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February 15, 2011

Fran Kammerer
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Office of Environmental Health Hazard Assessment
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(via e-mail: fkammerer@oehha.ca.gov)

Re: ACI comments on OEHHA proposed regulations for Green Chemistry Hazard Traits

Dear Ms. Kammerer:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the proposed regulations for *Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse* released on December 17, 2010 by the Office of Environmental Health Hazard Assessment (OEHHA) for the implementation of SB 509.

ACI is a trade association representing the \$30 billion U.S. cleaning products industry. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members support California's efforts under the Green Chemistry Initiative to seek new and innovative ways to examine and reassess existing chemistries and certain uses of those chemistries in an effort to identify opportunities to shift toward the use of alternative chemicals and processes that might reduce risks to health and the environment. Following are broad-based comments concerning the proposed regulations. More detailed substantive aspects of the proposed regulations concerning certain criteria and the manner in which they might be applied in this context are addressed in Attachment 1 of this letter. Further, we have included as Attachment 2 of this letter our comments to the August 2010 pre-regulatory draft from OEHHA so that they may be included in the public record of the proposed regulations. We hope by sharing the insights and experiences of our members we can enhance OEHHA's implementation of SB 509.

OEHHA should harmonize its regulations with the DTSC Safer Consumer Product Alternatives regulations and related activities.

The SB509 regulations proposed by OEHHA should be developed in collaboration with efforts by the California Department of Toxic Substances Control (DTSC) to implement AB 1879 through its Safer Consumer Product Alternatives regulations. It is apparent that the definitions provided in Article 1 were not developed in concert with DTSC by virtue of the differences between the two regulations. Moreover, DTSC is moving forward with its development of the TIC as evidenced by their April 8, 2010 Feasibility Study Report regarding the project. In

addition, both DTSC and OEHHA have been active participants in the Interstate Chemicals Clearinghouse which has a similar purpose as the TIC but as a multistate extra-governmental entity. There is no apparent coordination among these activities which leads to confusion among stakeholders and the public, likely duplication of efforts and potential conflicting technologies for the delivery of information. The Department, OEHHA and CalEPA should coordinate all of their related efforts on the Toxics Information Clearinghouse before moving forward with the SB 509 regulations.

OEHHA should provide a complete definition of “hazard traits.”

The definition of “hazard traits” is a circular definition that results in confusion cascading through the entire document. It should be clearly stated in the definition of “hazard traits” that it is an inherent property that leads to adverse effects in humans or wildlife. Such a definition would enhance many of the hazard trait sections of the regulation that follow.

OEHHA should eliminate the classification aspects of the proposed regulation as they are unnecessary, unauthorized and in some cases duplicative.

In several sections of the proposed regulations, there is an “Evidence for...Hazard Trait” section which details the related evidence by which a chemical is classified to have the particular hazard trait. The establishment of chemical classification criteria by OEHHA is not necessary or authorized by SB 509. Furthermore, OEHHA already classifies carcinogens, and developmental and reproductive toxicants through its Proposition 65 activities, so those sections of the proposed regulations are redundant. The classification elements of the regulations should be removed.

OEHHA should identify environmental hazard traits that are inherent properties of chemicals.

OEHHA has identified several complex processes that are influenced by numerous biological, chemical and physical factors within the ecosystem (e.g., eutrophication, loss of biological diversity) and attempted to characterize them as being the result of an individual inherent property of a chemical. While these processes are important concerns regarding the health of an ecosystem they cannot be readily attributed to a particular chemical alone. The environmental hazard traits should focus on toxicity to wildlife including plants and animals.

OEHHA should abandon their attempt to classify “exposure potential” as a hazard and relegate the related parameters to the “other relevant data” portion of the TIC.

OEHHA has taken the unusual step of identifying physicochemical properties of a chemical (alone) as hazard traits. Nowhere else in the world has such a leap been made because there is no scientific merit to this approach. While such properties are important information regarding the environmental fate of chemicals and human exposure to them and should be included in the Toxics Information Clearinghouse, they are not hazard traits. Article 5 – Exposure Potential Hazard Trait should be eliminated.

* * *

ACI would like to express its appreciation once again in being able to comment on the proposed regulations. We remains committed to working collaboratively with OEHHA to identify well recognized and reliable hazard traits, endpoints and other data for inclusion in the Toxics

Information Clearinghouse. We would be happy to further assist OEHHA in your development of regulations for the implementation of SB 509 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Sincerely,

A handwritten signature in black ink that reads "Paul C. DeLeo". The signature is written in a cursive, flowing style.

Paul C. DeLeo, Ph.D.
Senior Director, Environmental Safety

cc: The Honorable Linda Adams, Acting Secretary, CalEPA (LAdams@calepa.ca.gov)
Cindy Tuck, Undersecretary, CalEPA (ctuck@calepa.ca.gov)
Patty Zwarts, Deputy Secretary, CalEPA (pattyz@calepa.ca.gov)
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Enclosures:

ATTACHMENT 1: Editorial Comments from the American Cleaning Institute on Proposed OEHHA Regulations for Green Chemistry Hazard Traits
ATTACHMENT 2: September 13, 2010 Comments from the American Cleaning Institute on the August 11, 2010 OEHHA Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints

Attachment 1:
Editorial Comments from the American Cleaning Institute on
Proposed OEHHA Regulations for Green Chemistry Hazard Traits

The Initial Statement of Reasons for the proposed regulation 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. There are several existing hazard trait and toxicological end-point regimes in existence nationally and internationally which 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 development of the Toxics Information Clearinghouse (TIC), the OECD Harmonised 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.¹ 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. California should follow a similar format in development of the TIC to minimize expense and maximize utilization of publicly available chemical information.

Article 1. General

§69401.2 Definitions

- (b) “Authoritative organization” – this definition refers to “state, national or international governments and their supporting public health or environmental entities in regulating or otherwise protecting human health or the environment from threats posed by those chemical agents.” This has the potential to be confusing because there are no “international governments.” However, there are international treaties and conventions that have implications for chemical management. Therefore, this sentence could be amended as follows: “state or national governments or international conventions ~~governments~~ and their...”

Authoritative organizations are also identified in this definition to include the following: “(4) Canadian government agencies including Environment Canada and Health Canada, (5) Governmental bodies within the European Union, including the European Chemicals Agency and national governments...” The reliance on decisions of European Union and Canadian agencies is inappropriate. U.S. stakeholders are not a party to the development of the decisions by these foreign organizations. Further, as worded, essentially any governmental bodies in these other jurisdictions are defined as authoritative bodies.

¹ http://www.oecd.org/site/0,3407,en_21571361_43392827_1_1_1_1_1,00.html

Therefore, OEHHA should remove these two groups from the definition. Should OEHHA leave them in the definition, before it accepts the decisions of these organizations, it should first solicit input and comment on the substantive aspects of their decisions and criteria through regulatory proceedings and affirm them before adoption.

- (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 that hazard traits are types of hazards. Hazards are, in the context of chemicals, inherent properties that have the potential to lead to adverse effects in humans or wildlife under particular conditions and levels of exposure. In the context of the present regulation, they are toxicities. The definition should be amended accordingly.
- (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 the hazard trait itself, but could be any relevant data about a chemical in the TIC. 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 might be relevant and useful to be contained in the TIC, and easily accessible towards that end. Further, this definition refers to the term “non-endpoint data.” This is confusing. Either the term should be defined or it should be replaced with clearer text.
- (h) “Toxicological endpoint” – this definition lacks clarity because it is not specific to toxicity. 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 arbitrarily excludes any study which is not published in the open literature, or submitted to a government agency. The definition should be revised to read “*Well-conducted scientific studies*” means studies using methods and analyses which are scientifically valid according to internationally accepted principles.”

Article 2. Toxicological Hazard Traits – Carcinogenicity, Developmental Toxicity and Reproductive Toxicity

General Comments

At numerous points in this Article, references are made to “meeting criteria” for various hazard classifications. OEHHA should make it clear that it is not requiring any organization to carrying out its own assessment of hazards against criteria listed in the proposed regulation, but rather utilize available assessments of authoritative bodies with respect to the criteria.

The proposed regulation also cites as evidence for a certain hazard traits: “Recognition as a [hazard] by California, other states, the United States or other nations.” Similar to a previous comment, there should be no reliance on decisions of “other nations” unless it can be shown that U.S. stakeholders were a party to the development of the decisions of these foreign countries. Further, as worded, it leaves it open ended as to where or not the decisions of any governmental bodies in these jurisdictions, regardless of competence, would be adequate to conclude a substance meets the conditions to be classified. This sentence should be revised to make it clear it is only decisions by authoritative bodies, as defined in the proposed regulation that should be recognized.

§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.

§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.

§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

§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.

§69403.3 Endocrine Toxicity

(c) – the regulations should be clarified to define *endocrine disruptions* and *metabolic syndrome* here and throughout the text.

§69403.4 Epigenetic Toxicity

This section should be clarified to specify what constitutes an adverse outcome with respect to epigenetic toxicity.

§69403.5 Genotoxicity

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

§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.

§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 4. Environmental Hazard Traits

§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. 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.

§69404.2 Eutrophication

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

Eutrophication is the fertilization of surface waters by nutrients that were previously scarce. When a previously scarce (limiting) nutrient is added, it leads to the proliferation of aquatic photosynthetic plant life. This may lead to a chain of further consequences, including foul odor or taste, death or poisoning of fish or shellfish, reduced biodiversity, or production of chemical compounds toxic to humans, marine mammals, or livestock. In the U.S., most often the limiting nutrient is either nitrogen or phosphorus. However, it is the physical, chemical, and biological characteristics of the water body that governs the eutrophication process and not the inherent characteristics of a particular chemical.

§69404.3 Impairment of Waste Management Organisms

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.

§69404.4 Loss of Genetic Diversity, Including Biodiversity

This proposed hazard trait is unnecessary. 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. This section should be removed.

§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 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 Trait

Article 5 is unnecessary and lacks clarity. The state is proposing to establish that certain physicochemical 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. The individual items within this section (e.g., bioaccumulation, environmental persistence) are common chemical properties that are often reported and for which there may be substantial data to populate the TIC. It is fair to consider these properties as “other relevant data” and they should be included in the TIC.

§69405.2 Bioaccumulation

As noted above, bioaccumulation is not a hazard trait, however it is an important inherent chemical property that is often measured and reported. As such, it should 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.^{2,3} 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 biomagnification capacity of chemical substances.” One criterion found in the proposed regulation that was not the part 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 bioaccumulate and should be eliminated from the 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 in subparagraph (b) of this section should be eliminated.

² Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.

³ <http://www.setac.org/sites/default/files/ExecutiveSummary.pdf>

§69405.3 Environmental Persistence

OEHHA proposes to define persistence as the “propensity for a chemical substance to remain in the environment for a long time period subsequent to its release, by resisting chemical and biological degradation.” However, designating a chemical substance as “persistent” in the environment is not straightforward. A common misconception is that, like many physical and chemical properties, environmental persistence is an inherent property of the substance and can be easily measured. This is not the case. Rates of degradation of a substance in the environment are determined by a combination of substance specific characteristics and environmental conditions.⁴ Moreover, the potential risk of such a chemical to wildlife will be governed by a number of other factors related to the potential exposure to the chemical, such as bioavailability of the chemical in the environment. Consequently, as we have stated in several other places, it is inappropriate for OEHHA to include environmental persistence as a potential hazard trait and for chemicals to be classified under this proposed regulation with respect to persistence.

However, we acknowledge that there are a number of widely accepted standardized test methods that measure the half-life of a chemical, typically under laboratory conditions (e.g., OECD Guidelines for Testing of Chemicals⁵) and there are standardized reporting formats for the resultant data generated. It is appropriate for OEHHA to include biodegradability data, aerobic and anaerobic transformation data and other related data in the “other relevant data” portion of the TIC.

Article 6 Physical Hazard Traits

§69406.3 Flammability

Flammability is proposed to be identified as a hazard by reference to criteria in sections of the United Nation’s Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). This proposal fails to recognize that regulatory systems specifying criteria for flammability exist in the U.S., such as those of EPA, OSHA and CPSC. OEEHA would create confusion and added burden by calling for a different criterion than those that are already routinely being applied by regulators and manufacturers.

Further, should OEHHA proceed to incorporate elements of the GHS in this regulation, it would place OEHHA in the unique position of the being the first government entity in the U.S. to implement elements of the GHS into its requirements. This burden would be a particular concern to ACI members in view of the systems already in place in the U.S. to make these determinations and it would place upon OEHHA the unique burden of educating and training chemical producers and users on how to apply the criteria to chemicals.

ACI urges OEHHA to revise the criterion for flammability to reference existing U.S. regulatory criteria and remove references to the GHS.

⁴ Boethling, R., K. Fenner, P. Howard, G. Klečka, T. Madsen, J. Snape and M. Whelan. 2009. Environmental persistence of organic pollutants: Guidance for development and review of POP risk profiles. *Integrated Environmental Assessment and Management*, 5(4):539-556.

⁵ <http://www.sourceoecd.org/1607310X>

ATTACHMENT 2:

**September 13, 2010 Comments from the American Cleaning Institute on the
August 11, 2010 OEHHA Pre-Regulatory Draft Regulation for Hazard Traits
and Environmental and Toxicological Endpoints**



american cleaning instituteSM
for better living

September 13, 2010

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

Re: ACI comments on OEHHA Pre-Regulatory Proposal

Dear Ms. Kammerer:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Pre-Regulatory Draft Regulation for Hazard Traits and Environmental and Toxicological Endpoints* released on August 11, 2010 by the California Office of Environmental Health Hazard Assessment (OEHHA) for the implementation of SB 509.

ACI is a trade association representing the \$30 billion U.S. cleaning products industry. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. As a trade association for a particular consumer product sector (cleaning products) we are acutely aware of the public's concern for the safety of the products they purchase both in their homes during use and in the environment following disposal. There are numerous chemical management initiatives around the world taking place at the local, regional, federal and international levels in which we participate. We hope by sharing our insights from these experiences we can enhance OEHHA's implementation of SB 509.

We have a number of detailed comments below, but would like to share perspective on some more general considerations in your draft regulations.

California's identification of hazard traits and endpoints should be harmonized with other existing global systems defining those traits and endpoints.

There has been a global movement for several decades to standardize the way in which human health and environmental data are reported in order to provide global utility of that data. There are a number of harmonized systems which are being used to report data and the Toxics Information Clearinghouse (TIC) should be capable of leveraging data available in those formats. Examples include the OECD Screening Information Data Set (SIDS), the IUCLID format for reporting data under REACH, and US Occupational Safety and Health Administration (OSHA) Hazard Communication regulations which will shortly utilize the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) including its standard definitions for

hazard traits and endpoints, and standard formats for reporting hazard information. California should designate hazard traits and endpoints in such a fashion as to allow the TIC to take advantage of existing data and future data that will be generated and reported using such formats consistent with SB 509 and AB 1879.

The categories of “Toxicological Hazard Traits” in Section 3 are inconsistent with chemical human health hazard categories widely recognized and implemented internationally.

The categories of “toxicological hazard traits” described on pages 5-14 of the proposal are inconsistent with other widely recognized and implemented international categories. For example, updated hazard communications regulations recently proposed by OSHA utilize the GHS principles which include criteria for identifying hazard traits that are commonly used around the globe. Similarly, the member countries of the OECD have developed the Screening Information Data Set (SIDS) to understand chemical hazard, which is used broadly by OECD member states and others as a basis for developing information on and making regulatory decisions about chemicals. It is not clear why OEHHA failed to incorporate any aspects of these widely used and agreed upon systems in the TIC discussion document. The OSHA GHS and OECD hazard traits are ones typically encountered in discussions of chemical hazard and are based on the types of data routinely gathered in toxicity testing. In contrast, the OEHHA hazard traits classification system is overly specific. There is no need to break out systemic toxicity or target organ toxicity by specific systems (e.g., cardiovascular, gastrointestinal, liver, renal, etc.) when the goal is hazard identification. Instead, use of the OSHA GHS or OECD approaches, listing target organ effects, is more than adequate to describe a chemical’s hazard.

OEHHA should seek scientific consensus on the description of “emerging” hazard trait and endpoints.

For “emerging” traits like endocrine toxicity and epigenetic toxicity, OEHHA should seek scientific consensus on the description of the trait and the appropriate endpoint(s). OEHHA should be able to show that scientific consensus exists, or they should be establishing the process for reaching that consensus where none exist, but they should not be unilaterally establishing new hazard traits.

Exposure potential is not a hazard trait.

Hazard traits are *intrinsic properties* of a chemical that may lead to adverse effects. As part of the proposed regulation, OEHHA has invented the novel “Exposure potential hazard trait.” A number of physical-chemical attributes (e.g., particle size, persistence, global warming potential) have been defined as hazard traits without any scientific basis or precedent to support them. In fact, the notion of exposure potential as a hazard trait is contrary to well established principles of risk assessment, where risk is a function of hazard and exposure. Hazard and exposure are entirely separate contributing factors to risk and they should be treated as such. The individual “traits” described may be valuable physical-chemical data that could be included in the TIC as Other Relevant Data, but they are not hazard traits. The entire section should be struck from the regulation.

Environmental hazard traits should be greatly simplified to reflect the availability of the vast majority of relevant information.

The proposed regulations include, in Section 3b, an exhaustive accounting of potential biological responses in wildlife related to chemical exposures. While there are internationally harmonized test guidelines for pesticide testing, the vast majority of environmental data on non-pesticide chemicals will be aquatic toxicity data (acute, chronic and subchronic) for (freshwater species of)

algae, invertebrates (e.g., *Daphnia*) and fish. It would be the most economical use of State resources, and the best value for potential users of the TIC for environmental hazard traits to be focused on aquatic toxicity data initially, with an opportunity for the addition of other traits and endpoints as the TIC grows.

OEHHA should reconsider what “other relevant data” may be easily accessible and valuable within the context of the Toxics Information Clearinghouse.

The notion of other data that might be relevant within the use parameters of the Toxics Information Clearinghouse go beyond that of hazard traits. To the extent that the TIC is intended for businesses and consumers to understand more about chemicals and products in commerce, information regarding the market volume of chemicals, their uses and monitoring data may all be useful in the TIC. OEHHA should consider where such data may exist in standardized formats and the feasibility of incorporating it into the TIC.

California should not implement a new chemical hazard classification system.

The classification proposal should be abandoned entirely. SB 509 does not give California either the mandate or the authority to create a new hazard classification system. The classification system is a significant overstep of authority. Moreover, the entire classification provision is pejorative, unrealistic, and unhelpful. The proposal does not bring clarity to chemical information. Indeed, it increases opacity on all dimensions, as evidenced by the following:

- It inappropriately combines lack of information and a determination of no effect into a single result, “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.” Clearly this is unhelpful.
- Finally, it appears that, a chemical is categorized as having many of the toxicities listed until such time as OEHHA or DTSC determines otherwise. Again, this is less than helpful.

In addition to the general comments above, please find a number of detailed comments on the language of the proposed regulations below:

Section 2. Definitions

Adverse effect – the definition is overly broad and without context for the purpose of defining chemical hazard traits. The definition proposed is inclusive of every degree of

perturbations without consideration of a threshold for “adverse effect.” OEHHA should reconsider this definition using widely held precedents as a guide for seeking broad scientific consensus on a definition.

Adverse environmental effect – this definition suffers from the same deficiencies as the definition of “adverse effect.” OEHHA should reconsider this definition.

Authoritative organization – the criteria for accepting findings from “non-governmental entities” should be reconsidered. We propose the following definition and criteria:

“Authoritative body/organization” means a government agency or formalized scientific organization that satisfies all of the following requirements:

- It characterizes chemicals pursuant to an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- It is widely perceived to be objective, scientifically based, and does not engage in advocacy.
- 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 other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
- It publishes its characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

Chemical substance – this definition is not harmonized with the Safer Consumer Product Alternative regulations being developed by the Department of Toxic Substances Control. At a minimum, this definition should be consistent with the DTSC definition.

Class One chemical – this definition, and Section 4, should be deleted. The statute does not give the authority for California to be classifying chemicals, and the State does not have the resources or expertise to embark on a new chemical classification program.

Class Two chemical – delete this definition.

Exposure potential characteristic – this definition, and Section 3c, should be deleted. The notion of “exposure potential” as an inherent property of a chemical is not scientifically valid and is contrary to the tenets of risk assessment. Exposure will always be a function of the use conditions of a chemical.

Not Classifiable – delete this definition.

Other relevant data – the notion of other data that might be relevant within the use parameters of the Toxics Information Clearinghouse go beyond that of hazard traits. To the extent that the TIC is intended for businesses and consumers to understand more about chemicals and products in commerce, information regarding the market volume of chemicals, uses and monitoring data may all be useful in the TIC.

Well conducted scientific studies – limiting the definition of “well conducted scientific studies” to published studies assumes that all published studies are good, and those that are not published, are bad. The scientific literature is rife with studies that are not repeatable and have not been conducted using good methods. Similarly, there are a host of “no effects” studies that are well conducted, but will never be published. The definition may be sufficient if simply stated as: “*well conducted scientific studies*” means studies conducted using methods and analyses which are scientifically valid according to generally accepted principles.

Section 3. Specific Hazard Traits, and Endpoints and Other Relevant Data

- 3.a.i. Carcinogenicity** is a generally accepted hazard trait within all existing hazard identification systems. However, OEHHA should seek to harmonize their definition with those used by other widely accepted authoritative bodies (e.g., EPA, IARC, OSHA GHS, etc.).
- 3.a.iii. Dermatotoxicity** is not a trait commonly addressed through standard toxicity testing. Instead, various testing batteries include studies examining endpoints of dermal toxicity such as skin sensitization, phototoxicity, and dermal irritation.
- 3.a.xiv. Ocular toxicity** is an endpoint commonly addressed through testing for eye irritation and damage in standard acute toxicity tests. 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.
- 3.a.xvi. 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 related endpoints appear to fit more easily within other hazard trait categories as underlying mechanisms or modes of action. This trait should be eliminated.
- 3.a.xvii. Reproductive toxicity** is a generally accepted hazard trait within all existing hazard identification systems. However, some reproductive system changes observed in toxicity studies are produced only when doses exceed a maximum tolerated dose for the parental test animals and thus are not relevant for chemical hazard assessment. The omission of any discussion or consideration of exposure or dose levels when assessing the reproductive toxicity hazard trait is a significant flaw in the document.
- 3.b.vi. Loss of genetic diversity** occurs based on site-specific conditions within any ecosystem. It is not an inherent chemical trait and should not be included as a hazard trait. Even the most innocuous chemicals (e.g., table sugar) could be considered hazardous based on this definition. This trait should be eliminated.
- 3.b.vii. Eutrophication** occurs based on site-specific conditions within any ecosystem. It is not an inherent chemical trait and should not be included as a hazard trait.
- 3.c. Exposure potential hazard traits** - The notion of “exposure potential” as an inherent property of a chemical is not scientifically valid and is contrary to the tenets of risk assessment. Exposure will always be a function of the use conditions of a chemical. As such, Section 3c should be eliminated. However, a number physical-chemical parameters mentioned which may be “other relevant data” that could be included within the TIC;

e.g., bioconcentration factors (BCF), bioaccumulation factor (BAF), half-life, water solubility, pharmacokinetic data.

- 3.c.x. Toxic environmental transformation** – The concept proposed in this section is seriously flawed. For degradation of organic compounds, it is generally considered desirable for those compounds to be completely mineralized to carbon dioxide. However, CO₂ would likely be more persistent than many organic compounds resulting in irrelevant hazard identification. This is but one example of this ill-conceived concept.
- 3.d. Physical hazard traits** – Any identification of physical hazard traits should be consistent with terminology used by the Department of Transportation (DOT) and the Occupational Safety and Health Administration (OSHA).
- 3.d.iii. Nanomaterial hazard trait** – Recently, the International Standards Organization (ISO) Technical Committee (TC) 229 Nanotechnologies achieved the first international consensus definitions for core terms like nanotechnology and nanomaterial, as well as engineered nanomaterial and manufactured nanomaterial. ISO has established designated series number 80004 to facilitate the distribution and usage of consensus terms. California should harmonize their “nano” definitions to be consistent with other international bodies such as ISO.

While chemicals may exhibit different properties based on their relative size, to identify a chemical as hazardous based on this phenomenon is contradictory to chemical identification and hazard identification. The more appropriate approach to handling this phenomenon is to identify chemicals uniquely based on various structures, when appropriate, and to conduct hazard screening on the unique chemical.

Section 4. Sources and methodologies for identifying toxicological and environmental hazard traits.

This section should be eliminated entirely. SB 509 does not give California either the mandate or the authority to create a new hazard classification system. Moreover, the entire classification provision is pejorative, unrealistic, and unhelpful. The proposal system does not bring clarity to chemical information.

ACI would like to express once again its appreciation in being able to comment on the pre-regulatory draft regulations. We would be happy to further assist OEHHA in your development of regulations for the implementation of SB 509 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Sincerely,



Paul C. DeLeo, Ph.D.
Senior Director, Environmental Safety