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**RE: Proposed Regulation for Green Chemistry Hazard Traits (12/17/10)**

Dear Ms. Kammerer:

Amway is a \$9.4 billion multinational company that is proud to call California home for two of our facilities in which we employ over 800 California workers. We have been an active participant in the Green Chemistry Alliance (GCA) and endorse the comments submitted by that Alliance in a separate letter. Also, we respectfully submit the following additional comments in response to the Office of Environmental Health Hazard Assessment's (OEHHA) Proposed Regulation for Green Chemistry Hazard Traits ("regulation") released on December 17, 2010.

Amway was among the companies that lobbied actively in support of the bi-partisan measures that resulted in acceptance of legislation encouraging a science based framework for chemicals management during the 2008 California legislative session. We strongly supported what was then a broad based desire for state regulators, rather than the less well equipped legislators, to exercise expert scientific and engineering judgment and experience when determining appropriate regulatory actions affecting chemicals of concern in consumer products.

Following passage of this groundbreaking legislation, Amway joined the GCA for the express purpose of constructively informing the implementation effort so promulgated regulations might remain true to the objective and scientific ideals of the authorizing legislation. We continue to advocate for implementing the regulations to enable the full and success of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). Our hope is that public health and environmental protection will be enhanced and product and technology innovation promoted. However, we are particularly concerned that be done

without diminishing a healthy, globally competitive environment and business community that contributes to growth of the California economy.

### **Fundamental Concerns**

Chemicals management is a long-term commitment that must accommodate the ever-changing advances science and technology. Any system that purports to direct chemical development in a safer and more environmentally responsible path must have sufficient flexibility to recognize and incorporate advances in that development.

This issue of flexibility demands that OEHHA carefully consider the utility of the system that is being presented as a clearinghouse to "evaluate and specify hazard traits and environmental and toxicological end-points" (SB509). We at Amway are concerned that the proposed rulemaking is disconnected from the proposed regulations of Department of Toxic Substances Control (DTSC) and DTSC's expected utility of the Toxic Information Clearinghouse (TIC). The finalized OEHHA regulations will be fundamental in initiating the process for evaluating safer alternatives. Therefore, we urge OEHHA to more clearly define and scientifically anchor the hazard traits and endpoints to inform the prioritization process necessary to a fruitful implementation of the California Green Chemistry program.

We believe that OEHHA has exceeded the authority embedded in SB509 and has created a categorization that is unnecessarily novel and extensive. Had the proposed rule been limited to well accepted principles of hazard identification, there would have been a sufficient basis for action given DTSC without requiring that more speculative hazard categories and uncertain hazard endpoints be given significance. This unique chemical classification system threatens to render California Green Chemistry decisions inconsistent with some key principles of global chemical hazard assessment and to reduce the ability of the state to respond to the evolving risk assessment decisions being made within other chemical management systems.

### **Consistency with Existing Systems**

SB 509 specifically states. "The department shall consult with other states, the federal government, and other nations to identify available data related to hazard traits and environmental and toxicological end-points, and to facilitate the development of regional, national, and international data sharing arrangements to be included in the clearinghouse." This language clearly expects that the clearinghouse would be developed in such a way as to connect California Green Chemistry with the best principles of toxicology, risk assessment and risk management worldwide. However, the proposed chemical classification system will make it unnecessarily difficult to leverage existing information on chemicals. This inconsistent approach will needlessly slow the development of the TIC database as California agencies exert substantial agency effort requisite to convert available information to the unique California system. OEHHA has failed to acknowledge existing systems and explain why there is a need for a burdensome new system of classification.

We would like to express explicit concern for the identification of "exposure potential" as a hazard trait. Exposure is clearly an element of the well established science of risk assessment. Other chemical management systems have indicated a desire to incorporate risk assessment as a key element in prioritizing chemical management strategies. Notably, both EU Registration, Evaluation and Authorization of Chemicals (REACH) and Canadian Chemical Management Program (CMP) have identified parameters for the use of risk assessment in the management of all chemicals. However, no system has identified exposure potential as a hazard trait; hazard and exposure are delineated as separate elements of the risk assessment/ risk management plan.

As a simple example, OEHHA has identified ozone formation as an exposure potential hazard. Ozone has been identified as a hazardous substance by many classification systems. We would expect ozone to be identified as a hazard by OEHHA classifications. However, the potential to form ozone should be the subject of a strategy proposed by DTSC after they have prioritized ozone as a substance of concern for human health or environmental impact within the state of California. Maintaining a separation between hazard assessment and risk assessment gives the proper responsibilities to OEHHA and DTSC and allows an appropriate risk management plan to be implemented to protect California citizens and wildlife.

### **Prioritizing Ill Defined Hazard Traits –**

Before classifying a hazard trait, OEHHA should confirm scientific consensus on the description of traits that are still in process of definition. Appropriately validated study protocols for the endpoint(s) are needed prior to including these traits in the regulation. We do support OEHHA monitoring of new hazard traits and clearly announcing their intent to monitor. Periodic review of emerging science in classifying new hazards is something we would encourage and in which we would be pleased to participate. However, the mingling of hazards that may be ill defined hazards or those for which endpoints are not well characterized is counter productive to the intent of the clearinghouse.

An example of an ill defined hazard trait is endocrine toxicity. There is still no well accepted definition for endocrine effects nor is there a validated test to identify endpoints for such effects. We believe that this test protocol development is important and will support a validated hazard for inclusion. But until that can be done, DTSC should be given the opportunity to focus on well characterized hazards.

### **Potency of Hazard**

We concur with the GCA that OEHHA needs to include an indication of potency for traits characterizing a hazard. All substances, even those recognized as components of an essential diet, could be considered toxic. This creates a potential problem for DTSC in identifying substitutes for hazardous substances. Guidance for relative hazard will be critical for allowing the Green Chemistry program to advance smoothly. We agree that

OEHHA look toward existing systems to understand how other bodies have handled this critical issue.

### **Economic Cost of the Proposed Regulation**

OEHHA contends in the prologue to the proposed regulation that "(a)dooption of these regulations will not impose new duties on OEHHA or any other state agency other than the need to periodically review and update the regulation to keep up with changing scientific knowledge and methodologies." This implies a minimum cost impact from the implementation of the TIC. As we have outlined above, the proposed clearinghouse is a novel classification system in which either OEHHA or DTSC or both will have significant obligation for establishing endpoints and assessing relative significance of toxicological and environmental data. Amway is concerned that this burden will be so onerous that it will delay the implementation of the safer substitutes assessment and call into question the entire Green Chemistry program. At minimum, the novel elements of this program will demand increased staffing for both OEHHA and DTSC since OEHHA has not allowed for correlation with existing categorization systems such as CMP.

Amway also contests the OEHHA assertion that "the adoption of the proposed regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states." This assertion relies on the assumption that the TIC is merely "a repository of information. This completely ignores the purpose of the clearinghouse which is to provide a tool for prioritizing chemical ingredients restriction, ban or replacement. The rather extensive and arbitrary list of hazard traits could easily identify a laundry list of chemicals which will be subject to suspicion while awaiting assessment by DTSC many of these will be suspect because of novel classification unique to California. Unless the hazard trait assessment is coordinated with existing systems of chemical management, California manufacturers and marketers will be subject to a pressure to cease using the "listed" chemicals because the assessment that might judge them safe as used is not complete.

Amway greatly appreciates the effort expended by OEHHA to propose this extensive regulation. Nevertheless; we believe that OEHHA needs to give further consideration to their charge and modify the proposal to better achieve the intention of SB509.

Respectfully submitted,



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