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Fran Kammerer
Staff Counsel
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1001 I Street
Sacramento, CA 95812

Via e-mail to fkammerer@oehha.ca.gov

**Re: Comments on OEHHA's Proposed Regulation on "Green Chemistry Hazard Traits,"
December 2010**

Dear Ms. Kammerer:

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The Procter & Gamble Company (P&G)¹ appreciates this opportunity to comment on OEHHA's December 2010 Proposed Regulation on Green Chemistry Hazard Traits ("Proposed Regulation"). P&G continues to fully support what we believe was the original vision for California's inception and development of the Green Chemistry Initiative; that is, to create the opportunity and incentives to accelerate and promote sustainable innovation while making meaningful improvements in the protection of the environment and health of California consumers and their children.

P&G is a member of, and active participant in, the Green Chemistry Alliance, a group of major trade associations and companies that represent numerous broad industrial sectors in California. We support and have directly contributed to the robust written comments submitted today (2/15/11) by the Green Chemistry Alliance that address numerous elements and provisions deserving comment within the Proposed Regulation. P&G is also a member of the American Chemistry Council and Grocery Manufacturer's Association and fully supports their individual written comments addressing the Proposed Regulation. We have highlighted in our written comments a select few elements of the Proposed Regulation that we believe are especially problematic. Because of these significant concerns, P&G urges OEHHA to withdraw this proposal and work in collaboration with DTSC to re-propose both the Safer Consumer Product Alternatives Regulation and the Hazard Traits Regulation. It is imperative that the regulations work together to establish a credible, practical and successful Green Chemistry program that accomplishes meaningful improvements in the protection of the environment and the health of California consumers through the promotion of sustainable innovation.

OEHHA must work in coordination with DTSC. The Green Chemistry Hazard Trait Regulation should be developed in collaboration with DTSC's Safer Consumer Product Alternatives Regulation to accomplish the benefits expected from the Green Chemistry Initiative. We believe better coordination between the agencies is needed so that a useful system is developed in a cost-effective and timely

¹ The Procter & Gamble Company is the world's leading consumer products company operating in more than 80 countries worldwide. Our strong portfolio of recognized, quality and leadership brands includes numerous household, industrial and personal care products. Procter & Gamble is fully committed to helping solve sustainability challenges, which is embedded in our Company Purpose "to improve the lives of the world's consumers, now and for generations to come." Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

manner. Given the withdrawal of DTSC's Proposed Safer Consumer Product Alternatives Regulation, we urge OEHHA to withdraw the Proposed Regulation and coordinate revisions with DTSC to deliver consistent, harmonized regulations that accomplish the mandates of the statutes.

OEHHA should not create a unique California system for hazard trait nomenclature and classification. In the Proposed Regulation, beyond the traditional carcinogens, mutagens, reproductive, developmental, and acute toxicity, OEHHA needlessly lists additional specific organ toxicities. Existing global chemical hazard information systems (e.g. OECD², IUCLID³, REACH⁴, US HPV⁵) do not recognize the OEHHA concept. This means that implementation of the concept would impose a cost on the state to retrofit existing information when populating the Toxic Information Clearinghouse.

The enacting legislation, SB 509, requires the office "...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." However, the Proposed Regulation goes beyond the authority provided for in statute, by establishing a chemical classification system ("strong evidence" and "suggestive evidence") that would be unique to California. The Hazard Trait Regulation and Clearinghouse should be open to including all information available on a chemical, but remain as objective as possible, without introducing biases and subjectivity through a classification system. Since OEHHA does not have the authority or the mandate to create a novel California classification system, this element of the Proposed Regulation should be removed.

OEHHA must address the importance of reliable information and data quality and make use of existing systems. P&G believes that data included in the hazard classification process must be judged for reliability and quality in order to ensure that a hazard trait has a sound scientific basis. However, such data quality or reliability assessment is generally lacking from the OEHHA proposal. Neither peer-review alone nor submission to or conduct by an authoritative body is a sufficient metric of study quality. The OECD methodology for determining the quality of data in chemical dossiers, described in Chapter 3 of their Manual for Investigation of HPV Chemicals,⁶ is a globally accepted way to rate the reliability, relevance and adequacy of existing data. As such, it should be defined into these regulations and required for every study used to populate the Clearinghouse. It has been applied to all studies in the US and OECD HPV programs and is required for every study on all chemicals submitted under REACH. It has been found to be an excellent approach to separate good studies from those that are not of sufficient quality and reliability for science-based regulatory and product stewardship decisions.

OEHHA must consider weight of evidence. It is a general principle of hazard assessment that all available data must be considered and the totality of relevant and reliable information integrated in order to arrive at a scientifically defensible decision regarding chemical hazard. Since in many cases, dozens of toxicological studies will be available for review on any given chemical, the only valid scientific approach is to consider the weight of the scientific evidence. Without such an approach, the proposed regulation can be interpreted to suggest that a single study, regardless of its quality (and irrespective of other available relevant data), could be used to conclude that a chemical possesses "suggestive evidence" of a specific hazard trait. Additionally, with respect to cancer, developmental toxicity and reproductive toxicity hazards, it is likely that for many chemicals there will be multiple

² http://www.oecd.org/document/0,3343,en_2649_34365_36206733_1_1_1_1,00.html

³ <http://iuclid.eu/>

⁴ http://guidance.echa.europa.eu/public-2/getdoc.php?file=registration_en

⁵ <http://www.epa.gov/hpvis/>

⁶ OECD Secretariat, July 2007 http://www.oecd.org/document/7/0,3746,en_2649_34379_1947463_1_1_1_1,00.html

hazard assessments available from a variety of sources. As a result, specific discussion of how a weight-of-the-evidence assessment will be performed is needed.

Without use of weight of evidence, “sufficient evidence” of a hazard trait could be assigned to a chemical, for example, based on data from two poorly conducted studies even if there were several more reliable studies available that contradicted the results of those two studies. It is not scientifically valid to ignore this weight of the scientific evidence. Yet, while Section 69403.16 “Evidence for Toxicological Hazard Traits” proposes a framework for evaluating scientific results, it is not a weight of evidence approach. Instead, OEHHA is proposing to simply count the positive studies. This proposed approach of OEHHA fails to consider all the relevant information required for a causal determination. A scientifically sound weight of evidence analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies. In contrast to a true weight of evidence process, OEHHA’s proposal makes no mention of 1) evaluating negative studies, 2) evaluating the consistency of results across different studies and over time, and 3) evaluating biological plausibility. The framework that OEHHA should employ must provide for a transparent, scientifically-based evaluation of the overall weight of evidence that there is a causal relationship between an outcome of concern and exposure to a substance.

OEHHA must address chemical potency. Chemical potency is ignored in the current OEHHA proposal for assigning hazard traits. This is in direct conflict with general principles of hazard identification. It is a generally accepted principle of toxicology and hazard identification that the dose required to produce a toxic effect, which is a measure of the potency of the chemical to produce toxicity, is an important component of the evaluation process. Without some indication of potency, every substance, whether synthetic or naturally occurring, will be labeled as toxic. With respect to cancer, developmental toxicity and reproductive toxicity hazards, the issue of potency is included in most internationally recognized classification systems where it is recognized that some studies conducted at doses or routes of exposure irrelevant to human exposure must be carefully applied even in hazard identification.

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In summary, we have serious concerns about the novel approach OEHHA has proposed for hazard trait determination and classification and believe this to be an overstep of statutory authority. We strongly urge OEHHA to first undertake the necessary coordination with DTSC and then revise the Proposed Regulation to adopt a structure that allows existing chemical toxicity information and hazard trait determinations to be utilized in a scientifically rigorous manner to successfully fulfill the mandate under SB509.

Should you have any questions about these comments, please contact me at (513) 983-2531 or froelicher.jm@pg.com.

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