Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

September 13, 2010

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

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

RE: Draft Regulation for Hazard Traits & Environmental and Toxicological Endpoints (8/10/10)

Dear Ms. Kammerer:

On behalf of the Green Chemistry Alliance (GCA)* and its stakeholders, we respectfully submit the following comments and suggestions relative to the Office of Environmental Health Hazard Assessment's (OEHHA) *Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints* ("regulation") released on August 11, 2010.

In a proactive fashion, GCA members have invested countless hours over the last year and a half developing regulatory text and comments for implementing the broader framework for the Green Chemistry Initiative. This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy. This same group has come together to also provide insight and technical review of the draft regulations relative to hazard traits and endpoints.

Overarching Concerns

The task of chemicals management is a long-term endeavor driven by ever changing developments in science. Regardless of the resources directed toward development of data, there will always be more questions to ask and more data to gather – it is after all the nature of the scientific process.

Of all of GCA's concerns or questions, the overarching and recurring issue seems to be focused on how the information in the draft regulation will be used. It is generally unclear and disconnected from the DTSC proposed regulations and DTSC's vision for the Toxics Information Clearinghouse (TIC). The OEHHA regulations will be a critical launching point for the safer alternatives process, in particular; therefore, scrutiny needs to be employed in the development of applicable and definable hazard traits and endpoints in order to inform the prioritization process.

Although OEHHA staff has indicated a weight-of-evidence approach is envisioned for the regulation, it must be more clearly and specifically incorporated into the draft. A robust weight-of-evidence approach will give stakeholders confidence in the studies and data relied upon and feeding into the complex DTSC safer alternatives process.

GCA comments, which follow in Attachment 1, include the following items of significance:

- **Existing Systems -** 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. 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.

- **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 - the critical issue for chemical hazard classification should be identifying the most sensitive system(s) affected by chemical exposure.

- **Emerging Traits -** OEHHA should seek scientific consensus on the description of emerging traits and the appropriate study protocol for the endpoint(s) prior to including them in the regulation. OEHHA should not unilaterally establish definitions for new hazard traits.

- **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 actual hazard traits or endpoints, but rather preludes in multiple-step pathways that may or may not lead to disease or an adverse outcome.

- **Other Relevant Information - U**se category and volume information reported via U.S. EPA's Inventory Update Rule ((IUR) should be included as part of "other relevant information."

- **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 reliable than others, even when developed by authoritative bodies. OEHHA should look toward the robust study format used in the OECD's hazard assessment program and OECD harmonized templates as a model for providing information on study results and study quality.

- **Potency -** The proposal is defective as there is no indication of potency for traits which exhibit evidence of hazard. Without some indication of potency, every substance, whether synthetic or naturally occurring, will be labeled as toxic, even the "greenest" of substances. GCA recommends OEHHA look toward existing systems to understand how other bodies have handled this critical issue.

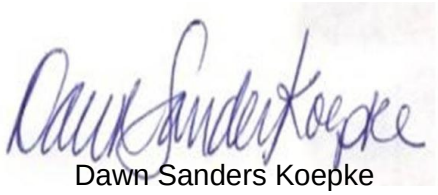
- **Classification -** The classification proposal should be abandoned entirely. SB 509 gives s OEHHA neither the mandate nor the authority to create a novel California classification system. DTSC has responsibility for what actually goes into the TIC, not OEHHA. ***The classification system is a significant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

The Green Chemistry Alliance and its members appreciate the work OEHHA has invested in developing this draft regulation; however, GCA remains highly concerned over the breadth and direction of the draft regulation. GCA remains committed to working with OEHHA and other stakeholders to finalize reasonable and effective regulations that reflect the intent and specific requirements of SB 509 relative to the identification of hazard traits and endpoints.

GCA respectfully submits the attached comments regarding the draft *Hazard Trait, Endpoints, and Other Relevant Data* regulation (August 10, 2010). For 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 Cindy Tuck, Undersecretary, CalEPA
The Honorable Patty Zwarts, Deputy Secretary for Policy, CalEPA
The Honorable Patrick Sullivan, CalEPA
The Honorable Joan Denton, Director, OEHHA
The Honorable Maziar Movassaghi, Acting Director, DTSC
The Honorable John Moffatt, 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, 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 implement 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 Home Appliance Manufacturers
Association of International Automobile 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
Dow Chemical Company
DuPont
Ecolab
Ellis Paint
ExxonMobil
Fashion Accessories Shippers Assoc
Florida Chemical Company, Inc.
Fragrance Materials Association
Goodrich Corporation
Grocery Manufacturers Association
Honeywell
Hyundai-Kia America
Independent Lubricant Manufacturers Association
Industrial Environmental Association
Information Technology Industry Council
International Sleep Products Association
Johnson & Johnson
Kern Oil & Refining Company
Koch Companies Public Sector
Metal Finishing Associations of Northern & Southern California
National Aerosol Association
National 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
SABIC Innovative Plastics
Silicones Environmental Health and Safety Council
Solar Turbines
Sporting Arms and Ammunition Manufacturer's Institute (SAAMI)
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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Attachment 1

Existing Systems

The Green Chemistry Alliance (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 (e.g., OECD and EPA test methods and guidelines, OECD SIDS, GHS[1]).

- Tens of thousands of tests for thousands of chemicals have been or will be performed and interpreted through these systems.
- If California wants to create a system that can be populated quickly and efficiently, these systems should be leveraged.
- Using such 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 that are not addressed at all in OEHHA's discussion draft.
- If California proceeds with a non-standard approach, not only will the database be slow to be populated, there will be a substantial agency effort required to convert the information to the unique California system both initially and on an ongoing basis. In a resource strapped economy, that makes no sense.

List of "icities"

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.*) when the goal is hazard identification. This is especially true since the critical issue for chemical hazard classification should be identifying the most sensitive system(s) affected by chemical exposure.

None of the prominent national or international systems list the vast number of "icities" 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

In the case of "emerging" traits such as endocrine disruption and epigenetics (and scores of other novel traits identified in the environment section), 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

[1] It should be noted that authors of the REACh legislation relied on these systems heavily, as do all countries of the OECD.

exists, or should be establishing the process for reaching that consensus where none exist, but they should not be unilaterally establishing new 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.

Other Relevant Information

Hazard information provided in the abstract is not terribly useful for people searching for alternatives, whether they are product manufacturers, DTSC staff, or lay citizens. EPA recently released a proposed rule for changes to its Inventory Update Rule (IUR) beginning with 2010 information collection. The Clearinghouse could include information reported by industry to IUR after this rulemaking is complete. Use categories and volume as reported by industry in the next round (2011) of the IUR should be integrated into the "Other Relevant Information" section of the TIC.

Further, while there is some interesting physical-chemical information that might be included as "other relevant information" in the TIC, to identify and classify chemicals based on "exposure potential" is unscientific and contrary to well established risk assessment principles.

Data Quality

In vitro studies and QSARs are generally recognized as appropriate tools prioritizing chemicals and in identifying the need for higher tier testing, not for making definitive declarations about toxicological properties as OEHHA proposes. The validity of many *in vitro* studies to human health is still in question, and they should not be the sole source of information used to assign a hazard trait to a chemical.

Additionally, *in silico* (computer simulation) QSAR is still in its infancy and should not be relied upon for definitive decisions. These methods have not been validated. All testing methods in the Draft should require validated methods. In decision-making a priority for *in vivo* rather than *in vitro* should be established in the regulation.

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 reliable than others, even if they are developed by authoritative bodies.

- 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?
- The notion of study quality is not addressed in the OEHHA draft. 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 required for every study used to populate the TIC. It has been applied to all studies in the US and OECD HPV programs and to those submitted under REACh. 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 decisions.
- Data quality and weighting considerations are 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.
- If the TIC is populated with ***ALL*** 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?
- OEHHA should look toward the robust study summary format used in the OECD's hazard assessment program[2] and OECD harmonized templates[3] as a model for providing information on study quality.

Potency

There is some 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?

- The OEHHA proposal is deficient in that there is no indication 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, will be labeled as toxic. As just one example, without information about the dose at which a substance causes acute toxicity, will everything in the TIC be marked as acutely toxic?

[2] See section 2.4.3 Robust Study Summaries in the *OECD Manual for the Investigation of HPV Chemicals.* See http://www.oecd.org/dataoecd/13/18/36045056.pdf.
[3] See http://www.oecd.org/document/0,3343,en_2649_34365_36206733_1_1_1_1,00.html.

- OEHHA has established a framework that will undoubtedly be misunderstood and certainly misused.
- We recommend that OEHHA look toward existing systems (see comments above) to understand how other bodies have handled this critical issue.

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 goes 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, as evidenced by the following:

- It combines lack of information and no effect (i.e., nontoxic) into "unclassifiable." This is not reflective of the real world and is of no utility to TIC users.
- It muddies the waters by lumping distinctions made in existing systems (e.g., IARC as just one example) for no apparent reason, actually *decreasing* information available on chemicals.
- Clearly there are chemicals where the scientific data has demonstrated that the chemical lacks certain hazard traits, including some of the most important concerns such as carcinogenicity and reproductive and developmental toxicity.
- Without identifying a class for hazard traits that recognizes the lack of activity for a chemical, rather than the lack of data, the system used to classify chemicals is flawed.
- It would be impossible to identify "non-toxic" chemicals using OEHHA's proposed classification scheme. Even the "greenest" of chemicals will be classified as hazardous or "unclassifiable."
- Finally, it appears that, a chemical is categorized as having many of the toxicities listed until such time as OEHHA or DTSC determines otherwise. Furthermore, the language within (i – page 28) could conceivably allow anyone using any study design of their choosing to publish something saying chemical X has hazard trait Z, and unless DTSC or OEHHA determined otherwise, it would be so. This approach will heighten controversy and fear while doing little to advance public health or environmental protection.

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