



February 15, 2011

**BY ELECTRONIC MAIL**

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**RE: COMMENTS ON OEHHA'S PROPOSED REGULATION ON GREEN CHEMISTRY HAZARD TRAITS, ENDPOINTS AND OTHER RELEVANT DATA**

Dear Ms. Kammerer:

The Personal Care Products Council<sup>1</sup> (Council) is pleased to submit the following comments and concerns regarding the Office of Environmental Health Hazard Assessment's (OEHHA) Proposed Regulation for Green Chemistry Hazard Traits and Toxicological Endpoints to be included in the Toxics Information Clearinghouse (regulation), which was issued on December 17, 2010.

As an initial matter, it bears noting that as of the date of these comments, the California Department of Toxic Substances Control (DTSC) has not submitted its Revised Proposed Safer Consumer Products Alternatives Regulation to the Office of Administrative Law. All indications are that DTSC's revised proposed regulations will undergo further review and modification, and therefore be subject to further public comment, before becoming final. Given that DTSC's regulation will ultimately inform OEHHA's hazard trait regulation, the Council urges OEHHA to

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<sup>1</sup> Based in Washington, D.C., the Council is the leading national trade association representing the \$250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation. The Council was previously known as the Cosmetic, Toiletry, and Fragrance Association (CTFA).

withdraw its proposed regulation until DTSC's regulatory approach becomes clear. Once DTSC has finalized its regulation, OEHHA can develop proposed regulations that are consistent with, and complementary of, the regulatory structure DTSC proposes.

With that in mind, the Council respectfully makes the following recommendations for improving OEHHA's proposed hazard trait regulation:

### **SPECIFIC COMMENTS**

#### **Leverage Existing Chemical Management Regimes.**

OEHHA's proposed hazard trait regulations introduce a new California-only chemical classification system that will make it unnecessarily difficult to leverage existing information on chemicals. Given the existence of both national and international hazard trait regimes,<sup>2</sup> it is unclear why OEHHA has decided to pursue a non-standard approach that will dramatically complicate the development of an online toxics clearinghouse. Worse, a California-only classification system would require substantial resources, money, and personnel to convert into the appropriate format any existing chemical information before it can be effectively utilized. This is true both at the development stage and going forward.

The Council believes that OEHHA should harmonize as much as practicable with existing international and national systems that already identify the information necessary to study and characterize chemicals. If California wants to create a system that can be populated quickly and efficiently – and will prove useful to regulators, manufacturers, and consumers – then existing systems should be utilized.

**OEHHA should not create unique hazard trait nomenclature.** In the proposed hazard trait regulation, OEHHA goes beyond the traditional listing of toxicities to include a long list of specific organ toxicities, creating the false impression that there are separate validated test

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<sup>2</sup> The OECD Harmonized Templates for Reporting Chemical Test Summaries are standard data formats for reporting chemical studies on human health and the environment. 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.

methods for each of these. No other existing classification system currently does this, leading to potential confusion among users and consumers.

The enacting legislation, SB 509, that is the basis for OEHHA's proposed hazard trait regulation, requires OEHHA 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.*" Unfortunately, OEHHA's proposed regulation goes well beyond the authority provided for in statute, establishing a chemical classification system that would be unique to California. The Council believes that OEHHA does not have the legislative mandate or the authority to create such a novel classification system.

**OEHHA should require scientific consensus on emerging hazard traits.** For emerging traits, such as endocrine disruption, the Council strongly believes that it is inappropriate to include them in the proposed regulation as "other" toxicological hazard traits. There should be scientific consensus on trait characterization and validated testing protocols *before* including them in the proposed regulation and online clearinghouse.

Consider, for example, that there is no universal definition of "endocrine disrupter." Moreover, endocrine disruption is not a valid endpoint so much as a mode of action. That is, endocrine activity is not a distinct toxicological hazard per se, but rather a measure of a chemical's ability to interact with components of the endocrine system. And evidence of interaction with endocrine processes does not necessarily give rise to adverse effects.

For these reasons, the Council believes that OEHHA should be required to demonstrate scientific consensus – or a process for reaching consensus where none exists – before including any emerging, non-conventional hazard traits in its regulation.

**Additional Concerns.**

Definitions. OEHHA's proposed hazard trait regulation defines *well-conducted studies* as "studies published in the open literature or conducted by or submitted to a local, state, national or international government agency, using methods and analyses which are scientifically valid according to generally accepted principles." Unfortunately, however, this definition differs significantly from the definition of "reliable information" that was put forth by DTSC in its proposed regulations. Nor does it establish a method for determining the reliability of data.

The Council recommends that OEHHA create a method for assessing the reliability, relevance and adequacy of underlying data before a chemical is added to the online clearinghouse.

Weight of Evidence. OEHHA's proposed regulation provides insufficient consideration to weight of evidence. Currently, the proposed classification system would weigh only positive data. A scientifically sound weight of evidence process depends on looking at both positive and negative data, as well as the ability to reproduce test results. Without these factors, the format proposed by OEHHA is hopelessly biased and not scientifically supportable. OEHHA should implement a weight of evidence approach that considers both positive and negative evidence before any chemical is included in the online clearinghouse.

Potency. The proposed regulation fails to take into account potency for traits which exhibit a hazard. Without some indication of potency, every substance could be considered toxic. Potency, like routes of exposure, is a standard part of hazard assessment. The Council recommends OEHHA include potency when assessing traits that exhibit a hazard.

#### **CONCLUSION**

The Council thanks OEHHA for the opportunity to provide these comments and would be pleased to provide additional information upon request. The Council is also a member of the Green Chemistry Alliance, and as such strongly supports the comments filed by the Alliance on February 15, 2011.

Very truly yours,



Thomas Myers  
Associate General Counsel