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September 12, 2011

Ms. Fran Kammerer  
Staff Counsel  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010  
Sacramento, CA 95812  
(via e-mail: [fkammerer@oehha.ca.gov](mailto:fkammerer@oehha.ca.gov))

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

Dear Ms. Kammerer:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the amended proposed regulations for *Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse* implementing SB 509 (2008) released on July 29, 2011 by the Office of Environmental Health Hazard Assessment (OEHHA).

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.

We were deeply disappointed that OEHHA elected to ignore most of the comments we provided on the proposed regulation released by OEHHA on December 17, 2010 in our letter of February 15, 2011. Further, it appears that OEHHA has chosen to ignore a number of well-reasoned comments from other stakeholders and the peer-reviewers of the proposed regulation. We continue to believe that the regulations are seriously flawed as is the process for this rulemaking by virtue of inadequate consultation with the Department of Toxic Substances Control (DTSC) and insufficient peer-review. We recommend that OEHHA retract the regulations and engage in additional consultation to develop the regulations. We offer the following supporting comments.

**The proposed regulations did not receive adequate peer review.** California Health and Safety Code Section 57004 requires that all California Environmental Protection Agency (CalEPA) organizations, including OEHHA, conduct an external scientific peer review for the scientific basis before the adoption of regulations. While the proposed regulation was sent to three qualified peer reviewers, we note that not a single reviewer had expertise or commented on the Environmental Hazard Traits, and only one reviewer had expertise and commented on the Exposure Potential Hazard Traits and Physical Hazard Traits. This does not constitute adequate external review of the proposed regulations. The regulations should not be finalized until an adequate and complete scientific peer review is completed.

**The amended proposed regulations are not consistent with related regulations which would implement AB 1879 (2008) and obligations under the California Government Code to assess new burdens and costs on DTSC and other state agencies have not been met.** In the Notice of Proposed Rulemaking for the proposed regulation released on December 17, 2010, OEHHA states on page 5 that “adoption of these regulations will not impose new duties on OEHHA or any other state agency” in response to their obligations under California Government Code Section 11346.5(a)(6). This is not the case. Section 25256 of SB 509 requires “the department (DTSC) [to] establish the Toxics Information Clearinghouse, which shall provide a decentralized, Web-based system for the collection, maintenance, and distribution of specific chemical hazard trait and environmental and toxicological end-point data. The department shall make the clearinghouse accessible to the public through a single Internet Web portal, and, shall, to the maximum extent possible, operate the clearinghouse at the least possible cost to the state.” By developing a California-specific set of hazard traits and endpoints, OEHHA is imposing unique burdens on DTSC in their development of the Toxics Information Clearinghouse. The OEHHA Hazard Traits do not permit DTSC to leverage existing globally accepted hazard trait definitions described in our February 15, 2011 comments or operate the clearinghouse at the least possible cost to the state.

In addition, the regulations would require new duties of the state in that individual classification of chemicals would be required. For example, the modified proposed regulations include a new neurodevelopmental toxicity hazard trait (Section 69403.11). In Section 69403.17 – Evidence for Toxicological Hazard Traits, the department proposes criteria for determining whether there is strong evidence or suggestive evidence for a hazard trait. The question is “Who at OEHHA, DTSC or elsewhere in CalEPA would be responsible for evaluating chemical data in order to make this determination?” These new duties are clearly unauthorized and unnecessary.

Also, on page 5 of the December 17, 2010 Initial Statement of Reasons (ISOR), OEHHA states “Further, OEHHA developed the proposed regulation in consultation with DTSC and other state agencies. This proposed regulation complements the regulations currently proposed by DTSC for Chapter 53.” The regulation referenced in the ISOR has been abandoned by the Department and it has publicly stated that it does not intend to introduce a new proposal before mid-October 2011. It is imperative that the OEHHA Hazard Trait regulations seamlessly dovetail with the DTSC Safer Alternatives regulations. OEHHA should suspend their rulemaking until DTSC has formulated more completely their rule and consulted very closely with the Department.

**The amended proposed regulations are inconsistent with obligations under the California Government Code by failing to consider reasonable alternatives that were brought to OEHHA’s attention.** In response to their obligations under California Government Code Section 11346.5(a)(13), OEHHA indicated on page 6 of the Notice of Proposed Rulemaking 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 the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.” In our February 15, 2011 comments on the proposed regulations we proposed several other reasonable alternatives that would be more effective and less burdensome in carrying out the purpose of the proposed action. We were disappointed that

these alternatives were not considered and incorporated in the modified proposed rule. OEHHA should revisit these alternatives and incorporate them into the regulations.

**The amended proposed definition of “hazard traits” remains unclear and should be replaced or, at a minimum, be made consistent with existing Federal definitions.** The modified definition of “hazard traits” does not sufficiently clarify the meaning of the term. We note that OEHHA has proposed a new unique term rather than relying on existing terminology that has been used for decades. For example, the Federal Hazardous Substances Act states that “The term *hazardous substance* means: Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.” This definition is clear in establishing a link between exposures and an adverse outcome based on inherent properties of the chemical. OEHHA should use longstanding definitions as the basis for its definition of *hazard traits*.

**The amended proposed regulations improperly include arbitrary assignment of some physicochemical properties as Exposure Potential Hazard Traits and others as Additional Relevant Data.** As stated above, we were very disappointed that most of our suggested changes were not adopted. We felt it important to reiterate our objection to the establishment of the unique and unprecedented “exposure potential hazard traits” which are completely unnecessary and unclear, and scientifically indefensible. For example, the proposed *Lactational or Transplacental Transfer* hazard trait would identify a chemical as hazardous if the chemical had the ability to transfer from a mother’s tissues into breast milk regardless of whether that chemical is an essential nutrients or a synthetic xenobiotic chemical. The extent to which a chemical has the proposed “exposure potential” hazard traits does not solely result in an adverse outcome but it may be important information to understanding the extent to which one may be exposed to a chemical. The amended proposed regulation includes a new section on Additional Relevant Data which includes a number of physicochemical properties. The “exposure potential” hazard traits would be better included in those properties.

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ACI would like to express its appreciation once again in being able to comment on the proposed regulations. 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](mailto:pdeleo@cleaninginstitute.org).

Sincerely,



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

Ms. Fran Kammerer  
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cc: The Honorable Matthew Rodriquez, Acting Secretary, CalEPA ([MRodriquez@calepa.ca.gov](mailto:MRodriquez@calepa.ca.gov))  
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