



September 12, 2011

Via email (fkammerer@oehha.ca.gov) and U.S. mail

Fran Kammerer
Office of Environmental Health Hazard Assessment
P. O. Box 4010
Sacramento, California 95812-4010

Re: Proposed Regulation for Green Chemistry Hazard Traits (July 2011)

Dear Ms. Kammerer:

E. I. du Pont de Nemours and Company (DuPont) submits these comments in response to the Office of Health Hazard Assessment (OEHHA) July 29, 2011 proposed regulation entitled Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse (Proposed Regulation for Green Chemistry Hazard Traits).

DuPont has been bringing world-class science and engineering to the global marketplace in the form of innovative products, materials, and services since 1802 while remaining rooted in safety, health and environmental stewardship. DuPont is a science company that values the use of sound scientific principles with regard to stewardship issues and in developing regulatory frameworks.

When final, it is expected that the Regulation on Green Chemistry Hazard Traits will be an important reference used during the implementation of California's Green Chemistry Initiative and perhaps other State environmental and health programs. Because of its anticipated influence on these programs, it is important to identify a framework that will promote decision-making based on sound science.

DuPont toxicologists and engineers have conducted careful review of the proposed Regulation on Green Chemistry Hazard Traits. While DuPont agrees with and fully supports the comments of the Green Chemistry Alliance and the American Chemistry Council, we highlight the following points as specific issues of concern:

(1) A new and unique classification system generated by the State of California is unnecessary and could create confusion.

Several well-established hazard trait and toxicological end-point classification systems exist and are in use across the globe, and these were described by the Green Chemistry Alliance during the previous comment round. Adopting a unique system in California would inhibit the State's ability to collaborate and coordinate with other state, federal and regional jurisdictions. To stray from existing and accepted systems is inviting conflict, confusion and inefficient use of resources as information from existing systems will ultimately have to be reconciled and translated for use in California. DuPont recommends that OEHHA adopt an existing classification system.

(2) Requirements for ensuring good data quality are not rigorous enough.

- In virtually every section of the proposed regulation, the phrase "other relevant data" is mentioned as reasonable evidence for establishing a given hazard trait. Application of "other relevant data" is unspecific and should not be sole justification for establishing hazard characteristics. There is a concern that this phrase allows inappropriate or poorly obtained scientific information into what should be a rigorous process for ensuring only high quality information is used establishing hazard traits.
- Articles 2-4 include an important section on the weight of evidence that would distinguish whether a chemical **strongly** exhibits a particular trait or whether the evidence is only **suggestive**; however, that important description of weight of evidence is missing for Article 5 (Exposure Potential Hazard Traits) and Article 6 (Physical Hazard Traits).

(3) The proposed regulation opens the door for inappropriate use of screening tools for robust analysis.

Certain tools mentioned in the regulation (e.g., in vitro studies, Quantitative Structure Activity Relationship (QSAR) models) are best used for screening level analyses and prioritization as opposed to a robust methodology to establish hazard traits.

- With regard to in vitro studies, we recommend the text be altered throughout the document to indicate that in vitro data can only be used to indicate the hazard trait when it can be conclusively demonstrated that the in vitro effect is directly related to an apical, whole-organism effect of interest.
- With regard to QSAR, this modeling capability has not been sufficiently developed for actual decision-making regarding chemical characteristics.

We recommend any reference to tests and modeling include a strict requirement for validation of that methodology before being acceptable for data submittal into this regulatory framework.

*SHE and Sustainable Growth Center
1007 Market Street
Wilmington, DE 19898*

Thank you for the opportunity to comment on this very important matter. DuPont looks forward to working with OEHHA and our fellow stakeholders to develop and implement a scientifically sound regulation that will position California as a leader in application of Green Chemistry.

Sincerely,

A handwritten signature in black ink, appearing to read "H. J. Campbell, Jr.", written in a cursive style.

Hugh J. Campbell, Jr.
Director
Chemical and Environmental Management Programs