american cleaning institute℠
for better living

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(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, CO_2 would likely be more persistent than many organic compounds resulting in irrelevant hazard identification. This is but one example if 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 (OSHA) 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

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Senior Director, Environmental Safety