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Joan Denton, Director
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95814

RE: Pre-Regulatory Draft: Green Chemistry Hazard Traits

Dear Director Denton:

On behalf of the Regulatory Committee of the California Nano Industry Network, I would like to offer the following comments regarding the Pre-Regulatory Draft of OEHHA's Green Chemistry Hazard Traits, Endpoints, and Other Relevant Data. 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 SME Coalition of the Society of Chemical Manufacturers and Affiliates, the Europe-based Nanotechnology Industry Association, the NanoBusiness Alliance, and a number of global companies.

The CalNIN Regulatory Committee recognizes the crucial role to be played by OEHHA in framing the overall Green Chemistry Regulatory Program. The Pre-Regulatory Draft goes a long way toward meeting those responsibilities. The common concern of our group, however, is narrowly with nanomaterials, and in that regard, **we strongly object to the proposed creation of a new category of "Nanomaterial hazard trait."**

As with chemical substances generally, some nanomaterials may exhibit specific hazardous traits iterated in the draft and would be appropriately categorized accordingly. However, there is no scientific foundation for creation of this separate hazard trait category; and doing so will undermine the goal of informed risk communication and pose serious implications for the future of this promising technology in California. Importantly, it also conflicts with the approach to nanomaterials being proposed in the larger Green Chemistry regulatory package.

Problem Definition

The proposal to define a new categorical "Nanomaterial Hazard Trait" is found on page 21, and reads:

iii. Nanomaterial hazard trait

1. *The nanomaterial hazard trait is defined as hazards due to a chemical substance having greater toxicity when in nanoparticle form than in bulk form.*
2. *Nanoparticles or nanosized fibers, that are particles that are 100 nm or less in any dimension, or would be defined as nanoparticles according to section 3.c.vi, may have this trait.*

Immediate questions surface regarding how this definition is to be read, particularly paragraph #1. For example, what if bulk material toxicity is very low and increases only modestly, still falling far below any threshold for any specific toxicity? In paragraph #2, the citation is incorrect, and should refer to section “3.c.vii” relating to respirability (a trait description to which we do not object).

However, the more fundamental questions become apparent when you dig deeper and consider how this is to operate in practice and how it is likely to be used. The reality is that this definition cannot be used in isolation to categorize any nanomaterial. There is no standard existent that measures “toxicity” categorically. Operationally, any hazard associated with any nanomaterial must be measured and assessed in terms of some other hazard trait or endpoint.

In essence, the only way this “nanomaterial hazard trait” could operate is through a nanomaterial-by-nanomaterial evaluation to determine 1) whether there is another “toxicity” (as defined in one of the other hazard traits) associated with the constituent material, and if so 2) whether that hazard trait is accentuated in the nanoparticle form.

In this regard, the category proves to be unnecessary. Any hazard trait that may apply to a particular nanomaterial is already listed independently in the document. Where methodologies for assessing these traits exist, nanomaterials can be tested-for and classified quite independently of the existence of any “Nanomaterial hazard trait” classification.

However, designating this trait does imply that there is somehow another dimension of hazard that is not captured by classification of the specific trait that applies to the nanomaterial. In this regard, creation of this category is counterproductive. It raises a “red flag” for nanomaterials that is not tied to any additional hazard and therefore misinforms users regarding potential additional risk. This is alarmist and will needlessly inhibit the appropriate development of this technology – a technology in which California is poised to take a leadership role. The creation of this new hazard trait category is therefore ripe for abuse.

It is also against convention. With respect to the basic idea of a “nanomaterial hazard trait,” our view is consistent with that expressed in the document published 6 July 2010 by the European Union’s Committee on Emerging and Newly Identified Health Risks, on the Scientific Basis for the Definition of the Term “Nanomaterial”. Specifically, that Report caveats its extensive findings with the following:

It should be stressed that “nanomaterial” is a categorisation of a material by the size of its constituent parts. It does not imply a specific risk, nor does it necessarily mean that this material actually has new hazard properties compared to its constituents.

We concur with this and believe the creation of this categorical “hazard trait” implies just the opposite – that there is somehow a common, shared characteristic hazard that derives solely from the nanoscale. This is without foundation and can do a grave disservice to emerging beneficial use of this promising new science and technology, by implying a threat that is quite unrelated to any specific scientific evidence. It is likely to be misinterpreted and misused in ways that defeat the intent of better-informed decision-making that underpins the Green Chemistry Program.

Compromises to the Green Chemistry Program

Unfortunately, this category of Nanomaterial hazard trait not only is unnecessary, but it confounds in a rather fundamental way the structure evolving with the Green Chemistry regulation. While that final Proposed Regulation is not yet public, there is every indication that it will incorporate language that specifically addresses nanomaterials. Significantly, that language will likely make clear that any nanomaterial (or other material possessing “nanoscale phenomena”) can be brought under scrutiny in the regulation.

Importantly, the way that such materials are brought under scrutiny is, in essence, by defining them to be the analogue of a unique chemical or formulation in terms of the regulation and the Green Chemistry Clearinghouse. A chemical could be classified as having certain hazard associated with it, given a priority based upon that and then certain products using that chemical in ways that accentuate that hazard can be prioritized for mandatory alternatives assessment.

Similarly, a particular type of nanomaterial could be classified as having a certain hazard associated with it and be given a priority based upon that hazard. Then certain products using the nanomaterial in ways that accentuate that hazard can be prioritized for mandatory alternatives assessment. In other words, nanomaterials and hazard traits associated with them are already addressed in the Green Chemistry regulation.

The problem created by a self-standing “Nanomaterial hazard trait” can be visualized if you conceptualize the Green Chemistry “Clearinghouse” in terms of a conventional matrix, in which the chemicals are arrayed down the rows of the matrix, and associated hazard traits arrayed across the columns. Under the approach contemplated in the draft Regulation, the nanomaterials are there in the rows along with the chemicals, with the logical “read-off” across the matrix to indicate specific hazard traits associated with them.

The approach contemplated by the OEHHA “Nanomaterial hazard trait” would operate in just the opposite fashion, with each “chemical row” assessed against that (non-operable) Nanomaterial hazard trait. This is not only at cross purposes with the approach of the operative elements of the regulation, but in the process, it casts a shadow over all nanomaterials that is independent of any actual hazard traits associated with them.

The larger imperative

This scenario of the two elements of the Green Chemistry regulatory program operating at cross-purposes calls to mind a larger imperative that becomes crucial as both the OEHHA and DTSC programs potentially bring regulatory elements soon to adoption. Simply stated, **CalEPA, DTSC and OEHHA must take steps prior to finalizing any draft to ensure that these two fundamental elements of the Green Chemistry Program are harmonized -- ensure they are consistent, practical and maintain the integrity of the science that must underlay this program.**

To date, the degree of coordination between the agencies has not been sufficient to ensure that harmonization. The conflicting approaches to handling of nanomaterials are clearly an example of the need to step-up this coordination before potentially complicating regulatory elements are set in concrete.

We strongly urge that this be attended to on a priority basis by DTSC and OEHHA with the active support and facilitation of CalEPA leadership. As an industry group with both a major stake in this and a reservoir of significant expertise, we are happy to cooperate with and lend support to this effort.

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

Sincerely,

(transmitted via email)

Thomas R. Jacob, Coordinator - California Nano Industry Network
Representing The DuPont Company

cc: G. Alexeeff, OEHHA
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