

September 9, 2011

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, California 95812-4010

RE: Office of Environmental Health Hazard Assessment Proposed Green Chemistry Hazard Traits (7/29/11)

(Delivered via Email)

Dear Ms. Kammerer:

The Association of Global Automakers, Inc.¹ (Global Automakers) appreciates the opportunity to provide comments to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) on the proposed regulations implementing Title 22, California Code of Regulations Section 69401 through 69406 – Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse, released July 29, 2011.

Global Automakers and its members are committed to supporting the development and use of safe chemicals and products available for use in the automotive industry. Through the application of green chemistry principles and sound scientific methods, Global Automakers believes that the design and development of new chemistries and technologies will continue to provide innovative solutions to current and emerging environmental challenges. Our goal is to ensure that our members have the opportunity to provide high quality, environmentally sound products and services. With these goals in mind, we look for ways to provide tools to our members to facilitate continuous improvement and to ensure that wherever possible we assist them to not only meet but exceed safety and environmental standards.

Thank you for the consideration of our comments. If you have any questions, please contact John Cabaniss, our Director, Environment & Energy, at jcabaniss@globalautomakers.org or (202) 650-5562.

Sincerely,



Michael J. Stanton
President & CEO

¹ The Association of Global Automakers, formerly known as the Association of International Automobile Manufacturers (AIAM), represents international motor vehicle manufacturers, original equipment suppliers, and other automotive-related trade associations. Our members' market share of both U.S. sales and production is 40 percent and growing. We work with industry leaders, legislators, regulators, and other stakeholders in the United States to create public policy that improves motor vehicle safety, encourages technological innovation and protects our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. For more information, visit www.globalautomakers.org.

Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse

Comments of the
Association of Global Automakers

The Association of Global Automakers, Inc. (Global Automakers) is providing the following comments to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) on the proposed regulations implementing Title 22, California Code of Regulations Section 69401 through 69406 – Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse.

Creation of a Toxics Information Clearinghouse (TIC):

As directed by enacted law SB 509 (Simitian, 2008) OEHHA is required 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.” OEHHA is further directed, “to the maximum extent possible, [to] operate the clearinghouse at the least possible cost to the state.”

This proposal and each of OEHHA's previous drafts has assumed as a starting point the creation of a new, stand-alone clearinghouse. Given the clear direction to explore the most cost effective way of fulfilling the TIC mandate, it is unclear why OEHHA has proposed to adopt an approach based on a new clearinghouse. Numerous commenters have suggested that there are existing systems that could be leveraged to meet the statute's requirements, minimize cost to OEHHA and California, maximize use of existing data sources, avoid the confusion and errors that multiple systems can cause, and assure a level of scientific integrity and inclusiveness that the current option lacks.

The Department of Toxic Substances Control (DTSC) will rely on the TIC as the foundation for the Alternative Assessment (AA) process under the pending Green Chemistry Regulation for Safer Consumer Product Alternatives (SCPA). All subsequent decisions regarding alternatives, substitutions, replacements and regulatory controls will flow from the information and data that populates the TIC. Global Automakers encourages OEHHA to reevaluate this stand-alone option with considerable focus on the following issues:

1. Cost

The cost of developing a stand-alone clearinghouse far exceeds the cost of leveraging existing systems that meet the specifications of SB 509. A more cost efficient solution would be to create a portal that would allow access to both nationally and internationally recognized systems. For example, the U.S. EPA recently announced the availability of *ACTor*, an online warehouse of all publically available toxicity data. The system provides access to information on over 500,000 chemicals, searchable by chemical name, structure or other accepted chemical nomenclature. In addition to toxicity data, *ACTor* provides access to EPA systems that house exposure data, production and use information, chemical screening results and other information relevant to risk assessment. In addition to *ACTor*, the Organization for Economic Cooperation and Development (OECD) created the *E-Chem Portal*, a system that provides access to similar information and data on over 62,000 chemicals. These are just two examples of comprehensive, functioning sources of data and information that would meet the requirements of SB 509 and avoid the cost of developing a brand new, stand-alone option.

2. Timeliness and Comprehensiveness

If OEHHA and DTSC envision a complete, operational system that will support the SCPA regulations in a timely way, creating a new California TIC system will slow progress, create confusion for the regulated community and frustrate the public as they try to access chemical information and data. We encourage OEHHA to explore utilizing existing systems and developing partnerships with the U.S. EPA and others to share data and contribute new information, such as the AAs, to existing, functioning systems. Populating a new California

system will take years to accomplish, will result in duplication of effort and may ultimately confuse the public rather than enhance their access to environmental data and information.

3. Quality Control / Quality Assurance (QA/QC)

In public hearings and throughout the course of the Green Ribbon Science Panel meetings, DTSC has made clear that California EPA (CalEPA) has limited resources to devote to QA/QC of data and information submitted to the Agency. Creating a portal to existing systems that contain data that has been developed using recognized Good Laboratory Practices and in many cases has been peer reviewed and undergone public scrutiny, will allow OEHHA and DTSC to provide more accurate information to the public. Additionally, by linking to an existing system(s), ongoing QA/QC and systems updates can be assured without requiring additional monetary resources from CalEPA.

4. Maintenance / Updates

Maintenance and upkeep of a TIC as envisioned by OEHHA is costly in terms of both dollars and staff time. Establishing a portal to an existing system(s) would leverage CalEPA resources and allow OEHHA and DTSC to invest in other high priority activities. One example of the latter is the development of tools and guidance materials to assist both industry and the public in participating more fully in the SCPA program.

5. Familiarity

Any new data system will require significant start up time for both staff and external users to become familiar with the system. Connecting to an established system will avoid that start up delay and will facilitate access and use of data.

Specification of Hazard Traits

Global Automakers appreciates the effort that OEHHA has made to harmonize the definitions and endpoints of the hazard traits identified in the proposal with those in other nationally and

internationally recognized systems. This type of consistency is imperative as multiple regulatory bodies strive to assess and manage the same universe of chemicals and products.

While the harmonization of definitions is an asset, definitions and endpoints alone provide no context within which to prioritize concerns associated with an individual chemical or among groups of chemicals. Yet, the document as proposed lacks any information in the hazard trait sections that would allow the user to assess the likelihood of occurrence of any particular effect. To be a robust risk assessment system, both hazard criteria and exposure data are necessary.

1. Hazard Criteria or Classification

OEHHA needs to include criteria that allow the user to understand the exposure levels at which impacts are likely to occur (potency). Users of the TIC will need to be able to compare the likelihood of effects at a given exposure level for each chemical being considered for substitution. In the absence of such criteria, the identification of safer alternatives will be difficult if not impossible. EPA's Design for the Environment (DfE) program has established assessment criteria for hazard evaluation that provide a good example of how to characterize and present relative degrees of potential hazard based on exposure levels.

Reproductive and Developmental Toxicity	High	Moderate	Low	Very Low
Oral (mg/kg/day)	< 50	50 – 250	> 250-1000	> 1000
Dermal (mg/kg/day)	< 100	100 – 500	> 500-2000	> 2000
Inhalation (vapor/gas) (mg/L/day)	< 1	1 - 2.5	> 2.5-20	> 20
Inhalation (dust/mist/fume) (mg/L/day)	< 0.1	0.1 - 0.5	> 0.5-5	> 5

Source: EPA DfE Assessment Criteria for Hazard Evaluation. Version 2.0

We recommend that OEHHA provide this critical information in whatever system they ultimately choose to adopt.

2. Exposure Information

In addition to providing information related to hazard potential based on exposure, the TIC will need to include both chemical and product exposure data in order for the public and other users to be able to determine if there is a health or environmental concern associated with any specific exposure scenario. As suggested earlier, information on hazard alone provides little insight into the potential for actual risk. The EPA and OECD databases mentioned earlier provide access to this important data.

3. Reference Information

There is no mention of the inclusion of studies and data that point to negative findings or a lack of concern. A balanced and complete system would need to include negative data, identify chemicals for which there is an incomplete or inadequate portfolio to assess either hazard or risk, and data demonstrating little or no concern with a chemical. In order to evaluate chemicals using a sound weight of the evidence approach, all data must be presented.

Emerging Areas of Toxicology

Global Automakers understands the desire to put in place a comprehensive set of hazard traits and endpoints by which to evaluate chemicals and products. However, with emerging fields of study, such as endocrine disruption and epigenetics, it is important to make sure that accepted test methods are in place and that scientifically valid methods for assessment have been developed. For both of these modes of action, valid test methods are still under development and, in some cases, unavailable. Until such time as there is general agreement in the scientific community that valid, acceptable tests and test methods are available, it would be premature to require testing and assessment for these concerns. Generation of data that may ultimately prove to be inadequate or erroneous may be misleading and counterproductive. In the interim, voluntary generation of such data could be encouraged.

Conclusion

Global Automakers understands the challenges that implementing California's SCPA regulations pose for both OEHHA and DTSC. We encourage OEHHA to coordinate closely with DTSC and put in place a system that is not overly cumbersome and that leverages existing systems wherever possible. Whatever approach OEHHA determines it will adopt, it should be a science based, comprehensive system that provides both hazard and exposure data; the ability to easily identify exposure levels of potential concern; and the tools to facilitate comparative assessments of chemicals and products. In the absence of these minimum requirements, neither the public nor the regulated community will have the ability to fully participate in the regulatory process.

We appreciate this opportunity to provide our input and would be pleased to discuss any of our comments or suggestions.