



September 13, 2010

Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Re: Submission of Comments on *Pre-Regulatory Draft, Green Chemistry: Hazard Traits, Endpoints, and Other Relevant Data*

Dear Sir:

The Nanotechnology Coalition (Coalition), an independent trade association affiliated with The Society of Chemical Manufacturers and Affiliates (SOCMA), is pleased to submit comments on the draft document, *Pre-Regulatory Draft, Green Chemistry: Hazard Traits, Endpoints, and Other Relevant Data*. The Coalition is composed of nanomaterial producers and users which focus on environmental, health, and safety issues to promote the safe development of nanomaterials, communicate industry positions to regulatory agencies, address standards and definitions in nanotechnology, and promote development of nanotechnology stewardship programs. SOCMA is the leading trade association serving the batch, custom and specialty chemical industry since 1921. SOCMA's nearly 300 members employ more than 100,000 workers across the country and produce 50,000 products valued at \$60 billion annually.

The pre-regulatory draft document seeks to identify important science-based hazard characteristics which will be used to evaluate chemical substances under the State of California's Green Chemistry Program. The draft identifies hazard traits, which, for the most part, are well-established factors that are broadly accepted within the scientific community. The discussion of nanotechnology and nanomaterials in this document lacks a scientific foundation and the SOCMA Nanotechnology Coalition offers the following comments in an effort to clarify the status of nanomaterials within a regulatory context:

General Comments

1. "Hazard traits" are properties of chemicals that fall into broad categories of toxicity, adverse environmental effects, physical hazards, or exposure potential characteristics. It is appropriate to be concerned about specific physical hazards such as explosivity, flammability, oxidization, self-reactivity and radioactivity. The term nanomaterial is not consistent with the others as this term effectively describes a physical property which is

not a hazard. Since size can contribute to hazard it may be appropriate to include size as a consideration in evaluating other listed hazards.

As such it may, over time, be shown that specific nanomaterials have a specific hazard trait but there is no scientific evidence to indicate that all nanomaterials present such a hazard. To include nanomaterials as hazards simply due to their size is improper and not supported by a body of scientific evidence.

2. Nanomaterials are chemical substances and there are multiple points within the current draft document which address these substances in a way which allows the Office of Environmental Health Hazard Assessment to fully evaluate the safety of individual substances without inappropriately considering all nanomaterials to be hazardous.

Specific Comments

1. **Section 3.d.iii. – Nanomaterial hazard trait.** The document appropriately indicates that “hazard traits” are properties of chemicals that fall into broad areas of toxicity, adverse environmental effects, physical hazards, or exposure potential characteristics. A more widely accepted definition of nanomaterial under discussion within the ISO/TC 229 delegation is a “material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale.” While this definition is still under discussion, there is virtually no discussion within the scientific community which universally associates nanomaterials and hazards.
2. **Section 3.d.iii.1 –** This section inaccurately identifies nanomaterials as a hazard trait. The size of a nanomaterial, correctly identified as being in the nanoscale, can be considered a physical trait of a substance but ***there is no scientific evidence to date indicating that all substances at the nanoscale are hazardous.*** While materials may have unique properties when produced at the nanoscale there is no evidence to indicate that such unique properties always present any additional hazards beyond those seen in their bulk counterparts.
3. **Section 3.d.iii. –** In establishing the size of nanoparticles and nanosized fibers this section refers to Section 3.c.vi., Mobility in Environmental Media, but the more appropriate reference would appear to be to Section 3.c.vi., Particle Size or Fiber Dimension.
4. Other sections within the pre-regulatory draft document are adequate for the evaluation of potential nanomaterial hazards. For example:
 - a. Section 3.a.xviii, Respiratory Toxicity, includes particle size distribution inclusive of respiratory particles and fibrous nature. These elements are sufficient to capture nanoscale materials within the proposed regulations.

- b. Enhanced mobility - The concern that very small particles could get to places larger sizes may be addressed under elements such as Lactational or Transplacental Transfer (Section 3.c.v.) and Mobility in Environmental Media (Section 3.c.vi.).
- c. Section 3.c.vii, Particle Size or Fiber Dimension, specifically addresses the issue of size by including nanoscale or respirable substances.
- d. Section 3.d.i, Explosivity, and Section 3.d.ii, Flammability, is suitable for capturing any nanomaterial exhibiting these physical characteristics. Particle size can contribute to these characteristics but all nanoscale substances are not explosive or flammable.

Summary

It is reasonable to conclude that the size of a chemical substance may be a contributor to health and safety effects. However, ***it is scientifically inaccurate to conclude that all substances at the nanoscale are hazardous.*** The document provides sufficient regulatory language to allow OEHHA to assess the safety of nanomaterials without incorrect references to nanomaterials. The establishment of requirements for these materials lacks a scientific body of evidence which indicates that all nanomaterials may be hazardous.

Small businesses in particular have limited resources and are particularly susceptible to the burden of regulations that are not grounded in sound science. SOCMA represents a diverse membership of small, medium and large chemical companies, making us the leading authority on this sector. Our member companies are located around the world and encompass every segment of the industry.

The SOCMA Nanotechnology Coalition is prepared to assist the Office of Environmental Health Hazard Assessment in developing science-based regulations to support the Green Chemistry Program in the State of California and appreciates this opportunity to lend our voice to this important effort.

Sincerely,



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Submitted via email to:

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