T. R. Jacob & Associates, LLC

Environmental Policy – International Affairs

1079 Sunrise Ave, Suite B-166
Roseville, CA 95661 USA

916-782-1266 phone
916-782-1290 fax
916-990-1195 mobile

thomas.r.jacob@gmail.com

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

RE: Proposed Regulation of 12/17/10: Green Chemistry Hazard Traits

Dear Ms. Kammerer:

On behalf of the Regulatory Committee of the California Nano Industry Network, I would like to offer the following comments regarding the Proposed Regulations of December, 2010, regarding Green Chemistry Hazard Traits. The California Nano Industry Network is a virtual network of over 20 regional, statewide, national and international associations plus numerous companies that share a common interest in nanotech policy matters in California. Among active participants on our Regulatory Committee are the California Manufacturers & Technology Association, the American Chemistry Council Nanotechnology Panel, the Nanotechnology Coalition of the Society of Chemical Manufacturers and Affiliates, the Europe-based Nanotechnology Industries Association, the NanoBusiness Alliance, and a number of global companies.

General Comment

The CalNIN Regulatory Committee recognizes the crucial role to be played by OEHHA in framing the overall Green Chemistry Regulatory Program. While much of the attention to this proposal has been focused upon its role in defining parameters of the Clearinghouse called for in SB 509, we are also conscious of the fact that the operative section of the Green Chemistry laws adopted in AB 1879 prescribes that:

> *In adopting regulations pursuant to this section, the department shall develop criteria by which chemicals and their alternatives may be evaluated. These criteria shall include, but not be limited to, the traits, characteristics and endpoints that are included in the clearinghouse data pursuant to Section 25256.1.*

The application of these proposed regulations therefore becomes crucially important to the operation of the larger suite of regulations implementing the two Green Chemistry laws. This

offers a different lens through which the Proposed Regulations must be viewed and their adequacy assessed. Our comments are colored by this larger context.

In that larger context of how these regulations will nest and function within the overall suite of Green Chemistry regulations, it is of great concern to us that this simply cannot be assessed at this juncture. With the suspension of activity on the Safer Consumer Product Alternatives regulations proposed by the Department of Toxic Substances Control (DTSC), we are all in limbo regarding just how that larger regulatory package will be structured and therefore how the specifics of these OEHHA Proposed Regulations will actually operate. **We therefore urge OEHHA to suspend consideration of these Proposed Regulations, pending emergence of greater clarity regarding the overall regulatory package.**

We further reiterate the recommendations from our comments on the Pre-Regulatory Draft (enclosed), in particular that CalEPA, **DTSC and OEHHA take steps to ensure that these two fundamental elements of the Green Chemistry Program – the DTSC and OEHHA regulations - are harmonized, and ensure they are consistent, practical and maintain the integrity of the science that must underlay this program.**

Specific Comments

Nanomaterials in the Proposed Regulation: The primary focus of our group is on application of the Green Chemistry regulations to nanomaterials. It is our view that the potential for hazard traits associated with certain nanomaterials is appropriately addressed in the Proposed Regulation. While nanomaterials share a common property of being at the nano scale, the term is applied to an increasingly broad range of materials that possess an extraordinary array of properties and which may exist in a broad range of matrices. Given this, nanomaterials fit into this Proposed Scheme just as other chemicals do: depending upon the traits that the specific material actually exhibits.

§ 69403.15 Respiratory Toxicity: As with many of the "traits" cited in these Proposed Regulations, there is a conspicuous absence in this definition, of language that would clearly differentiate potential exposures at insignificant levels. This poses the possibility of materials being "classified" as having respiratory toxicity hazard where no hazard logically exists. From the perspective of nanomaterials, this is a concern because of the potential interaction with *§ 69405.7 Particle Size or Fiber Dimension* (see below). **We therefore recommend the addition of language at the end of (c), to clarify intent to deal with significant exposure threats. Specifically, we recommend it to read:**

> *(c) Other relevant data include but are not limited to: in vitro evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers; long half-life in the lung; chemical reactivity; redox potential; structural or mechanistic similarity to other chemical substances with the respiratory toxicity hazard trait.* ***In interpreting the above, anticipated exposure must be detectable or substantial at levels above background.***

We would also call to your attention the inclusion in this definition of "*particle size distribution inclusive of respirable particles; respirable fibers;"* This is appropriately applied as a consideration relevant specifically to Respiratory Toxicity. This should be noted in the context of the recommendations below, which find fault with the definition of these considerations as a separate "hazard trait" independent of any consideration of respiratory toxicity.

Article 5. Exposure Potential Hazard Traits

§ 69405 General: Exposure potential is not a hazard. The CalNIN disagrees with OEHHA in trying to identify Hazard Traits based purely on exposure potential, and specifically for the inclusion of "Particle Size or Fiber Dimension" as a hazard. Exposure alone cannot be a hazard.

Rather hazard is an intrinsic trait that requires adequate exposure to demonstrate the hazard, i.e., hazards can only be manifest when the exposure are sufficiently high. One would not expect to demonstrate a hazard from exposure to a single molecule of a substance. This concept is embodied in the Prop 65 statutory language and Safe Harbor levels that OEHHA has set for hazardous substances.

While exposure potential is certainly germane to risk, it is so only in the context of a particular chemical having a specific hazard associated with it. To label these considerations of exposure potential as hazard traits independent of any specific toxicity endpoints is both misleading and ripe for abuse. **We therefore recommend deletion of this section and incorporation of relevant parameters of exposure potential directly into each of the descriptions of the toxicological hazard traits. If such information is to be incorporated into the Clearinghouse and the larger regulatory framework, it should be expressly stated that these considerations are not relevant in isolation and should not be the basis for any categorization or classification for purposes of these regulations independent of any specific information relating to a toxicological hazard.**

Section 69405.7 – Particle Size or Fiber Dimension: Particle size and fiber dimension only impact deposition in the respiratory tract. Particle size or fiber dimension convey hazard **only** if the substance itself can cause the hazard in that they influence the deposition of the substance in the respiratory tract. Thus, particle size and fiber dimension are appropriately included in Section **69403.15** of Respiratory Hazards which states "Other relevant data include but are not limited to: *in vitro* evidence for respiratory toxicity; particle size distribution inclusive of respirable particles; respirable fibers...". By themselves, particle size and fiber dimension do not convey hazard, only deposition probability in the respiratory tract, and therefore inclusion of this separate category as a "hazard trait" is inappropriate and misleading. **We therefore recommend deletion of this Section.**

Beyond the fundamental inconsistency referenced above, the operative elements of this definition are problematic in their own right, and should be revised in the context of any consideration of particle size or fiber dimension taken into account as "other relevant data" in any of the toxicological hazard traits. The following are specific problems:

- **Implication of "small size" is inappropriate.** In part (a) of Section **69405.7**, there is no definition of "small". With respect to application of this to nanomaterials, this appears to invite inappropriate inclusion of "nanoparticles" without sufficiently defining them. Furthermore, these "small" particles are included only if they have the "propensity to form into such small-sized particles". Such a phenomenon is without any basis for nanomaterials, which have the propensity to form **larger** particles through agglomeration or aggregation. **Any consideration of size must be refined to be more precise and consistent in its potential application.**

- **Dermal or ingestion exposure.** In addition, the fiber description does mention respirable, but complicates that by also citing "dermal or ingestion exposure" as concerns. We recognize that these are legitimate toxicological concerns, particularly from an occupational health perspective. However, size (or in this case, dimensions) is neither a limiting nor a determining consideration for either dermal or ingestion exposure. **We therefore view the reference to "dermal or ingestion exposure" as confusing *to the overall focus on inhalation, and inappropriate; and recommend deletion of that reference.***

- **3:1 aspect ratio is inappropriate for small particles or fibers.** The definition cites a "3:1 aspect ratio" as relevant to considerations relating to potential hazard. This is incorrect unless the particle or fiber is at least 1 micron in diameter. A recent article by Sturm and Hofmann (J. Haz Mater 170, 210-218, 2009) looked at the impact of aspect ration for fibers of varying diameter (CNTs up to asbestos). Their calculations show that

an aspect ratio of 3 has an impact **only** when the diameter is at least 1 micron. In fact, even an aspect ratio of 100 has little impact on the aerodynamic diameter for a fiber of 1 nanometer diameter. This is aside from any biological effect, for which we already have some experimental data (Poland et al, 2008; Muller et al, 2009 ; Porter et al, 2010) to demonstrate length-dependent effects.

- **MMAD may not be best method for "small" particles.** There may also be some ambiguity as to how aerodynamic diameter should be quantified. There are a number of protocols for quantifying MMAD including direct measurement (e.g., cascade impactor) and indirect calculation based on mass weighted geometric diameter, shape factor, and specific gravity. It would be inappropriate for materials to be classified under this hazard trait based on MMAD calculated indirectly from the primary particle size rather than the actual measured aerosolized diameter. Dispersed materials are frequently in an aggregated or agglomerated format. Using a calculated MMAD based on mass distribution of primary particle size may result in large aggregates and non-respirable particles being classified under this hazard trait. This type of quantification could lead to unrealistic classification of nanomaterials, which are not typically present in respirable fractions because they are agglomerated (>10 um MMAD).

Finally, we want to iterate the support of the California Nano Industry Network Regulatory Committee for the more general comments being offered by the Green Chemistry Alliance, with which we have coordinated in this review.

Please feel free to contact me if you have any questions or wish to discuss.

Sincerely,

(transmitted via email)

Thomas R. Jacob, Principal
Coordinator of the California Nano Industry Network

cc: G. Alexeeff, OEHHA
M. Marty, OEHHA
L. Zeise, OEHHA