that the scientific basis of the regulation be thoroughly and comprehensively peer reviewed to establish that the proposed rule is based upon sound scientific knowledge, methods, and practices.

Existing Systems – A new California-only chemical classification system as proposed under the proposed regulation is inefficient, duplicative, and will make it unnecessarily difficult to leverage existing information on chemicals. A non-standard approach will slow the development of the TIC database as there will be a substantial agency effort required to convert the information to the unique California system, both initially and on an ongoing basis. Given that there are existing systems currently in use worldwide, it is not clear why OEHHA has chosen to develop a California-unique system. Most importantly, OEHHA has failed to discuss why existing systems are inadequate and why there is a need for a unique and costly system.

Classification – The classification proposal should be abandoned entirely. SB 509 gives OEHHA neither the mandate nor the authority to create a novel California classification system. DTSC has responsibility for what actually gets placed into the TIC, not OEHHA. The classification system is a significant overstep of OEHHA's authority.

List of "icities" – There is no need to break out systemic toxicity or target organ toxicity by specific systems as proposed in the draft regulation when the goal is hazard identification. Notwithstanding GCA's contention that OEHHA lacks the statutory authority to create a classification system, the critical issue for chemical hazard classification should be identifying the most relevant sensitive system(s) affected by chemical exposure. Thus, it is more than adequate to describe a chemical's hazard by listing the sensitive target organ effects, which is the method used by every other hazard classification system currently in use. Apart from identifying target organs of toxicity, cancer hazard and reproductive toxicity hazard are usually

considered separately. Furthermore, as virtually every chemical at some dose will produce toxicity in some organ system, the proposed classification approach, taken at its face, would lead to every chemical substance being classified. This is not the intent of the Green Chemistry Hazard Traits thrust.

Emerging Traits – OEHHA should seek scientific consensus on the description of emerging traits and in doing so define the appropriate validated study protocol for the endpoint(s) prior to including them in the regulation. OEHHA should not unilaterally establish definitions for new hazard traits, nor rely on non-validated test methods for ascertainment of such traits. This is of particular concern when it is suggested that unvalidated *in vitro* study protocols could be used as a basis for identifying such hazard trait listings.

Endpoint Lists – Each of the toxicological and environmental traits in the OEHHA proposal is accompanied by a list of possible endpoints. However, the listings are not all actual hazard traits or endpoints. In some cases, the endpoints listed are considered to be adaptive changes that may or may not lead to adverse effects in organisms. The fact that certain changes may not lead to disease or an adverse outcome could lead to erroneous classification of a chemical.

Other Relevant Information – The proposed regulation fails to include any concept of potential exposure which is a critical part of prioritizing chemicals to be reviewed in the hazard risk assessment process. Thus, use category and production volume information reported via U.S. EPA's Inventory Update Rule (IUR) should be included as part of "other relevant information" in order to at least provide some measure of potential for human exposure.

Attachment 2 reviews many of the outstanding issues that are not resolved by the proposed regulation. In many cases, OEHHA has indicated that a particular task is DTSC's responsibility. GCA is concerned over a possible disconnect between the Hazard Trait regulation, DTSC Safer Consumer Products Alternatives Regulation and TIC. These are critical components of the Green Chemistry enabling legislation that must be discussed and resolved prior to finalizing this proposed regulation. Each of the hazard traits identified and evaluated in this regulation will affect the other steps in the overall Green Chemistry Initiative. It is for this reason that it is critical for a more coordinated and cohesive effort to be undertaken between DTSC and OEHHA prior to OEHHA moving forward on this regulation. This attachment will review the specific issues and concerns related to these points, including:

Data Quality – *In vitro* studies and QSARs are generally recognized as appropriate tools for prioritizing chemicals, but not for making definitive declarations about toxicological properties as proposed. OEHHA needs to clearly identify how certain types of data should be weighed when assessing chemical hazards, recognizing that certain types of data are less defensible than others, even when developed by authoritative bodies. OEHHA should recognize that assessments should use the best available data from validated test methods and related hazard characterization tools within a scientific hierarchy that affords greater weight to measured data from validated methods compared to analog data and modeled data. It is inappropriate and scientifically unsound to rely on data from non-validated methods alone. OEHHA should look toward the robust study format used in the Organization for Economic Cooperation and Development's (OECD's) chemical hazard assessment program and OECD harmonized templates as the internationally accepted model for providing information on study results, study quality and reliability.

Potency – The proposal is defective as there is no indication of potency for traits which exhibit a hazard. Without some indication of potency, every substance, whether synthetic or naturally occurring, could be considered toxic, even the "greenest" of substances. The concept of dose-response is a standard part of hazard assessment. GCA recommends OEHHA look toward

existing systems, particularly the OECD's robust summaries, to understand how other bodies have handled this critical issue.

Weight of Evidence – The proposed regulation provides insufficient consideration to weight of evidence. As framed, the proposed classification would proceed with weight given only to positive data. There are inadequate procedures for considering negative data. A scientifically sound weight of evidence process depends on looking at both positive and negative data and the reproducibility of results. Without considering these, the format proposed by OEHHA is skewed and not scientifically supportable. OEHHA must implement a weight of evidence approach considering both the positive and negative evidence that may be available about substances under evaluation in the TIC. Such information must also consider potency – the current proposal ignores this critical information.

Exhibit 1, GCA comments to OEHHA dated September 13, 2010 regarding Pre-Draft Hazard Trait Regulation Comment Letter –is included and incorporated by reference.

# # # # #

ATTACHMENT 1

GCA OVERARCHING CONCERNS

Independent Scientific Peer Review

The scientific portions of the proposed regulation have not yet been subjected to independent external scientific peer review. Although public comments have been solicited by OEHHA, the public comment process is not equivalent to scientific peer review, and does not substitute for scientific peer review.[1] Under California Health and Safety Code Section 57004 (HSC 57004), all CalEPA organizations, including OEHHA, are required to conduct an external scientific peer review of the scientific basis for any rule proposed for adoption, and a final regulation cannot be issued until such a scientific peer review has been completed. HSC 57004 recognizes the ramifications any science based regulations may have, and therefore imposes the general peer-review requirements which must be satisfied. OEHHA's proposed regulation would create a novel, California-only method of hazard classification or designation. Therefore, it is imperative that the scientific basis of the regulation is thoroughly and comprehensively peer reviewed by external scientific experts to establish that the proposed rule is based upon sound scientific knowledge, methods, and practices. In accordance with HSC 57004, the most appropriate body for conducting the external scientific peer review is the National Academy of Sciences (NAS), since the proposed regulation represents scientifically questionable deviations from well established, internationally agreed upon systems for evaluating and describing chemical hazards.,. In addition, the NAS is best suited to conduct the required external scientific peer review because of its global stature and proven track record for tackling complex toxicology and risk assessment issues. Moreover, adoption of a novel California-specific method of hazard trait identification could have global ramifications, since the California economy represents 13-14% of the US GDP and is the world's eighth largest economy. For all of these reasons, scientific peer review of the OEHHA proposal is critical to establish that the proposed rule is based upon sound scientific knowledge, methods, and practices.

Existing Systems

The Initial Statement of Reasons states that in complying with its statutory obligation under Government Code subsection 11346.5(a)(13), "OEHHA has determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, would be more effective in carrying out the purpose for which this action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action." This is simply not the case.

Several existing hazard trait and toxicological end-point regimes currently in existence nationally and internationally are widely in use and could be easily leveraged by California in harmony with existing practice. The hazard criteria proposed by the US Occupational Safety and Health Administration (OSHA) to modify its existing Hazard Communication Standard (HCS) to conform with the United Nations' (UN) Globally Harmonized System of Classification and Labeling of Chemicals (GHS; *74 FR 50279*, September 30, 2009) constitute one set of hazard traits that will be widely used in commerce in the US and across the globe. Perhaps more applicable to the

[1] The differences between public comment and independent scientific per review are explained in EPA's Peer Review Handbook, 3rd Edition (2006), pg 14.
http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf

development of the Toxics Information Clearinghouse (TIC), the OECD Harmonized Templates for Reporting Chemical Test Summaries are standard data formats for reporting studies done on chemicals to determine their properties or effects on human health and the environment.[2] These templates are the basis for the International Uniform Chemical Information Database (IUCLID) which is the standardized format for reporting chemical test data in the USEPA and OECD High Production Volume Chemical Challenge Programs, and the European REACH chemical management program.

GCA is concerned that having a new California-only system as proposed under the draft regulation is inefficient, duplicative, and will make it unnecessarily difficult to leverage existing information on chemicals. For conventional hazard traits, OEHHA should harmonize as much as possible with existing international and national systems that already identify the information elements necessary to study and characterize chemicals. If California wants to create a system that can be populated quickly and efficiently, these systems should be leveraged. Tens of thousands of tests for thousands of chemicals have been or will be performed and interpreted through these systems. Leveraging these existing systems will provide a framework for things like the use of categories, tiered testing, acute vs. chronic toxicity, judging study quality/reliability, and weight of evidence approaches, all of which are inadequately addressed at all in OEHHA's proposed regulation.

If California proceeds with a non-standard approach, not only will the database take years to develop and populate, but there will be a substantial Agency effort (time, resources, cost) required to convert the information in the tens of thousands of available studies to the unique California system both initially and on an ongoing basis. Given that there are existing systems currently in use worldwide, it is not clear why OEHHA has chosen to develop a unique system. OEHHA has failed to discuss why existing systems are inadequate and why there is a need for a unique system. Moreover, instead of creating a novel, California-unique designation of toxicities and endpoints that will require significant state resources to populate even with existing information, OEHHA could offer a far more cost efficient solution by leveraging existing data already provided to the world's governments and create a master portal that provides easy access to existing information sources. Such an approach would avoid a California-unique approach that makes no sense and would be a drain on an already fragile economy.

Classification

The classification proposal should be abandoned entirely. SB 509 gives OEHHA neither the mandate nor the authority to create a novel California classification system. DTSC has responsibility for what actually gets placed into the TIC, not OEHHA. The classification system is a significant overstep of OEHHA's authority into DTSC's responsibilities. Moreover, the entire classification provision is pejorative, unrealistic, and unhelpful. The OEHHA proposal does not bring clarity to chemical information. Indeed, it increases opacity on all dimensions.

ARTICLE 1 – GENERAL

Section 69401.2 – Definitions

(b) "Authoritative organization" – This definition fails to account for the concept of "deliberative review" in coming up with scientific findings versus creation of derivative lists. Referencing "other states" is particularly concerning, where there are generally no authoritative

[2] http://www.oecd.org/site/0,3407,en_21571361_43392827_1_1_1_1_1,00.html

processes in place. However, on page 4 (of 24) the wording suggests that "authoritative organizations" are limited to those listed.

(c) "Chemical substance" – this definition is broadly expansive and different from DTSC's proposal.

(e) "Hazard Traits" – this definition lacks clarity in that it does not actually define what a hazard trait is, but states (in a circular fashion) the types of hazards. Hazards are, in the context of chemicals, inherent properties that lead to adverse effects in humans and wildlife. In the context of the present regulation, they are toxicities. The definition should be amended accordingly.

(f) "Mechanistic similarity" – this definition is sweeping and imprecise and is not consistent with the terms usually applied within the toxicological community. This definition should be expanded to include not only a similar mode of action/toxicological effect, but also considerations on the toxicokinetic profile of the chemical (such as in their absorption, distribution, metabolism, and excretion (ADME) profile, for example, or in their Physiologically-based, Pharmacokinetic (PBPK) models). The toxicokinetic profile is important to establish whether the same level of concern is warranted for a chemical with a similar mode of action.

(g) "Other relevant data" – this definition lacks clarity and consistency with the authorizing statute (SB 509) in that OEHHA has narrowly interpreted the scope of the definition. The statute states that the office shall specify "any other relevant data that are to be included in the clearinghouse." These other relevant data are not restricted to only hazard traits, but could be any relevant data about a chemical in the TIC. Potential exposure is but one example. Is it permitted in commerce in the United States? Is it widely used in commerce in the US? What kind of applications is the chemical used for? Information addressing these questions is very relevant and useful to be captured by the TIC, and easily accessible towards that end.

Much more than hazard information alone is needed for people searching for alternatives, whether they are product manufacturers, DTSC staff, or lay citizens. EPA is finalizing changes to its Inventory Update Rule (IUR) which will collect 2010 chemical information. The Toxics Information Clearinghouse should include information reported by industry to IUR. Use categories, chemical functional uses and production volume will be reported by industry in mid-2011 and should be integrated into the "Other Relevant Information" section of the TIC.

Further, while there is important physical-chemical information that should be included in the TIC, to try to characterize this information as "exposure potential hazard traits" is unscientific and contrary to well established chemical management practices. This information rightly belongs in the "other relevant information" segment of the TIC.

(h) "Toxicological endpoint" – this definition lacks clarity because it is not specific to toxicity and the potential to cause harm. This definition should be revised as such, and additional definitions for other hazard trait endpoints should be defined as necessary.

(i) "Well-conducted scientific study" – this definition lacks clarity and consistency in that it might arbitrarily exclude any study which is not published in the open literature, or submitted to a government agency. Furthermore, this definition is different and inconsistent with DTSC's "reliable information" definition, which attempts to address the critical need of understanding

the quality and reliability of a study. GCA recommends that OEHHA withdraw the "well-conducted scientific studies" terminology and replace it with the following definition:

> *"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."* [3]

ARTICLE 2 – TOXICOLOGICAL HAZARD TRAITS

Section 69402.2 – Evidence for Carcinogenicity Hazard Trait

This entire section is unnecessary and unauthorized by the statute (SB 509) in that the state is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints. Furthermore, this section of the regulations is duplicative of the office's function of identifying carcinogens under Proposition 65. This section should be eliminated.

Section 69402.4 – Evidence for Developmental Toxicity Hazard Trait

This entire section is unnecessary and unauthorized by the statute (SB 509) in that the state is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints. Furthermore, this section of the regulations is duplicative of the office's function of identifying developmental toxicants under Prop. 65. This section should be eliminated.

Section 69402.6 – Evidence for Reproductive Toxicity Hazard Trait

This entire section is unnecessary and unauthorized by the statute (SB 509) in that the state is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints. Furthermore, this section of the regulations is duplicative of the office's function of identifying reproductive toxicants under Prop. 65. This section should be eliminated.

ARTICLE 3 – OTHER TOXICOLOGICAL HAZARD TRAITS

List of "icities"

OEHHA has justified its position on use of the long list of toxicities as hazard traits by stating that each trait was chosen in part because of listings within a textbook of toxicology, where discussions are broken out by target organ systems. Regardless of the fact that toxicology textbooks may organize information based on target organs, it is a generally accepted method for hazard identification to describe hazards in terms of either durations of exposure (*i.e.* toxic effects seen after acute exposure, toxic effects see after chronic exposures) or local versus systemic toxicity. Then, under the hazard trait of "systemic toxicity," the target organs would be identified (*i.e.* liver, kidney, heart, etc.). It is unnecessary to break out systemic toxicity or target organ toxicity by specific systems (*e.g.* cardiovascular, gastrointestinal, liver, renal, etc.) when

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

the goal is hazard identification. Instead, listing target organ effects is more than adequate to describe a chemical's hazard. This is especially true since the critical issue for chemical hazard classification should be identifying the most sensitive system(s) affected by chemical exposure, not simply a laundry list of toxicity. Thus, when the goal is hazard identification, GCA argues that there is no need to break out systemic toxicity or target organ toxicity by specific systems as proposed in the draft regulation (e.g., cardiovascular, gastrointestinal, liver, renal, etc.).

It is also important to consider that none of the prominent national or international systems list the vast number of "icities" contained in the OEHHA proposal. On the human heath side for instance, chemicals are characterized for "acute toxicity" and "chronic toxicity" (sometimes "systemic toxicity"). Organ systems impacted are noted, but there is no presumption of separate and distinct test for every organ system that the OEHHA proposal implies. The structure presented by OEHHA could be misinterpreted in such a way. Noting which organ system(s) is most sensitive is more than adequate to describe a chemical's hazard. Said differently, a single test can cover many different "icities," and the TIC should be structured in a way that makes that more apparent to users.

Emerging Traits

With regard to "emerging" traits, endocrine disruption (Section 69403.3) and epigenetics (Section 69403.4), for example, are mechanisms of potential toxicity, not toxic end-points themselves and thus not hazard traits. As such, OEHHA should not unilaterally establish these or other new hazard traits.

Section 69403 – General

The regulations should be clarified and made consistent with the general practice of organizing toxicological hazards among acute toxicities and repeat dose toxicities.

Section 69403.3 – Endocrine Toxicity

Endocrine toxicity is a new emphasis within chemical risk assessment and toxicity testing. It is standard practice in toxicology and risk assessment to describe toxic effects on endocrine organs as part of the systemic toxicity of chemicals, or as part of the hazard trait of reproductive toxicity or developmental toxicity, since toxicity to these systems is related to effects on endocrine systems. OEHHA fails to discuss the fact that many of the endpoints listed in this section have not been validated as unique endpoints for identifying endocrine toxicity of chemicals. Moreover, the listing of endocrine toxicity as a unique hazard trait is somewhat redundant when reproductive and developmental toxicity are listed.

Section 69403.4 – Epigenetic Toxicity

Epigenetic toxicity as defined by OEHHA is overly broad as it could include adaptive as well as adverse effects on organisms. The omission of a discussion of adaptive changes versus adverse effects of chemicals is a flaw that affects all steps in the process of identifying hazard traits. The changes listed should be manifested in standard toxicity testing as endpoints of systemic toxicity and would include changes in either biological function or tissue structure (pathological or histopathological changes). If such changes do not manifest in acute or repeat dose toxicity studies, then they may be adaptive changes only and not relevant for chemical hazard assessment. OEHHA fails to provide any scientific basis for including "epigenetic toxicity" as a separate discrete hazard trait apart from systemic toxicity.

Section 69403.5 – Genotoxicity
This section should be clarified to specify what constitutes an adverse outcome with respect to genotoxicity.

Section 69403.8 – Immunotoxicity

Section (b) states "Endpoints include" but then the list of items appear to be more of a mix of overall endpoint outcomes, syndromes and measurable effects/observations. It appears confusing to have allergic sensitization alongside changes in circulating immune cells. Moreover there is no context in their relative significance. Alteration in cytokine production and release are observations that might be relevant as entry points in the assessment of sensitization, immunostimulation/suppression or autoimmunity. Data could be from humans or laboratory animals but no distinction is made here. In any case, there has to be tiered approach in terms of what experimental data you would need in order to be able to determine whether sufficient or insufficient to conclude upon immunotoxicity. This also makes (c) awkward to interpret – why are only two items cited here - is there some other more specific text that provides the context for what evidence is needed to substantiate structural/mechanistic similarity? Only the definition for mechanistic similarity is provided.

Section 69403.12 – Ocular Toxicity

This section should be clarified to specify what constitutes an adverse effect (not change) with respect to genotoxicity.

Ocular toxicity is an endpoint commonly addressed through testing for eye irritation and damage in standard acute toxicity tests in animals. As a result, ocular effects are included as a hazard trait within many classification systems. Since testing for eye irritation, for example, is commonly included within standard toxicity testing batteries, it is unclear why OEHHA has chosen to deviate from the standard approach to identifying hazards to the eye.

Section 69403.14 – Reactivity in Biological System

This section should be clarified to specify what constitutes an adverse outcome with respect to reactivity in biological systems.

Reactivity in biological systems is an overly broad trait that is not useful for hazard evaluation since all chemicals could be considered to "react" with biological systems simply by being absorbed into a cell. The endpoints mentioned in the OEHHA proposal appear to fit more easily within other hazard trait categories as underlying mechanisms or modes of action.

Section 69403.15 – Respiratory Toxicity

This section should be clarified to specify what constitutes an adverse effect (not change) with respect to reactivity in biological systems.

Respiratory toxicity is also a standard endpoint of systemic toxicity that would be monitored in most acute as well as repeat dose toxicity studies. As already discussed above for other endpoints of systemic toxicity, it is not clear why OEHHA has chosen to isolate changes in respiratory function apart from systemic toxicity when most other toxicity classification and hazard identification systems would include such endpoints within the scope of defining chemical hazard in terms of systemic toxicity. Also, some of the endpoints listed in the proposal have not been validated as indicators of adverse effects as opposed to adaptive changes (*e.g.* increased inflammatory cytokine expression.)

Section 69403.16 – Evidence for Toxicological Hazard Traits

This entire section is unnecessary and unauthorized by the statute (SB 509) in that the office is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints. Furthermore, while it will be critical that only high quality information is included in the Toxics Information Clearinghouse (TIC), it is the purview of the Department of Toxic Substances Control to establish the criteria for inclusion of any particular study, or other data or information in the TIC.

ARTICLE 3 & 4 – TOXICOLOGICAL & ENVIRONMENTAL HAZARD TRAITS

Endpoint Lists

Each of the toxicological and environmental traits in the OEHHA proposal is accompanied by a list of possible endpoints that could demonstrate that a chemical has the respective trait. However, the hazard traits and endpoints listed are not actual hazard traits or endpoints. Rather, much of what is listed in the draft are preludes in multiple-step pathways that may or may not lead to disease or an adverse outcome (i.e., these are actually mechanisms and not endpoints; examples include epigenetic adverse perturbations and electrophilic potential). This will not further the Green Chemistry goals or provide the certainty necessary to make prioritization decisions or weigh chemical alternatives.

ARTICLE 4 – ENVIRONMENTAL HAZARD TRAITS

Section 69404.1 – Domesticated Animal Toxicity

This section is unnecessary in that it is making a distinction with respect to the inherent toxicity of a chemical based on the route of exposure of that chemical, which is not an inherent property. Furthermore, it is one more example of the development of a California-unique system that does not mesh with other established systems and associated data/criteria. This section should be eliminated and any data which might be included in the TIC that is relevant to domesticated species should be generally included with all other data for animals and wildlife.

Section 69404.2 – Eutrophication

This proposed hazard trait section is unnecessary, lacks clarity and should therefore be eliminated. Eutrophication is a complex process that is influenced by a number of physical, biological and chemical factors within the ecosystem. It is not an inherent property of a chemical, and therefore, should not be considered a hazard trait of a chemical.

Section 69404.3 – Impairment of Waste Management Organisms

This proposed hazard trait is unnecessary and should therefore be eliminated. While there are specific internationally accepted standardized tests to determine the potential for a chemical to impact organism in biological waste treatment systems, it is just another facet of environmental toxicity. The regulations would be clearer if generally accepted terminology was used rather than California developing new terminology.

Section 69404.4 – Loss of Genetic Diversity, Including Biodiversity

This proposed hazard trait is unnecessary and should be removed. The potential for a chemical to adversely affect the community structure of an ecosystem is no different than the environmental toxicity of a chemical. Moreover, it is not possible to objectively quantify the effect a chemical may have on a particular ecosystem since the health of any ecosystem will be the subject of a great number of factors. For this and all subsequent traits that have a field data component, there is a major problem in that potential effects in the field exist in the context of multiple stressors and it is frequently not possible to parse out the causative stressor(s) responsible for the observed effect. Use of field data will require additional confirmatory data, e.g., from lab studies, etc., in order to be indicative of a particular hazard trait in most instances. This includes data on things like wildlife reproductive impairment based on field data.

Section 69404.10 – Evidence for Environmental Hazard Traits

This entire section is unnecessary and unauthorized by the statute (SB 509) in that the office is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints. Furthermore, while it will be critical that only high quality information is included in the Toxics Information Clearinghouse (TIC), it is the purview of the Department of Toxic Substances Control to establish the criteria for inclusion of any particular study, or other data or information in the TIC.

ARTICLE 5 – EXPOSURE POTENTIAL HAZARD TRAITS

Article 5 is unnecessary and lacks clarity. The state is proposing to establish that certain physical-chemical properties of a chemical are hazards. This notion has no basis in science and there is no precedent anywhere in the world.

The “exposure potential hazard trait” concept should be stricken from this regulation. Exposure potential is not a hazard. Rather hazard is an intrinsic trait that requires adequate exposure to demonstrate the hazard, i.e., hazards can only be manifest when the exposure are sufficiently high. One would not expect to demonstrate a hazard from exposure to a single molecule of a substance. This concept is embodied in the Prop 65 statutory language and Safe Harbor levels that OEHHA has set for hazardous substances.

While exposure potential is certainly germane to risk, it is so only in the context of a particular chemical having a specific hazard associated with it. The appropriate manner in which to incorporate consideration of exposure potential is therefore directly in the consideration related to each specific hazard trait, as identified in earlier sections of the Proposed Regulation, where such consideration may be relevant as “other relevant data.” To label these considerations of exposure as hazard traits is both misleading and ripe for abuse.

Some individual items within this section (*e.g.* bioaccumulation, environmental persistence) are important chemical properties that are often reported and for which there may be substantial data to populate the TIC. While it is fair to consider these properties as “other relevant data” and include them in the TIC as such, they should not be considered stand-alone hazard traits.

Additionally, the following sections in Article 5 are currently subject to existing regulations set forth by the U.S. EPA's National Ambient Air Quality Standards, U.S. EPA’s Stratospheric Protection Division's Regulations, and/or California Air Resources Board’s (CARB's) Greenhouse Gas Rules.

- Section 69405.1 Ambient Ozone Formation;
- Section 69405.4 Global Warming Potential;
- Section 69405.7 Particle Size or Fiber Dimension; and
- Section 69405.8 Stratospheric Ozone Depletion Potential.

SB 509 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." Therefore, if Article 5 is not deleted, an exemption from each of the sections referenced above should be included for products subject to current and draft regulations.

Section 69405.1 – Ambient Ozone Formation

Ozone formation is not a hazard trait and should therefore be removed from the regulation. By definition of the reference cited in OEHHA's draft regulation[4] "Ozone, the tri-atomic form of oxygen, is a gaseous atmospheric constituent. In the troposphere, ozone is created both naturally and by photochemical reactions involving gases resulting from human activities." The formation of ozone may amount in measurable concentrations that reach an effect level for organisms that are exposed; however ozone formation in itself is not a hazard trait.

Section 69405.2 – Bioaccumulation

As noted above, bioaccumulation is not a hazard trait and should be removed from the regulation as such. Although bioaccumulation has been defined by various credible entities[5], none have defined it as a hazard trait. That said, it is an important inherent chemical property that is often measured and reported. As such, it could be included in the Toxics Information Clearinghouse as "other relevant data."

OEHHA should use the best available science when identifying appropriate bioaccumulation data to be included in the TIC. Recently, the Society of Environmental Toxicology and Chemistry (SETAC) conducted a Pellston workshop on POPs and PBTs that explored the current state of bioaccumulation science.[6] 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 bioconcentration factor (BCF), bioaccumulation factor (BAF), biomagnification factor (BMF, both laboratory and field), trophic magnification factor (TMF), 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 "BCF is no longer recognized to be a good descriptor of the biomagnifications capacity of chemical substances." One criterion found in the OEHHA proposed regulation that was not the subject of the SETAC exercise is "inhibition of an efflux transporter;" this concept is not generally accepted by the scientific community as a measure of the potential for a compound to

[4] The Intergovernmental Panel on Climate Change, IPCC Fourth Assessment Report: Climate Change 2007. World Health Organization and United Nations Environment Programme, Annex I Glossary. (The annex is incorrectly cited in the draft regulation; Annex 1 contains the glossary).
[5] From USGS Toxics Substances Hydrology Program website: http://toxics.usgs.gov/definitions/bioaccumulation.html
[6] Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and KPlotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.

bioaccumulate and should be eliminated from the OEHHA proposal. OEHHA should consider including the other six criteria (BCF, BAF, BMF, TMF, K_{OW}, and K_{OA}) in the TIC as "other relevant data" as they are common chemical measures.

As has been stated previously, OEHHA has proposed to classify chemicals as a bioaccumulation hazard if its bioaccumulation factor (BAF) is greater than 1000, or it has a log octanol-water partition coefficient greater than or equal to 5. Bioaccumulation is not a hazard, and OEHHA has neither the mandate nor the authority to be classifying chemicals as such. Therefore, this classification aspect of bioaccumulation should be eliminated.

Section 69405.3 – Environmental Persistence

The identification of classification threshold values for this trait is unauthorized by the statute (SB 509) in that OEHHA is attempting to classify chemicals when it is only authorized to specify hazard traits and endpoints.

Furthermore, persistence is not a hazard characteristic. Persistence is a characteristic whereby the chemical resists photolytic, biological and chemical degradation.[7] Because it is persistent, a material could become measurable in environmental media and depending on the level, it may be present in high enough concentrations to each an effect level for organisms that are exposed; however, persistence in itself is not a hazard trait. OEHHA should include persistence as "other relevant data" as it is a common chemical measure.

Section 69405.4 – Global Warming Potential (GWP)

Global Warming Potential (GWP) is not a hazard trait and should therefore be removed from the regulation. By definition of the reference cited in OEHHA's draft regulation,[8] GWP is "An index, based upon radiative properties of well mixed greenhouse gases, measuring the radiative forcing of a unit mass of a given well mixed greenhouse gas in today's atmosphere integrated over a chosen time horizon, relative to that of CO2. The GWP represents the combined effect of the differing lengths of time that these gases remain in the atmosphere and their relative effectiveness in absorbing outgoing infrared radiation."

Section 69405.6 – Mobility in Environmental Media

Mobility in environmental media is not a hazard trait and should therefore be removed from the regulation. Mobility in air, water or soil/sediment will depend on external conditions, such as temperature, humidity, organic content of soil and sediment. Mobility is not an inherent characteristic of a chemical and it is not a hazard trait.

Section 69405.7 – Particle Size or Fiber Dimension

Particle Size or Fiber Dimension is not a hazard trait and should therefore be removed from the regulation. By themselves, particle size and fiber dimension do not convey hazard, only deposition probability in the respiratory tract, and therefore inclusion of this separate category as a "hazard trait" is inappropriate and misleading. Furthermore, it is unclear if the dimensions cited could encompass all nanomaterials.

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[7] Ritter L; Solomon KR, Forget J, Stemeroff M, O'Leary C.. "Persistent organic pollutants". *United Nations Environment Programme*. http://www.chem.unep.ch/pops/ritter/en/ritteren.pdf. Retrieved 2007-09-16.

[8] The Intergovernmental Panel on Climate Change, IPCC Fourth Assessment Report: Climate Change 2007. World Health Organization and United Nations Environment Programme, Annex I Glossary. (The annex is incorrectly cited in the draft regulation; Annex 1 contains the glossary).

Section 69405.8 – Stratospheric Ozone Depletion Potential

Stratospheric Ozone Depletion Potential (ODP) is not a hazard trait and should therefore be removed. According to EPA's Ozone Layer Protection Glossary[9] "Ozone Depletion Potential (ODP): a number that refers to the amount of ozone depletion caused by a substance The ODP is the ratio of the impact on ozone of a chemical compared to the impact of a similar mass of CFC-11. Thus, the ODP of CFC-11 is defined to be 1.0. Other CFCs and HCFCs have ODPs that range from 0.01 to 1.0."

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[9] http://www.epa.gov/ozone/defns.html

ATTACHMENT 2

The Green Chemistry Alliance (GCA) questions OEHHA proceeding with regulatory action related to Green Chemistry Hazard Traits at this time in light of Secretary Adams' announcement of December 23, 2010 that she has directed the Department of Toxic Substances Control (DTSC) to take additional time to develop regulations for the California Green Chemistry Initiative.[10] OEHHA's actions in this regard seem to fly in the face of the Secretary's decision and signal a very troubling lack of coordination in CalEPA among OEHHA, DTSC and the Secretary. This apparent lack of coordination with the DTSC proposed regulations and DTSC's vision for the Toxics Information Clearinghouse (TIC) signifies the need for additional time and action by the Secretary, DTSC and OEHHA to employ the vision of developing and implementing the very best program possible, one that is workable and addresses key policy concerns.[11]

To develop and implement a program that is firmly grounded in science, one that is workable and one that addresses key policy concerns greater coordination between the CalEPA, DTSC and OEHHA is critical. The novel approach OEHHA has proposed for hazard trait determination oversteps its statutory authority. Further, in many instances the proposed approach represents scientifically questionable deviations from well established, internationally agreed upon systems for evaluating and describing chemical hazards.

Given the lack of coordination thus far and recent change in Administration, it is important that incoming leaders and DTSC and OEHHA have the opportunity to provide the Brown Administration's input regarding the path forward for the overall Green Chemistry Initiative. The OEHHA regulation will both define content for the Toxics Information Clearinghouse (TIC) and be considerations in defining "Chemicals of Concern," per the laws. Without clarity on the regulatory structure into which the traits must fit, there is too much uncertainty regarding both their operative impact and sufficiency.

GCA strongly urges OEHHA to first undertake the necessary coordination with DTSC and the CalEPA Secretary and then to revise the proposed regulation to adopt a structure that allows existing chemical toxicity information and hazard trait determinations to be utilized in a scientifically rigorous manner to more quickly and cost effectively fulfill its mandate under SB 509.

With these points and concerns as a basis, Attachment 2 reviews many of the outstanding issues that are not resolved by the proposed regulation. In many cases, OEHHA has indicated that a particular task is DTSC's responsibility. GCA is concerned that the gray areas between the responsibilities of CalEPA, DTSC, and OEHHA are critical issues that must be discussed and resolved prior to finalizing this proposed regulation. The following points address specific issues and concerns regarding OEHHA's regulation for which OEHHA may or may not have the authority or responsibility to address, but nonetheless must be considered and included as part of the bigger approach for green chemistry.

[10] http://www.dtsc.ca.gov/upload/GRSP-12-23-2010.pdf
[11] ibid

ARTICLE 1 - GENERAL

Classification

It is important to note that DTSC, in its Toxics Information Clearinghouse Feasibility Study Report[12], suggests that the user will make their own judgment as to the hazards, based on the information presented. (p.26)

> *"DTSC will not be conducting any safety assessments and do not want to imply that inadvertently. The Clearinghouse is envisioned to provide access to all of the information; and any determinations and interpretation of the data will be left to the user based on the information in the Clearinghouse."*

Thus, the Hazard Trait Regulation and Clearinghouse should be open to including all information available on a chemical, but remain as objective as possible, without introducing biases and subjectivity through a classification system.

And while GCA objects to OEHHA's classification approach (lack of authority), the approach completely fails to address potency and weight of evidence (see discussion below regarding Section 69403.16 – Evidence for Toxicological Hazard Traits). These two components must be addressed in any classification system and in fact are addressed in OSHA's GHS.

Potency

There is a dose level that produces an effect for every chemical. How will the TIC address the very real issue of potency before declaring that substance possesses a toxicity trait? Potency is a measure of the hazard potential and is a critical part of any hazard identification process.

The OEHHA proposal is deficient in that there is no indication of consideration of potency for the hazard traits for which there is evidence of hazard. Without some indication of potency cutoff values, every substance, whether synthetic or naturally occurring, could be considered toxic. As a case in point, without information about the dose at which a substance causes acute toxicity, will everything in the TIC be marked as acutely toxic?

OEHHA has established a framework that will undoubtedly be misunderstood and certainly misused.

We recommend that OEHHA look at existing systems, particularly the OECD Harmonized Templates for Reporting Chemical Test Summaries (see comments above) to understand how authoritative and respected bodies have handled this critical issue.

Data Quality

OEHHA needs to clearly identify how certain types of data should be weighed when assessing chemical hazards, recognizing that certain types of data are less appropriate than others, even if they are developed by authoritative bodies. Evaluation of chemicals should be based on the best available data. Best practices in toxicology use the following order of preference: 1) measured data on the chemical being evaluated, 2) measured data from a suitable analog, and 3) estimated data from appropriate models.

[12] Toxics Information Clearinghouse Feasibility Study Report. DTSC. April 8, 2010.

In vitro studies and QSARs are generally recognized as appropriate tools prioritizing chemicals and identifying the need for more complex biological system testing, but are limited in their ability by themselves to make decisions about risk or even classification of toxicological properties as OEHHA proposes. There are significant efforts underway nationally and internationally to reduce the need for unnecessary animal testing and GCA supports those programs. However, the validity of many *in vitro* studies to human health is still being evaluated and should be considered for assigning hazard traits to a chemical only after it has been clearly demonstrated that the specific method is scientifically valid and achieves an acceptable level of sensitivity (false negative rate) and specificity (false positive rate). There are multiple validated assays that have false positive rates that exceed validated *in vivo* methods (*e.g. in vitro* micronucleus assays). Additionally, *in silico* (computer simulation) methodology holds great promise, but in its current state, should be applied cautiously and only for select classes of materials and endpoints for which the models have been scientifically justified. Currently most *in silico* and *in vitro* assays only provide an indication of potential hazard and should not be the sole basis of decisions such as assigning or classifying a hazard trait. This is recognized by regulatory bodies worldwide, and is exemplified by OECD's development of internationally harmonized guidance on the validation[13] and regulatory acceptability[14] of QSAR models and alternative test methods for predicting biological effects and toxicity. All testing methods in the proposed regulation should be based on national and international standard protocols or validation by an appropriate authoritative body.

> "*It will always be necessary to evaluate relevance, reliability, sensitivity, and specificity of advanced high-throughput molecular screening and computational profiling methods prior to regulatory acceptance so that regulatory agencies, the regulated community, and the public have sufficient confidence in the decisions based on such methods. While traditional structures for conducting method validation and demonstrating model predictivity may not be practical, approaches such as those discussed by the National Research Council, Committee on Applications of Toxicogenomic Technologies to Predictive Toxicology, Board of Environmental Studies and Toxicology, Board of Life Studies, Division of Earth and Life Studies (2007b) with respect to validation of toxicogenomic technologies as well as practices embodied in the Organization for Economic Cooperation and Development (OECD) principles and guidance for the validation of quantitative structure activity relationships (OECD, 2007) and evidence-based toxicology (Guzelian et al., 2005; Hoffmann and Hartung, 2006) should be considered."*[15]

What kind of quality control and/or contextual information will accompany data and information from *in vitro* and QSAR studies? OEHHA has indicated that this is a DTSC responsibility and that they do not plan to address these issues in their regulation. Is DTSC prepared to develop data quality guidance (and perhaps test methods) for all of OEHHA's various toxicities? How and to what degree are the two agencies coordinating, given that OEHHA's actions directly impact DTSC's 1879 implementation? What implications does DTSC see for the safer alternatives process?

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[13] Guidance Document No. 69 on the Validation of (Quantitative) Structure-Activity Relationship [(Q)SAR] Models (see http://www.oecd.org/dataoecd/55/35/38130292.pdf)

[14] Guidance Document No.34 on the Validation and International Acceptance of new or Updated Test Methods for Hazard Assessment http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2005)14&doclanguage=en

[15] Becker, Richard and James Bus. Toxicity Testing in the 21st Century: A View from the Chemical Industry. Toxicological Sciences (2009),doi:10.1093/toxsci/kfp234

The notion of “reliable information” and study quality is not addressed in the OEHHA draft other than marginally via a “well-conducted scientific studies” concept. Peer-review alone is an insufficient metric of study quality. The OECD methodology for determining the quality of data in chemical dossiers described in their Manual for Investigation of HPV Chemicals is a globally accepted way to rate the reliability, relevance and adequacy of existing data; as such, it should be defined into these regulations and required for every study used to populate the TIC. It has been applied to all studies in the US and OECD HPV programs and is required of all chemicals submitted under REACh (4300 high volume and high hazard chemicals submitted as of January 2011). It has been found to be an excellent approach to separate good studies from those that are not of sufficient quality and reliability for science-based regulatory and product stewardship decisions.

Data quality and weighting considerations are critical in ensuring good decision making in Prioritization and Alternative Analysis. Use of poor quality data can result at a minimum in needless action and at worst, unintended consequences. This is particularly important in the context of evaluating potential hazards associated with metabolic products and environmental breakdown products. For example, a study showing that a parent compound can be broken down to toxic metabolites under artificial conditions in a laboratory setting should not serve as the basis for assigning hazard traits unless there is evidence of such process occurring under actual environmental conditions. Weighting consideration are also important in the context of relevance for human health hazard where data collected in a non-standard species of unknown relevance to human physiology should not be given equal weight as compared to a study conducted in a standard laboratory animal species whose physiology is known to be relevant for human health hazard assessment.

If the TIC is populated with all available data and information in the absence of quality and reliability screens; how is any user, technical expert or lay citizen, supposed to identify what’s truly relevant for making a decision? Even users with technical backgrounds will require an enormous amount of time to sift through the TIC if there are no quality control measures in place.

Questions of data quality and quantity raise the issue of resources DTSC will need to put toward its data quality and management obligations under SB 509. What are DTSC’s plans for populating the TIC, making data quality decisions, etc.? What importance will DTSC put on information generated through validated test guidelines versus other types of studies?

To address these issues and to harmonize with national and international approaches, OEHHA together with DTSC should adopt the robust study summary format used in the OECD’s hazard assessment program and OECD harmonized templates as a model for populating the TIC and, as a result, providing internationally accepted information on study quality and reliable information. This has the additional benefit of enabling a quick start-up of the TIC, since information from hundreds of thousands of studies on over 4300 chemicals has now been submitted to REACH and was rated according to this approach. Studies on thousands of additional chemicals will be forthcoming in this format in future years.

ARTICLE 2 – TOXICOLOGICAL HAZARD TRAITS

Section 69402.2 – Evidence for Carcinogenicity Hazard Trait

The lead agency should clearly state that there are a number of modes of action that are causally linked to tumor induction in lab animals that are not relevant to human health and therefore are not appropriate for use as evidence of a carcinogen hazard trait. Examples

include, but are not limited to, high-dose cytotoxicity which stimulates compensatory cell proliferation, certain receptor mediated responses and male rat kidney tumors caused by accumulation of α-2microglobulin.

ARTICLE 3 – OTHER TOXICOLOGICAL HAZARD TRAITS

Emerging Traits

True hazard traits should be measurable by recognized, validated tests. OEHHA should seek scientific consensus on the description of the trait and the appropriate study protocol for the endpoint(s) prior to including it in the regulation. OEHHA should be able to show that scientific consensus exists, or should be establishing the process for reaching that consensus where none exist, but they should not be unilaterally establishing new hazard traits.

Section 69403.3 – Endocrine Disruption

Endocrine disruption (Section 69403.3) is not an endpoint, but rather a mode of action. It has been standard practice in toxicology and risk assessment to describe toxic effects mediated by the endocrine system based on the apical adverse effects that are induced. Thus, a chemically-induced change on a component of the endocrine system that is of sufficient magnitude/duration/nature to cause an adverse effect on an organ system has, in practice, been evaluated as target organ toxicity (which includes assessment of reproductive toxicity or developmental toxicity). The OEHHA document fails to discuss the fact that many of the endpoints listed in their section have not been validated as unique endpoints for identifying endocrine disrupting chemicals.

As OEHHA is well aware, endocrine activity, consistent with the principles expressed in EPA's Endocrine Disruptor Screening Program (EDSP), 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. Interaction with or modulation of endocrine processes may or may not give rise to adverse effects; EPA states, "The fact that a substance may interact with a hormone system, however, does not mean that when the substance is used, it will cause adverse effects in humans or ecological systems." Toxicological tests that evaluate the induction of adverse effects in validated test systems (EPA's EDSP Tier 2 tests), not mechanistic screens, are to be used for hazard identification. As EPA has stated, "At this stage of the science, only after completion of Tier 2 tests will EPA be able to determine whether a particular substance may have an effect in humans that is similar to an effect produced by a naturally occurring EAT, that is, that the substance is an endocrine disruptor." The World Health Organization's definition of an endocrine disruptor is very similar to that of the EPA: "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

Section 69403.4 – Epigenetic Toxicity

Epigenetic toxicity (Section 69403.4) is an even newer concept within toxicology and has been examined as the basis for identifying mechanisms of systemic toxicity. In fact, "epigenetics" is defined as a mechanism of action for potential toxic effects, not an endpoint for toxicity testing. Epigenetic changes such as DNA methylation or histone modification, as listed in the OEHHA Proposal, may not lead to stable expressions of an altered, adverse phenotype, which is what would be needed in order to identify a specific endpoint of hazard or toxicity. The changes listed in Article 3 in association with epigenetic toxicity, however, should be manifested in standard

toxicity testing as endpoints of systemic toxicity and would include changes in either biological function or tissue structure (pathological or histopathological changes). If such changes do not manifest in acute or repeat dose toxicity studies, then they may be adaptive changes only and not relevant for chemical hazard assessment. OEHHA fails to provide any scientific basis for including "epigenetic toxicity" as a separate discrete hazard trait from systemic toxicity.

Section 69403.15 – Respiratory Toxicity

As with many of the "traits" cited in these Proposed Regulations, there is a conspicuous absence in this definition, of language that would clearly differentiate potential exposures at insignificant levels. This poses the possibility of materials being "classified" as having respiratory toxicity hazard where no hazard logically exists. From the perspective of nanomaterials, this is a concern because of the potential interaction with *§ 69405.7 Particle Size or Fiber Dimension* (see below). GCA recommends the addition of language at the end of (c), to clarify intent to deal with significant exposure threats. Specifically, we recommend it to read:

> *(c) Other relevant data include but are not limited to: in vitro evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers; long half-life in the lung; chemical reactivity; redox potential; structural or mechanistic similarity to other chemical substances with the respiratory toxicity hazard trait. In interpreting the above, anticipated exposure must be detectable or significant at levels above background.*

We would also call to your attention the inclusion in this definition of "*particle size distribution inclusive of respirable particles; respirable fibers;"* This is appropriately applied as a consideration relevant specifically to Respiratory Toxicity.

Section 69403.16 – Evidence for Toxicological Hazard Traits

It is a general principle of hazard assessment that all available data must be considered and weighted 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 data. Without such an approach, the document can be interpreted to suggest that a single assessment, regardless of its quality could be used to conclude that a chemical possesses "suggestive evidence" of a specific hazard trait. Additionally, with respect to cancer, developmental toxicity and reproductive toxicity hazards, it is likely that for many chemicals there will be multiple hazard assessments available from a variety of sources. As a result, specific discussion of how a weight-of-the-evidence assessment should be, and will be, performed is needed.

Without use of WOE, "sufficient evidence" of a hazard trait could be assigned to a chemical, for example, based on data from two poorly conducted studies even if there were several more reliable studies available that contradicted the results of those two studies. It is not scientifically valid to ignore this weight of the scientific evidence. Yet, while Section 69403.16 Evidence for Toxicological Hazard Traits proposes a framework for evaluating scientific results, it is not a WOE approach. Instead, OEHHA is proposing to simply count the positive studies, OEHHA's proposed approach fails to consider all the relevant information required for a causal determination and falls well short of the scientific standard of practice for weight of evidence evaluation in toxicity determinations. A scientifically sound WOE analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies. In contrast to a true WOE process, OEHHA's proposal makes no mention of 1) evaluating negative studies, 2) evaluating the consistency of results across different studies and over time, 3)

evaluating biological plausibility. The framework that OEHHA should employ must provide for a transparent, scientifically-based evaluation of the overall weight of evidence that a there is a relationship between an outcome of concern and exposure to a substance.

ARTICLE4 – ENVIRONMENTAL HAZARD TRAITS

Section 69404.5 – Phytotoxicity

Since this is the first time that in vitro evidence is discussed in the context of environmental hazard trait, it may be important to highlight the fact that *in vitro* approaches are not always predictive of whole organism effects for any number of reasons (*e.g.* whole organism physiology and metabolism capabilities are not always reflected in *in vitro* data). It would be useful to suggest that the text be altered throughout the document to indicate that *in vitro* data can only be used to indicate the hazard trait when it can be conclusively demonstrated that the *in vitro* effect is directly related to an apical, whole-organism effect of interest.

ARTICLE 5 – EXPOSURE POTENTIAL HAZARD TRAITS

Section 69405.7 – Particle Size or Fiber Dimension

According to the Statement of Reasons, the express intent of this is to focus on particles which may pose respiration hazard – clearly airborne nanomaterials can be respirable. However, the trait definition, itself, seems not narrowly tied to respiration. The particle description does not even mention respiration. It should be amended to add something to the effect that particles have to be free in the environment or measurably released. If opportunities for release are minimal or zero, the provision doesn't apply.

The fiber description does mention respirable, but complicates that by also citing "dermal or ingestion exposure" as concerns. This reference to "dermal or ingestion exposure" should be stricken. While getting material on skin or hand and transferring to mouth is often taken into account, size is not a defining property in the likelihood of that happening. This should not be mixed-up with the size-related respiratory hazard consideration.

Would this requirement encompass "regular" molecules? What factors would distinguish which chemicals to provide size/dimensional information on and which not?

Particle size and fiber dimension only impact deposition in the respiratory tract. Particle size or fiber dimension convey hazard only if the substance itself can cause the hazard in that they influence the deposition of the substance in the respiratory tract. Thus, particle size and fiber dimension are appropriately included in Section 69403.15 of Respiratory Hazards which states "Other relevant data include but are not limited to: *in vitro* evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers..."

Beyond the fundamental inconsistency referenced above, the operative elements of this definition are problematic in their own right, and should be revised in the context of any consideration of particle size or fiber dimension taken into account as "other relevant data" in any of the toxicological hazard traits.

# # # # #

EXHIBIT 2

Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

OEHHA Proposed Hazard Trait Regulation Concerns

August 31, 2011

1) DISCONNECT BETWEEN DTSC/OEHHA REGULATION

- OEHHA's proposed regulations are unclear and disconnected from DTSC's proposed regulations and vision for the Toxic Inventory Clearinghouse. OEHHA regulations are integral to the safer alternatives process. Scrutiny is critical in the development of applicable, definable and scientifically defensible hazard traits and endpoints which will inform the DTSC prioritization process.

- An important ancillary issue to keep in mind is that, the statute requires all hazard trait submissions to be exempted from CBI/trade secret protections. If all chemicals are deemed to exhibit hazard traits per the OEHHA regulation then trade secret protection could be compromised and innovation and the overall goal of the green chemistry process would stall upon implementation. OEHHA regulations should be developed concurrent with DTSC's safer consumer alternatives regulations as they closely interrelate.

2) BEYOND AUTHORITY PROVIDED IN STATUTE

- SB 509 (Simitian, 2008) requires "the Office of Environmental Health Hazard Assessment (OEHHA) to evaluate and specify the hazard traits and environmental and toxicological endpoints and any other relevant data that are to be included in the clearinghouse." This directive is simple and clear; however, the proposed regulation goes beyond the authority provided for in statute, by establishing a unique to California chemical classification system. (See Attachment 1)

- Classification – OEHHA's classification proposal should be abandoned entirely. SB 509 gives OEHHA neither the mandate nor the authority to create a novel California classification system. DTSC has responsibility for what actually goes into the TIC, not OEHHA. The classification system is a significant overstep of OEHHA's authority.

3) FAILS TO CONFORM TO EXISTING GLOBAL SYSTEMS

- The system of hazard traits envisioned by OEHHA is unlike any adopted by major countries and global cooperatives on chemical management. Why would California implement a unique chemical management data system that will not immediately be able to employ the extensive existing chemical data from around the world?

- The information contained in over 2100 chemical datasets that are publicly available under the OECD and US HPV program databases, over 3900 chemicals already available in the European Union's REACH database, and the 680,000 chemical data records contained in the OECD's eChemPortal provided by the 30 OECD member countries will be unusable in OEHHA's envisioned Hazard Trait system until it is laboriously converted from the global standard to OEHHA's approach. This is a scientifically ludicrous exercise, a waste of taxpayer funds and will significantly delay the use of the information in advancing Green Chemistry in California.

- Furthermore, a non-standard approach will slow the development of the TIC database and there will be a substantial agency effort required to convert the information to the unique California system, both initially and on an ongoing basis. The proposed regulation should use and conform to other systems that already exist, thereby fulfilling the provisions of the statute that contemplate reliance on existing systems and avoidance of duplication.

EXHIBIT 2

Attachment 1

Regulatory Authority Limited to the Department of Toxic Substances Control

The green chemistry law (AB 1879/SB 509) which is now codified in Article 14 of Chapter 6.5 of the California Health and Safety Code (Sections 25251 – 25257.1) authorizes the Department of Toxic Substances Control (the "Department") to promulgate regulations to implement its provisions. The statute references the Department's responsibility to promulgate regulations no fewer than fifteen (15) times. No other agency is given the express authority to promulgate regulations.

The statutory references to the regulatory authority of the Department include:

- Section 25252(a)
- *"On or before January 1, 2011, **the department** shall adopt regulations . . ."*
- *"**The department** shall adopt these regulations in consultation with the office . . ."*

- Section 25252 (b) (1)
- *"In adopting regulations pursuant to this section, **the department** shall develop criteria . . ."*

- Section 25252 (b)(2)
- *"In adopting regulations pursuant to this section, **the department** shall reference and use . . . "*

- Section 25252 (b)(3)
- *"Paragraph (2) does not require **the department,** when adopting regulations pursuant to this section, to reference and use . . ."*

- Section 25252.5 (a)
- *"Except as provided in subdivision (f), **the department**, in adopting the regulations. . . "*

- Section 25252.5 (b)
- *" . . . and information collected by **the department** in preparation for adopting the regulations ..."*

- Section 25252.5(c)
- *" . . following notice from **the department** that it intends to adopt regulations."*

- Section 25252.5 (d)
- *" . . . **the department** shall adopt revisions to the proposed regulation . . . "*

- Section 25252.5 (f)
- *"Notwithstanding subdivision (a), **the department** may adopt regulations . . ."*

- Section 25253 (a) (1)
- *"On or before January 1, 2011, **the department** shall adopt regulations . . . "*
- *"**The department** shall adopt these regulations in consultation with all appropriate state …"*

- Section 25253 (c)
- *"**The department**, in developing the processes and regulations pursuant to this section . . ."*

- Section 25255 (d) -*" The panel may . . . "*
- *"Advise **the department** in the adoption of regulations required by this article."*

- Section 25257.1(c)
- *"**The department** shall not duplicate or adopt conflicting regulations for product categories . . ."*

OEHHA Has Not Been Expressly Delegated Any Authority Other Than to *Evaluate* and *Specify* Information and to *Consult* With the DTSC Regarding that Evaluation

In contrast, to the comprehensive regulatory role described for the Department, the sum total of the responsibilities of the Office of Environmental Health Hazard Assessment (the "Office") under the green chemistry law is contained in only one portion of the law: Section 25256.1. This reads:

*"On or before January 1, 2011, **the office** shall evaluate and specify the hazard traits and environmental and toxicological end-points and any other relevant data that are to be included in the clearinghouse. **The office** shall conduct this evaluation in consultation with the department and all appropriate state agencies, after one or more public workshops, and an opportunity for all interested parties to comment. **The office** may seek information from other states, the federal government, and other nations implementing this section."* (Emphasis added).