

Ms Fran Kammerer  
September 13, 2010



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Fran Kammerer  
Staff Counsel  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95812  
Or via e-mail to [fkammerer@oehha.ca.gov](mailto:fkammerer@oehha.ca.gov)

**Re: Comments on OEHHA's pre-Draft Regulations on "Green Chemistry Hazard Traits, Toxicological Endpoints, and Other Relevant Data"<sup>1</sup> based on SB 509**

Dear Ms. Kammerer:

Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe.

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

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<sup>1</sup> <http://oehha.ca.gov/multimedia/green/pdf/081110prereghazard.pdf>

The food, beverage and consumer packaged goods industry in the United States generates sales of \$2.1 trillion annually, employs 14 million workers and contributes \$1 trillion in added value to the economy every year.

GMA believes that any state agency embarking on the green chemistry initiative should focus its limited resources on the chemicals and exposures of greatest impact to public health. This can only be accomplished by assuring that key criteria are established to identify, prioritize, assess, and manage high priority chemicals. Generally, we support:

- Risk-based prioritization to identify chemicals of highest concern through exposure, use, and hazard data relevant to the U.S. population; and
- A “weight-of-evidence” approach to chemicals prioritization that evaluates authoritative information on hazard traits, and considers the most severe hazards first.

GMA supports the concepts behind the nationwide Green Chemistry Initiatives (GCI), and advocates for state regulations that are workable, practical, and consistent and ensure protection of public health and the environment. GMA continues to strive for development of policies that stimulate Green Chemistry innovation and the promotion of greener technologies. GMA has been actively engaged in California’s green chemistry effort from legislation to implementing regulations and now development of its Toxics Information Clearinghouse. GMA appreciates the opportunity to provide further feedback on OEHHA’s pre-Draft Rule: Green Chemistry Hazard Traits, Endpoints, and Other Relevant Data (released August 10, 2010).

GMA supports California’s Green Chemistry Alliance (GCA) comments, and respectfully submits that:

- Responsibilities on classification of chemicals should remain with international entities such as the Organization for Economic Cooperation and Development (OECD) and others that have already instituted an elaborate system for classifying chemicals;
- Chemical Use Information and Potency Information should be among “Other Relevant Data”; and
- Data quality considerations, appropriate test methodologies, and effective Clearinghouse template design should all be integral to the Toxics Information Clearinghouse. It is important to address these in the Context of Clearinghouse hazard traits and endpoints even though these fall under DTSC’s purview.

GMA recognizes the substantial amount of work that both OEHHA and DTSC have done in this vein. However, GMA stresses the need for better coordination between these departments on their individual activities as well as the need for increased transparency of their combined efforts, so that a useful system is developed in a cost-effective and timely manner. Also, OEHHA should use only terms in their pre-draft regulations that

are the same as those used in federal and international systems. Interested stakeholders can then better understand how this Clearinghouse will be developed, and its implications in seeking alternatives to a chemical of concern in a priority product.

## **I. Classification of Chemicals**

### **Existing National and International Systems**

Existing scientific organizations worldwide have already established classification systems for chemicals, depending on the traits exhibited by the chemical. Chemicals must satisfy established criteria before being classified in a higher hazard tier, or a lower one, for each identified trait/endpoint. OEHHA should not embark on creating a new classification system that does not align with pre-existing ones. A new California-only system will be duplicative and exhaust California's limited resources. Maintaining and revising Clearinghouse entries would demand additional resources. Beyond these primary concerns, data showing a lack of effect should be captured under a separate category.

OEHHA should leverage the work already completed or underway nationally and internationally, and harmonize with existing systems that already identify the various elements necessary to study and characterize chemicals<sup>2</sup> (e.g., OECD and EPA test methods and guidelines, OECD's Screening Information Data Set (SIDS), Global Harmonization System (GHS) Classification criteria, etc.) In any case, the SB 509<sup>3</sup> legislative mandate does not appear to give OEHHA the authority to create a new California classification system. Moreover, CA should not create a system in advance of final OSHA rulemaking for federal classification requirements<sup>4</sup>.

It is important to note that DTSC, in its Feasibility Study Report<sup>5</sup>, suggests that the user will make their own judgment as to the hazards, based on the information presented. (p.26 in Report)

“... [T]he use of red for “hazard trait information available” may look like a judgment on chemical safety. 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.”

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<sup>2</sup> Examples include OECD ([http://www.oecd.org/document/40/0,3343,en\\_2649\\_34377\\_37051368\\_1\\_1\\_1\\_1.00.html](http://www.oecd.org/document/40/0,3343,en_2649_34377_37051368_1_1_1_1.00.html)) and EPA test methods and guidelines ([http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series870.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm); <http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>), OECD's Screening Information Data Set (SIDS) ([http://www.oecd.org/document/63/0,3343,en\\_2649\\_34379\\_1897983\\_1\\_1\\_1\\_1.00.html](http://www.oecd.org/document/63/0,3343,en_2649_34379_1897983_1_1_1_1.00.html)), EU's Global Harmonization System (GHS) Classification criteria ([http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/index_en.htm)), etc.

<sup>3</sup> [http://www.chemicalspolicy.org/legislationdocs/California/CA\\_SB509.pdf](http://www.chemicalspolicy.org/legislationdocs/California/CA_SB509.pdf)

<sup>4</sup> Proposed rule at Federal Register Vol. 74 no. 188, September 30, 2009

<sup>5</sup> Toxics Information Clearinghouse Feasibility Study Report. DTSC. April 8, 2010.

Thus, the Clearinghouse should remain as objective as possible, without introducing biases and subjectivity.

#### Non-Conventional Toxicities – Organ Specific Toxicities

In the current pre-draft regulations, OEHHA lists additional specific organ toxicities beyond the conventional Carcinogens, Mutagens, and Reproductive/ Development Toxicants (CMR), subchronic toxicity, etc. Rather than separating out each of these additional non-conventional toxicities (e.g., cardiovascular, gastrointestinal, liver, renal, etc.) in the Clearinghouse, and misleading the user to believe that validated test methods exist for each, these additional toxicities should be lumped together into a separate category, for example, under systemic toxicity or target organ toxicity. Information on any of these toxicities (from chemical evaluation summaries) will be appropriately captured here. Organ systems impacted are noted, but there should be no presumption of separate and distinct test for every organ system that the OEHHA proposal implies. Industry's proposed approach would mirror that of most prominent national or international systems.

#### Non-Conventional Toxicities – Emerging Traits

For "emerging" traits such as endocrine disruption and epigenetics, further scientific clarification and consensus on the trait characterization is a necessary first step prior to inclusion into the Clearinghouse.

To-date, "suspected" endocrine disruption status has not been confirmed for any chemical by any international authoritative bodies. Furthermore, a universal definition of what an "endocrine active substance" or "endocrine disrupter (ED)" is has yet to be agreed upon. For example, as evidenced by the lack of any currently validated protocols to evaluate substances for their endocrine disruption potential (EPA has decided that it can't classify an agent as an endocrine disrupter based on screening assays in its Endocrine Disruptor Screening Program - the Agency only labels them as "potential endocrine disruptors," which raises their priority for definitive testing and is not a definitive classification in itself), it's clear that this is a field of science that is in relative infancy compared with other toxicology endpoints. In addition, the relationship of certain human diseases to the endocrine system is poorly understood and scientifically controversial. Uniform and universally accepted test procedures and criteria must be established in order to evaluate the validity and quality of investigating potential endocrine disruption effects and in identifying chemicals as having or not having such traits.

On epigenetics, scientific consensus is far beyond reach. The nascent field of epigenetics is under extensive scientific investigation with a "normal" baseline undefined as of yet.

Thus, OEHHA should be able to show that scientific consensus exists, or should be establishing the process for reaching that consensus where none exist, but should not be unilaterally establishing new hazard traits.

## **II. Chemical Use Information and Potency Information as “Other Relevant Data”**

### **Chemical Use Information**

Use categories<sup>6</sup> as reported by industry in the next round of the Inventory Update Rule can be integrated into Other Relevant Data. EPA recently released a proposed rule for changes to IUR reporting beginning with 2010 information collection. The Clearinghouse could include information reported by industry to the IUR after this rulemaking process is complete.

Additional use data can be housed under “Other Relevant Data” as well. Often in US/OECD HPV submissions, chemical environmental monitoring data has been presented, using robust summary studies (with reliability ratings). This information in addition to volume and use categories information would help provide context to chemical uses, and is scientifically well founded. An additional example could be an aggregate exposure analysis, covering a variety of “uses” of a chemical, using model and/or monitored data. These too can be rated for reliability under the OECD’s approach (e.g. models used are well-accepted in scientific/regulatory circles). OEHHA should consider giving industry the opportunity to provide use information. REACH submissions will always include use and exposure information.

### **Potency Information**

There is some dose level that produces an effect for every chemical. Quality toxicological studies may have identified an appropriate threshold beyond which a chemical exhibits a specified hazard trait and use of the OECD robust study summary format will capture this information. This is critical information in determining the relative level of concern of a chemical.

## **III. Data quality considerations, appropriate test methodologies, and Clearinghouse template design**

### **Data Quality Considerations and Appropriate Test Methodologies**

DTSC/OEHHA should look to the OECD harmonized template<sup>7</sup> (SIDS dossier) for overall organization of information about a chemical and to the robust study summary<sup>8</sup> for documenting individual studies. DTSC/OEHHA should require that the OECD robust study summary template be required for every study used to populate the Clearinghouse. Both are found in the OECD Manual for Investigation of HPV Chemicals

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<sup>6</sup> Reported by industry in the next round of the Inventory Update Rule (proposed rule at Federal Register Vol. 75, no. 156, August 13, 2010)

<sup>7</sup> See [http://www.oecd.org/document/0,3343,en\\_2649\\_34365\\_36206733\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/0,3343,en_2649_34365_36206733_1_1_1_1,00.html).

<sup>8</sup> 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>.

as a model for providing chemical information. This provides a common approach that is internationally agreed and accepted and will assist database users in finding and utilizing the information.

The OECD methodology for determining the quality of data in chemical dossiers described in their Manual<sup>9</sup> for Investigation of HPV Chemicals is a globally accepted way to rate the reliability, relevance and adequacy of existing data. DTSC/OEHHA should require that the OECD methodology be applied to every study used to populate the Clearinghouse. It has been applied to all studies in the US and OECD HPV programs and is required of all studies submitted under REACH. It's 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.

The validity of many *in vitro* studies and their relevance 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. A formal validation study would be necessary to investigate the relationship between *in vitro* and *in vivo* endpoints, to ensure that results from *in vitro* assays are predictive of *in vivo* toxicity and human health outcome thereby establishing an *in vitro/in vivo* correlation.<sup>10</sup> Peer-review alone is an insufficient metric of study quality.

Additionally, the Clearinghouse should rely on conclusions and information from predominantly "authoritative" sources, rather than the peer-reviewed literature that is primarily hypothesis driven and often represents vastly unsettled science. Generally, an authoritative entity or body should be defined as a government agency or formalized scientific organization that satisfies all of the following requirements:

1. It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, and communicate directly with the authoritative body through written and oral comments.
2. It does not engage in advocacy.
3. It bases its characterization of chemicals on a weight-of-evidence approach. To the extent available, it considers multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and gives full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any

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<sup>9</sup> [http://www.oecd.org/document/7/0,2340,en\\_2649\\_34379\\_1947463\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html) - 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.

<sup>10</sup> For example, see Draft Guidance Document on Using Cytotoxicity Tests to Estimate Starting Doses for Acute Oral Systemic Toxicity Tests (<http://www.oecd.org/dataoecd/17/0/43325517.pdf>)

other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.

4. It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or peer-reviewed publications.

Aside from data quality and reliability considerations, DTSC/OEHHA need to clearly identify how certain types of data will be weighed when assessing chemical hazards and identifying chemicals of concern, recognizing that certain types of data are less relevant to human and/or environmental health than others.

Furthermore, *in vitro* studies and Quantitative Structure-Activity Relationships (QSARs) are generally recognized as appropriate tools for prioritizing chemicals only.<sup>11</sup> These methods should not be used to make definitive declarations about toxicological properties without further information from higher tier studies.

To summarize, the OEHHA pre-draft regulation leaves much to be desired:

- (i) What kind of quality control and/or contextual information will accompany data and information from *in vitro* and QSAR studies? Contextual information similar to those in OECD's robust study summary section ought to be included for any study, to help summarize and rate the quality of the study.
- (ii) DTSC ought to be prepared to develop a data quality guidance document and identify appropriate test methods that will be the basis for qualifying data for use in the Clearinghouse, before any information is uploaded into the Clearinghouse. For example, what importance will DTSC put on information generated through validated test guidelines versus other types of studies?
- (iii) Which department would be responsible for evaluating the available data on a particular chemical, and authorizing information to be posted?

#### Clearinghouse Template Design

GMA suggests that the OECD baseline template, the SIDS dossier, be used for the Clearinghouse. It is consistent with regulatory practice across all OECD members. It is the basis for the IUCLID Dossier used in Europe. All of the various components are listed -- all of the "traditional" physical-chemical properties, environmental fate information, human toxicity data, environmental toxicity data, to include information on identified uses and available exposure information, including exposure estimates for identified use scenarios. Where there are multiple studies for a toxicological endpoint, they are separately identified and can be separately accessed. The robust summary of a given

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<sup>11</sup> See Rusyn, I. and Daston, G.P. Aug 2010. *Environ. Health Perspect.* 118 (8):1047-1050.

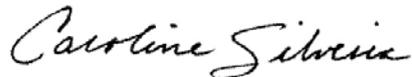
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study provides all of the key information about the study, including a No-Observed-Adverse-Effect-Level (NOAEL) or other indication of threshold effect level.

Although a conceptually consumer friendly "check-box" approach to identifying chemical hazards is quite appealing, toxicological information is rather complex and DTSC/OEHHA should not attempt to oversimplify available data. Oversimplification would be the result of subjective interpretations, and will likely introduce biases and unsubstantiated assumptions into the Clearinghouse. Inaccurate and inconsistent characterization of chemical information will certainly mislead the User and undermine the objectives of the Clearinghouse.

If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,



Caroline Silveira  
Director, State Affairs  
Grocery Manufacturers Association  
1350 I St NW, Suite 300,  
Washington, D.C.,  
20005

Cc: Linda Adams, Secretary, CalEPA  
Cindy Tuck, Undersecretary, CalEPA  
Patty Zwartz, Deputy Secretary for Policy, CalEPA  
Patrick Sullivan, CalEPA  
Joan Denton, Director, OEHHA  
Maziar Movassaghi, Acting Director, DTSC  
John Moffatt, Office of the Governor