



ENVIRONMENTAL DEFENSE

finding the ways that work

A response to ABA's "Regulating Nanomaterials Under TSCA Section 5"¹ *Why "existing chemical SNURs" won't suffice to protect human health and the environment*

August 31, 2006

[NOTE: This document is *not* applicable to those engineered nanomaterials (hereafter NMs) that possess novel chemical structures, which clearly are subject to PMN requirements. This discussion is focused on NMs with chemical structures corresponding to those of substances already listed on the TSCA Inventory.]

Environmental Defense's objective

- Ensure that, before commercialization, EPA conducts a meaningful review and addresses the potential risks of engineered nanomaterials whose novel or enhanced properties differentiate them from substances with the same chemical structure that are already in commerce.

Summary of our concerns with ABA's analysis of TSCA Section 5's applicability to NMs

- Not an objective analysis; reflects only the interests of chemical industry (its authors).
- Omits key arguments for considering NMs with existing chemical structures to be "new" substances.
- Most problems ABA identifies apply equally to its proposal to use existing chemical SNURs.
- Understates the barriers and limits to use of existing chemical SNURs.

Key arguments omitted from or downplayed in ABA's paper (see our May 22, 2006 letter to Ann Klee² for details)

- TSCA itself distinguishes "molecular identity" from "chemical structure"
 - o The former includes physical, chemical and biological properties.
- EPA has long considered more than chemical structure where that alone is insufficient to define a substance.
 - o TSCA listings can and do refer both to physical and chemical properties and to process parameters, as needed to sufficiently and unambiguously identify and name a substance.
 - o It is precisely this situation that applies to engineered nanomaterials: Characteristics other than chemical structure largely determine the properties of the material.
 - o UVCBs are a prime example (more below).

¹ This document summarizes Environmental Defense's response to "Regulating Nanomaterials under TSCA Section 5," Section II of the recent briefing paper titled "Regulation of Nanoscale Materials under the Toxic Substances Control Act," prepared by the Section of Environment, Energy and Resources, American Bar Association, and dated June 2006.

² Available at www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf.

ABA's "technical challenges" that face regulating NMs as "new" chemical substances

- Size and agglomeration state don't clearly distinguish nanoscale from conventional substances.
- Distinctions based on morphology (shape, structure) would have to be defined case-by-case.
- NMs would be "very difficult to regulate as a single class" of substances.

Response

- Yes, these are difficult challenges, but ... all of them apply equally to ABA's proposed alternative to rely on existing chemical SNURs.
- The PMN process by definition requires that each submission be considered singly and allows for case-by-case evaluation.

EPA's TSCA Inventory practice and conventions

- ABA claim #1: EPA ignores factors other than chemical structure in defining a substance for purposes of determining whether it is already on the Inventory.
 - o Response: EPA does so when chemical structure is sufficient to unambiguously identify a substance, and considers factors *in addition to* chemical structure when structure alone is not dispositive.
 - o Case in point: UVCB substances, as discussed in EPA's Guidance:³
 - "Some UVCB substances are not adequately described by their CA [Chemical Abstracts] Names. Their names are not specific or complete enough to permit unambiguous identification. ... These substances have *supplemental definitions that are considered integral parts of the names for TSCA purposes.*"
 - "[A]ny substance that matches a CA Name on the TSCA Inventory but is not covered by the corresponding substance definition is *not considered to be covered by that Inventory name.*"
 - "Chemical substance definitions often include such information as the typical or allowed carbon number ranges or *physical property ranges*, the types of atoms or substances that may be included, and the raw material sources or *processes of manufacture.*"
- ABA claim #2: The nanoscale version of an existing chemical is defined identically and has the same "molecular identity."
 - o Response: Chemically identical substances can be listed separately on the Inventory, based on consideration of other factors.
 - o Cases in point:
 - Different physical forms of carbon and silicon dioxide have separate Inventory listings, as noted by ABA.
 - EPA's UVCB guidance:⁴ "Fundamental to the Inventory as a whole is the principle that entries on the Inventory are identified as precisely as possible. ... *Substances that are chemically indistinguishable, or even identical, may be listed differently on the Inventory.*"

³ See www.epa.gov/oppt/newchems/pubs/uvcb.txt, pages 3-4, emphases added.

⁴ See www.epa.gov/oppt/newchems/pubs/uvcb.txt, Introduction, page 1, emphasis added.

- ABA claim #3: Declaring NMs “new” would put some producers into non-compliance.
 - o Response: Some accommodation may well be in order, but ABA’s alternative is *no* review: Existing chemical SNURs cannot be used to cover existing uses!
- ABA claim #4: Consideration of other factors such as physical and chemical properties could affect regulation of conventional materials as well.
 - o Response: EPA already considers such properties for certain classes of materials, when it needs to.
 - o While EPA has not always been entirely consistent in its approach, that fact is *not* a basis for ABA’s unsupported assertion that ignoring such factors is EPA’s policy.

ABA’s proposed solution

- Declare all NMs with chemical structures already on the Inventory to be “existing” chemical substances.
- Issue “existing chemical SNURs” covering these substances to address any concerns.

ABA confuses new vs. existing chemical SNURs

- ABA argues that using SNURs is straightforward and easy, claiming that more than 700 SNURs have been issued using notice & comment rulemaking.⁵
- In fact:
 - o EPA has issued only 41 “existing chemical SNURs” as of 5/06.⁶
 - o The vast majority of SNURs have been issued in conjunction with PMN review for **new** chemicals: As of the end of 2005, EPA had issued 1,309 “new chemical SNURs”.⁷
- “New chemical SNURs” can be and usually are issued as direct final rules,⁸ whereas “existing chemical SNURs” must proceed through full notice & comment rulemaking.

In other words, to the extent that SNURs are viewed as a viable and expeditious means to regulate NMs, both EPA’s SNUR authorities and its history of issuing SNURs are strong arguments *for* – not *against* – the designation of NMs as “new” chemicals.

Other limitations to a SNUR-driven approach

- The scope of a SNUR’s coverage must be precisely defined – so all of ABA’s technical challenges reappear!
- By definition, a SNUR cannot be used to regulate any existing use.
- EPA has an evidentiary burden that will be a greater challenge to meet in the relatively information-poor environment surrounding NMs.⁹

⁵ The basis for ABA’s claim is unclear, as no source was provided.

⁶ List provided by OPPT on August 22, 2006.

⁷ Personal communication from Anna Coutlakis, New Chemicals Program, OPPT, August 20, 2006, updating statistics provided in the EPA document “Overview: Office Of Pollution Prevention And Toxics Programs, December 24, 2003, available at www.epa.gov/oppt/pubs/oppt101c2.pdf; see Table 1.3-2, p. 11.

⁸ In 1989, EPA issued regulations specifying an “expedited process” for issuing new chemical SNURs, whether in conjunction with a Section 5(e) consent order (CFR 721.160) or not following such an order (CFR 721.170). The expedited process provides for such SNURs to be issued as direct final rules in most cases. According to EPA, all but 17 of the new chemical SNURs it has issued used the expedited process, though not all of those were done through direct final rules.

Environmental Defense's position

- An engineered nanomaterial is a “new” substance under TSCA (and thus subject to PMN review), even if its chemical structure is identical to a substance already included on the Inventory, unless its chemical and physical properties are demonstrably identical to that existing conventional substance.
- EPA should use PMN reviews, supplemented with new chemical SNURs, to ensure all such materials are reviewed before commercialization and subjected to controls as needed to ensure they do not pose an unreasonable risk to human health or the environment.

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⁹ As noted by ABA, EPA must consider several factors, including the projected production and processing volume of the chemical substance; the anticipated extent to which the use changes the type or form, and increases the magnitude and duration, of exposure to humans or the environment associated with the new use; and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.