September 12, 2011

Fran Kammerer
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Sacramento, CA 95812
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Re: Comments on OEHHA's Revised Proposed Regulations on "Green Chemistry Hazard Traits", July 2011

Dear Ms. Kammerer:

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

GMA supports California's Green Chemistry Initiative (GCI) and advocated for the passage of AB1879 and SB509 as key elements in establishing authority to identify, assess, and manage high priority chemicals and to establish a portal for chemical safety information. We appreciate the opportunity to submit this letter in response to OEHHA's July 29, 2011 Revised Proposed Regulation for Green Chemistry Hazard Traits, to support the mandate in SB 509.

GMA is extremely concerned that OEHHA chose to not address most of the comments on the December 2010 Proposed Regulation provided in our letter of February 15, 2011 (incorporated by reference) and similar comments made by many stakeholders, including extensive comments by the Green Chemistry Alliance (GCA). Many of the most serious concerns were also noted by OEHHA's Peer Reviewers, and have been detailed in GCA's September 12, 2011. GMA is a member of the GCA and supports the Alliance's detailed comments on the Revised proposal.

GMA believes that any state agency embarking on the green chemistry initiative should focus its limited resources on establishing a state approach that makes full use of existing national and international chemical management systems to enable efficient and timely state actions on the chemicals and exposures with the greatest impact on public health and the environment.

The Revised regulation offers no significant changes in this area compared to the December proposal, thus failing to address the issue. The proposed establishment of a unique to California

system of hazard trait nomenclature will substantially increase the difficulty, cost and timing of populating and deploying the Toxics Information Clearinghouse. The proposed classification system is unnecessary and unauthorized, going beyond the statutory authority provided in SB509. There continues to be inadequate attention to the importance of data quality, reliability and weight of evidence in identifying the hazard traits of a chemical.

The system of hazard traits envisioned by OEHHA is unlike any adopted by major countries and established by global cooperation on chemical management at the Organization for Economic Cooperation and Development and the United Nations Environmental Program. Why would California implement a unique chemical management data system that will not immediately be able to employ the extensive existing chemical information from around the world? The proposed approach would be a waste of taxpayer funds and will significantly delay the use of the information in advancing Green Chemistry in California. Peer reviewers Dr. Meek and Dr Zeigler raised concerns about these issues as well.

GMA previously raised concerns about insufficient coordination between OEHHA and DTSC to produce Green Chemistry regulations that will work in harmony and achieve the objectives of the legislation. This has clearly not been addressed, since OEHHA is proposing these revisions containing minimal changes in advance of DTSC's issuing revisions to its regulations.

Taken together, these issues would establish regulations that fail to fulfill the SB 509 statutory mandate to operate this system "at the least possible cost to the state". In light of these concerns, GMA believes that OEHHA should withdraw this proposal and work in collaboration with DTSC to re-propose the Safer Alternatives regulation and the Hazard Traits regulation. It is critical that the regulations work in concert to establish a credible, workable, and successful Green Chemistry program that accomplishes the intended result of improving public health and the environment for Californians.

If you have any questions or comments, please feel free to contact me by phone at 916-447-9425 or email at JHewitt@gmaonline.org. We look forward to our continued work together on this important public policy initiative.

Sincerely,

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20005

cc. Matt Rodriguez, Secretary, CalEPA
George Alexeeff, Acting Director OEHHA
Debbie Raphael, Director, DTSC
Office of the Governor

February 15, 2011
Fran Kammerer
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Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812
Or via e-mail to fkammerer@oehha.ca.gov

Re: Comments on OEHHA's Proposed Regulations on "Green Chemistry Hazard Traits", December 2010

Dear Ms. Kammerer:

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

GMA supports California's Green Chemistry Initiative (GCI) and advocated for the passage of AB1879 and SB509 as key elements in establishing authority to identify, assess, and manage high priority chemicals and to establish a portal for chemical safety information. We appreciate the opportunity to submit this letter in response to OEHHA's December 2010 Proposed Regulations on Green Chemistry Hazard Traits, to support the mandate in SB 509.

GMA believes that any state agency embarking on the green chemistry initiative should focus its limited resources on establishing a state approach that makes full use of existing national and international chemical management systems to enable efficient and timely state actions on the chemicals and exposures with the greatest impact on public health and the environment.

GMA commented on OEHHA's the Pre-Draft Rule, "Green Chemistry Hazard Traits, Endpoints, and Other Relevant Data" on 9/15/2010, incorporated by reference. There continue to be major concerns with the Proposed Regulation including the following issues, addressed in more detail in the attachment to this letter:

- Insufficient coordination between OEHHA and DTSC to produce Green Chemistry regulations that will work in harmony and achieve the objectives of the legislation.
- The establishment of a unique to California system of hazard trait nomenclature that will substantially increase the difficulty, cost and timing of populating and deploying the Toxics Information Clearinghouse.
- The inclusion of non-conventional, emerging hazard traits where further scientific clarification and consensus is needed.
- A proposed unique to California classification system that is unnecessary and unauthorized, going beyond the statutory authority provided in SB509.
- A lost opportunity to include useful information as "other relevant data" such as use and exposure information.

- Inadequate attention to the importance of data quality, reliability and weight of evidence in identifying the hazard traits of a chemical.

Taken together, these issues would establish regulations that fail to fulfill the SB 509 statutory mandate to operate this system "at the least possible cost to the state". In light of these concerns, GMA believes that OEHHA should withdraw this proposal and work in collaboration with DTSC to re-propose both the Safer Alternatives regulation and the Hazard Traits regulation. It is critical that the regulations work in concert to establish a credible, workable, and successful Green Chemistry program that accomplishes the intended result of improving public health and the environment for Californians.

GMA is a member of the Green Chemistry Alliance (GCA) and supports the Alliance's 2/15/2011 detailed comments on the Proposed Regulation.

If you have any questions or comments, please feel free to contact me by phone at 916-447-9425 or email at JHewitt@gmaonline.org. We look forward to our continued work together on this important public policy initiative.

Sincerely,

John Hewitt
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cc. Linda Adams, Secretary, CalEPA
Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary for Policy, CalEPA
Allan Hirsch, Acting Director OEHHA
Leonard Robinson, Acting Director, DTSC
Cliff Rechtschaffen, Office of the Governor

Grocery Manufacturers Association

Detailed Comments— Green Chemistry Hazard Traits Proposed Regulation

OEHHA must work in coordination with DTSC. The Green Chemistry Hazard Trait Regulation should be developed in collaboration with DTSC's Safer Alternatives Regulation to accomplish the benefits expected from the Initiative. It is clear that this has not been the case. For example important definitions and approaches are not harmonized, e.g. chemical substance; well conducted study/reliable information, proposed chemical classification system. GMA stresses the need for better coordination between the agencies so that a useful system is developed in a cost-effective and timely manner. Given the withdrawal of DTSC's Proposed Regulation, OEHHA's proposal should also be withdrawn, so that the agencies develop coordinated revisions that will work in harmony to accomplish the mandates of the Statutes.

OEHHA should not reinvent a unique hazard trait nomenclature. In the Proposed Regulation, beyond the traditional carcinogens, mutagens, reproductive, developmental, and acute toxicity, OEHHA needlessly lists additional specific organ toxicities. There are several concerns with separating out each of these additional toxicities (e.g., cardiovascular, gastrointestinal, liver, renal, etc.). First, in the context of the Clearinghouse it may mislead the user into believing that separate validated test methods exist for each of these. Second, existing global chemical hazard information systems (e.g. OECD[1], IUCLID[2], REACh[3], US HPV[4]) do not recognize the OEHHA concept. This means that implementation of the concept would impose a cost on the state to retrofit existing information when populating the Clearinghouse, as well as a significant time delay on its availability. Information about these toxicities should be traditionally organized, under acute, subchronic or chronic toxicity that may contain information about Systemic or Target Organ Toxicity. Organ systems impacted are always noted in study results, but there should be no presumption of separate and distinct tests for every organ system that is implied by the OEHHA proposal. Also, the office should be working to use terms in the Regulation that are the same as those used in federal and international systems. Not to do so will promote confusion among users.

OEHHA should await scientific consensus on non-conventional emerging traits. For emerging traits such as endocrine disruption and epigenetics, it is inappropriate to include them as "other" toxicological hazard traits. Further scientific clarification and consensus on trait characterization and validated testing protocols are necessary first steps prior to inclusion into these regulations and the Clearinghouse.

To date, a universal definition of what an "endocrine active substance" or "endocrine disrupter" is has yet to be agreed upon. Endocrine disruption 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 this 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

[1] http://www.oecd.org/document/0,3343,en_2649_34365_36206733_1_1_1_1,00.html
[2] http://iuclid.eu/
[3] http://guidance.echa.europa.eu/public-2/getdoc.php?file=registration_en
[4] http://www.epa.gov/hpvis/

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."[5] EPA, which is leading the world in developing validated protocols, has determined that it can't classify an agent as an endocrine disrupter based on Tier 1 screening assays in its Endocrine Disruptor Screening Program. Positive results in the screening raise their priority for Tier 2 testing but standing alone, do not support a definitive classification. 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 potential adverse endocrine effects and to identify chemicals as having or not having such traits.

On epigenetics, scientific consensus is far beyond reach. It 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. The nascent field of epigenetics is under extensive scientific investigation with a "normal" baseline undefined at this time.

Thus, OEHHA should be able to show that scientific consensus exists that these areas are in fact hazard traits that are endpoints for toxicity testing, or should be establishing the process for reaching consensus and validation where none exist, but should not be unilaterally establishing endocrine disruption or epigenetics hazard traits, nor relying on non-validated test methods for their determination.

The proposed classification system is unauthorized and unnecessary. The enacting legislation, SB 509, requires the office "…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." However, the proposed regulation goes beyond the authority provided for in statute, by establishing a chemical classification system ("strong evidence" and "suggestive evidence") that would be unique to California.

It is important to note that DTSC, in its Toxics Information Clearinghouse Feasibility Study Report[6], 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.

If such a unique to California classification system were to be implemented as a part of the Regulation, it would add a significant cost burden on the state to perform a scientific review on all information for every chemical and to assign a classification.

[5] EPA (2009). Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening.

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

Given that OEHHA has neither the authority nor the mandate to create a novel California classification system, that it is unnecessary in DTSC's plans for the Clearinghouse, and that it would create an unnecessary cost burden, this element of the regulations should be removed.

OEHHA should establish a category for "Other Relevant Data". As noted above, SB 509 foresaw the need for "Other Relevant Data". This is appropriate—not all information that is useful in chemical assessment and management can strictly be considered to be "hazard trait" information.

Article 5 identifies what OEHHA terms "Exposure Potential Hazard Traits". This is a novel term, not used elsewhere in the world and thus is unnecessary and confusing. However there are some important properties identified in this section, such as bioaccumulation and persistence, which should be captured as part of the information about a chemical in the Clearinghouse. Together with other physical/chemical properties (which are not uniformly included in OEHHA's proposal), these would fit well in the "Other Relevant Data" information.

Chemical use and exposure information would also fit well. Chemical volume information, as well as use and functional categories, which will be reported by industry to EPA's 2011 Inventory Update[7], can be integrated into Other Relevant Data. Where available, chemical environmental monitoring information can be useful as well. Such data has often been presented in US and OECD HPV submissions, using robust summary studies (with reliability ratings). This use and exposure information can help provide context to chemical hazards, and is scientifically well founded. An additional example could be an aggregate exposure analysis, covering a variety of "uses" of a chemical, using modeled and/or monitored data. These too can be rated for reliability under the OECD's approach. REACH submissions will always include use and exposure information.

Thus, OEHHA should reframe "Exposure Potential Hazard Traits" as "Other Relevant Data" and add additional physical/chemical characteristics and exposure information items that will be useful in the Green Chemistry Program and to the public.

OEHHA must address the importance of reliable information and data quality and make use of existing systems. The Proposed Regulation defines well-conducted studies as "studies published in the open literature or conducted by or submitted to a local, state, national or international government agency, using methods and analyses which are scientifically valid according to generally accepted principles". There are several concerns with this definition. First, it is an altogether different term and definition than the "Reliable Information" concept used by DTSC in its Proposed Regulation. Second, it does not establish a discriminating method for determining the reliability of data. Third, it does not identify how data should be weighed when assessing chemical hazards. And fourth, it does not support a method for consistent presentation of information in the Clearinghouse.

<u>Consistent definition on reliable information/data quality</u>. The notion of "reliable information" and study quality is not addressed in the OEHHA draft other than marginally via the "well-conducted scientific studies" concept. Neither peer-review alone nor submission to/conduct by an authoritative body are sufficient metrics of study quality. The OECD methodology for determining the quality of data in chemical dossiers, described in Chapter 3 of their Manual for Investigation of HPV Chemicals[8], 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 Clearinghouse. It has been applied to all studies in the US and OECD HPV programs and is required for every study on all chemicals submitted under REACh

[7] Proposed rule at Federal Register Vol. 75, no. 156, August 13, 2010

[8] OECD Secretariat, July 2007 http://www.oecd.org/document/7/0,3746,en_2649_34379_1947463_1_1_1_1,00.html

(over 4300 high volume and high hazard chemicals were submitted to REACh 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. This topic must be addressed in a harmonized way by both OEHHA and DTSC in their Regulations.

Scientifically sound approach to weighing data. OEHHA needs to clearly identify how data should be weighed when assessing chemical hazards, recognizing that certain types of data are less appropriate than others, even if authoritative bodies develop them. 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.

In vitro studies and QSARs are generally recognized as appropriate tools for prioritizing chemicals and identifying the need for more complex biological system testing, but have limits in their ability to predict risk or even identify classification of toxicological properties as OEHHA proposes. There are significant efforts underway nationally and internationally to develop alternative methods, reducing the need for unnecessary animal testing and GMA supports those programs. However, the predictability of many QSAR and *in vitro* methods to human health is still being evaluated. Results from such a QSAR or in vitro method should only be considered for assigning hazard traits to a chemical 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[9] and regulatory acceptability[10] 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.

Consistent presentation of information. DTSC and OEHHA should make use of the OECD harmonized template[11] (SIDS dossier) for overall organization of information about a chemical and to the robust study summary[12] for documenting individual studies. Both are found in the OECD Manual for Investigation of HPV Chemicals as a model for providing chemical information. This approach was adopted in the International Uniform ChemicaL Information Database (IUCLID)[13] system for documenting REACh information. Thus, it provides a common approach that is internationally agreed and accepted and will enable a much faster means to populate the Clearinghouse with existing data as well as assist database users in finding and utilizing the information.

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

[10] 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

[11] See http://www.oecd.org/document/7/0,3746,en_2649_34379_1947463_1_1_1_1,00.html

[12] 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.

[13] http://iuclid.eu/