

Toxic Substances Control Act and Engineered Nanoscale Substances

a report by

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There is considerable attention these days focused on the implications of engineered nanoscale materials. Governments worldwide are urged to get the policy and regulatory framework 'right' to enable nanotechnology to realise its full societal value, while at the same time effectively addressing health and environmental issues posed by nanotechnology. In the US, the Toxic Substances Control Act (TSCA) is the law that regulates new and existing chemical substances and provides a regulatory framework to address chemicals throughout their production, use and disposal.

This article considers three issues in applying TSCA to engineered nanoscale materials, defined as materials that are intentionally manipulated by human activity and not naturally occurring nanoscale particles (volcanic ash), or incidental nanoscale materials (combustion byproducts). The article demonstrates that the US Environmental Protection Agency (EPA) has robust authority under TSCA and that new legislation intended to address any potential risks engineered nanoscale materials might pose is unnecessary. EPA has broad existing authority to assess engineered nanoscale materials under TSCA Section 5(a) as new chemicals, to review under TSCA new uses of existing chemical substances, to review comprehensively exemptions from full premanufacture notification (PMN) requirements and to collect information on and compel and enforce reporting obligations with respect to engineered nanoscale materials.

EPA's stated commitment to issue guidance on whether existing (TSCA Inventory-listed) chemicals engineered at the nanoscale level can be considered a 'new' chemical and, if so, under what circumstances will greatly assist the regulated community. In the interim, chemical manufacturers should consider carefully their

TSCA compliance obligations, obtain legal advice when necessary and seek EPA's views regarding the regulatory status of engineered nanoscale materials believed to consist of existing substances, either through a pre-PMN submission meeting with EPA or the submission of a *bona fide* intent to commence manufacture.

Background

Nanotechnology, the "understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications"², is expanding rapidly. Global demand for engineered nanoscale materials, nanoparticles and nano-intermediates was US\$1 billion in 2004, and is expected to be US\$40 billion in 2008.

One of the key reasons governments globally are focusing on nanotechnology is the lack of information regarding the health, safety and environmental effects of exposure to engineered nanoscale materials. Some suggest that caution is needed. The small size of certain nanoparticles facilitates uptake into cells and movement through the body more readily than their macro counterparts.³ The fact that nanoscale materials can have unusual properties – properties that do not conform to 'conventional' physics and chemistry – may increase the potential for risk.

TSCA and Nanotechnology

There are three key issues that have arisen in connection with EPA's authority under TSCA to regulate effectively engineered nanoscale materials. These include: whether engineered nanoscale materials that consist of existing chemicals should be regulated under TSCA as new chemicals, thus triggering pre-manufacture EPA review; whether certain exemptions from TSCA premarket

2. National Nanotechnology Initiative (NNI) "What is Nanotechnology?", available at <http://www.nano.gov/html/facts/whatIsNano.html>

3. Oberdörster G, Oberdörster E, Oberdörster J, "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles", *Environ Health Perspect* (2005);13(7): p. 823.

approval requirements should apply to engineered nanoscale substances; and whether TSCA's reporting provisions are sufficiently robust to address issues arising in connection with engineered nanoscale materials.

Whether Existing Engineered Nanoscale Chemicals Should Be Regulated as New Chemicals

Environmental Defense (ED) and the Natural Resources Defense Council (NRDC) have questioned whether TSCA is well-suited to manage potential health and safety risks believed to be posed by engineered nanoscale substances. They recommend that nanoscale versions of existing chemical substances be considered new chemicals under TSCA.⁴ ED argues that EPA's "longstanding application of TSCA's definition of 'chemical substance' routinely encompasses more than the substance's molecular structure where molecular structure alone is insufficient to define the substance."⁵ It points to, among other arguments, EPA's definition of and listing on the TSCA Inventory of unknown or variable composition, complex reaction products, and biological materials (UVCB substances) as demonstrating that EPA considers physical properties in defining a chemical substance.

Others disagree. The American Chemistry Council (ACC) Nanotechnology Panel believes that nanoscale versions of existing substances are not new chemical substances and cannot be considered 'new' based on the definition of the term 'chemical substance' in TSCA. A 'chemical substance' is defined by its 'molecular identity,' and the definition makes no mention of a substance's physical and chemical properties. EPA's regulatory definition of a 'new chemical substance' mirrors the statutory definition: a new chemical substance is any

chemical substance not listed on the TSCA Inventory.⁶ In ascertaining whether a particular substance appears on the Inventory, all that appears to matter legally, according to the Panel, is whether, based on the substance's molecular identity, it is listed on the Inventory.⁷

Others acknowledge that arguments can be made that the statutory term "particular molecular identity" is sufficiently flexible as to take into account physical properties, or other defining characteristics in addition to molecular structure, at least to a limited degree, but concludes that molecular structure is the definitive characteristic in most instances. For example, the American Bar Association (ABA) Section of Environment, Energy and Resources (SEER) considered the subject and noted that the definition of chemical substance includes "any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature."⁸ EPA has relied on this definition to include UVCB substances on the Inventory. Some of these entries consider factors including manufacturing process and physical properties.

The ABA SEER Paper notes, however, that UVCB substances are 'combinations' rather than discrete molecular entities and that EPA developed the UVCB approach for complex reaction products – for which there is no definite or known molecular formula or chemical structure information – and considered a range of other information in the absence of a precise chemical description. As such, this example may not be applicable to most nanoscale materials since these materials are typically not combinations and usually have very defined particular molecular identities.⁹

The foregoing discussion is illustrative of the complexity of the question raised and the

4. *Natural Resources Defense Council et al., "EPA Proposal to Regulate Nanomaterials Through a Voluntary Pilot Program", at 11–12 (July 1, 2005), available in EPA Docket OPPT-2004-0122 at <http://www.regulations.gov>; Letter from Environmental Defense to EPA at 3 (2 Sep. 2004), http://www.environmentaldefense.org/documents/4457_NanotechLetterToEPA.pdf*

5. *Letter from Denison R, and Florini K, to Klee A, at 4 (22 May 2006) (ED Letter), available at http://www.environmentaldefense.org/documents/5265_StatusofNMsUnderTSCA.pdf#search=%22define%20the%20substance%22*

6. See 40 C.F.R. §§ 710.3, 720.3(v), 720.25(a).

7. See 69 Fed. Reg. 65565, 65567 (Nov. 15, 2004) (stating "[t]he only way to determine if a substance is new or existing is by consulting the TSCA Inventory"); 42 Fed Reg 64572, 64591 (23 Dec. 1977) (promulgation of the original Inventory reporting regulations, stating that the Inventory "defines what is a 'new chemical substance' for purposes of [the PMN requirements in] section 5(a)(1)(A)")

8. TSCA § 3(2)(A)(i), 15 U.S.C. § 2602(2)(A)(i).

9. *The American Bar Association (ABA) Section of Environment, Energy, and Resources (SEER), Regulation of Nanoscale Materials under the Toxic Substances Control Act at 9–10 (June 2006) (ABA SEER Paper), available at <http://www.abanet.org/environ/nanotech>*

challenging legal issues EPA is now confronting. It is unclear how EPA intends to resolve these issues. What is clear is that further guidance from EPA is needed, and EPA has promised to issue guidance, perhaps later in 2006 or early in 2007.

EPA's Draft White Paper on Nanotechnology, issued in late 2005, offers hints on what it may use as a starting point for its analysis of how best to address under TSCA nanosized versions of TSCA Inventory-listed chemicals.¹⁰ There, EPA organized nanoscale materials into four types:

- carbon-based materials (composed entirely of carbon taking a particular form);
- metal-based materials (quantum dots, nanogold, nanosilver and reactive metal oxides like titanium dioxide);
- dendrimers (nano-sized polymers built from branched units); and
- composites (combinations of nanoparticles with other nanoparticles or with larger, bulk-type materials).

The debate over whether an existing chemical substance reconfigured at the nanoscale level constitutes a new chemical substance for TSCA purposes may depend in part upon how EPA considers each type of nanoscale material in each of these categories, as the determination for TSCA regulatory purposes varies.

For example, a nanoparticle of a conventional TSCA Inventory-listed chemical may be considered by EPA to be an "existing" chemical if only the chemical's surface area is increased (due to its nanoscale) to enhance its catalytic potential. On the other hand, certain carbon-based nanomaterials would appear to be considered by EPA new even though carbon is listed on the Inventory, as evidenced by EPA's recent decision to grant a Low Release and Exposure (LoREX) polymorphonuclear leucocytes (PMN) exemption application for at least one type of carbon nanotube.¹¹ In so doing, EPA apparently concluded that a carbon nanotube, at least this particular carbon nanotube, was a 'new' chemical substance. EPA may

have concluded the chemical's structure was decidedly and sufficiently different from the Inventory-listed substance to be considered new even though the chemical's molecular formula was the same as the conventional form of the chemical.

Even if EPA were to conclude otherwise and announce that nanosized versions of Inventory-listed chemicals are existing and not new chemicals for TSCA purposes, it nonetheless has broad authority under TSCA to consider any potential risks posed by nano-configured substances. The ABA SEER Paper emphasizes that EPA has broad authority under a combination of other provisions of TSCA to address potential risks posed by engineered nanoscale materials beyond EPA's PMN authority, including Section 5(a)(2) (authority to issue a significant new use rule (SNUR)); Section 6 (authority to restrict or ban the manufacture, processing, distribution in commerce, use or disposal of a chemical substance upon a showing that the substance presents or will present an unreasonable risk); Section 7 (authority to address imminently hazardous chemical substances); and Section 8 (authority for information-gathering and reporting).

Appropriateness of Certain PMN Exemptions as Applied to Engineered Nanoscale Substances

ED has urged EPA "not to apply mass-based or other exemptions in the PMN program, unless the underlying scientific rationale is appropriate when applied to nanomaterials."¹² A key issue here is the relevance of mass- and volume-based criteria as applied to engineered nanoscale materials. The low volume exemption (LVE) exempts from PMN requirements "a new chemical substance manufactured in quantities of 10,000kgs [22,000lbs] or less per year."¹³

At first glance, the suitability of the LVE exemption to nanoscale materials may seem questionable in this context, but a closer review may suggest otherwise. The exemption is not self-executing and requires explicit prior EPA approval. EPA's review is extensive. For example, EPA's review of an exemption for a carbon nanotube, originally submitted as an LVE but later converted

10. Science Policy Council, EPA, *Nanotechnology White Paper (Dec. 2, 2005)*, available at <http://es.epa.gov/ncer/nano/publications/whitepaper12022005.pdf>

11. See 8EHQ-0403-15319 (Apr. 10, 2003), available at <http://www.epa.gov/oppt/tasca8e/pubs/8ehq/2003/april03/8ehq-0403-15319a.pdf>

12. Florini K et al., "Nanotechnology: Getting It Right the First Time", *Sustainable Development Law & Policy*, (Spring 2006); Vol. VI, Issue 3: pp. 46, 51.

13. ED Letter at 4, *supra* note 5.

to a LoREX, took approximately one year and consumed considerable EPA resources.¹⁴ Thus, the LVE exemption is not really an exemption at all. EPA's review is focused, demanding and by no means cursory. Accordingly, there is little reason to believe the LVE exemption, or LoREX exemption, as applied to engineered nanoscale materials and as intended, will allow risky materials into commercial use.

Appropriateness of Reporting Obligations Under TSCA Section 8 Authority to Engineered Nanoscale Materials

Another issue that has been raised is whether certain TSCA reporting obligations apply to nanoscale chemicals, particularly TSCA Section 8(e). EPA has made it clear that TSCA Section 8(e) applies to all chemicals, including nanoscale materials consisting of chemical substances.¹⁵ Under the Section 8(e) provision, anyone manufacturing, importing, processing or distributing in commerce a chemical substance "who obtains information which reasonably supports the conclusion that such substance presents a substantial risk of injury to health or the environment" must inform EPA of the information immediately.¹⁶ If a person learns that a nanoscale-sized version of an existing chemical substance poses hazards different from those associated with its bulk counterpart, and if that information reasonably supports the conclusion that the nanoscale-sized version presents a substantial risk of injury, it would appear that TSCA Section 8(e) reporting is required.¹⁷ Similarly, TSCA Section 8(c) reporting obligations

apply to persons manufacturing, importing, processing or distributing in commerce engineered nanoscale materials. Such persons must maintain, and make available to EPA for inspection, records of significant adverse reactions alleged to have been caused by the engineered nanoscale material. Under EPA's Section 8(c) implementing regulations, this means that if anyone, including but not limited to a company's employees, customers or neighbours, makes a written or oral statement to the effect that the company's nanoscale material caused a significant adverse effect on human health or the environment, the company must maintain a record of that allegation. Notably, EPA defines "manufacture" for purposes of TSCA Section 8(c) broadly to include manufacture for test marketing and manufacture for research and development.¹⁸ EPA has emphasised over the past few years that these provisions clearly apply to engineered nanoscale materials.

Conclusion

The debate over TSCA's application to engineered nanoscale materials will continue for some time. The foregoing demonstrates that EPA has broad TSCA authority to review engineered nanoscale materials. EPA guidance is needed, however, and is anxiously awaited. ■

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14. Phibbs P, "Manufacture of New Carbon Nanotube Approved by EPA Under an Exemption", Daily Env't Rep, (21 Oct. 2005); A-1.
 15. Alwood J, EPA, Presentation to American Chemistry Council/SOCMA Global Chemical Regulations Conference (22 Mar. 2005) (TSCA Section 8(e) reporting applies to nanoscale material).
 16. TSCA § 8(e), 15 U.S.C. § 2607(e).
 17. To date, EPA has received at least one Section 8(e) submission addressing an engineered nanoscale material, although it is not clear from the submission whether the nanoscale material was "existing" or "new." See 8EHQ-0403-15319 (Apr. 10, 2003), available at <http://www.epa.gov/oppt/tscas8e/pubs/8ehq/2003/april03/8ehq-0403-15319a.pdf>. The submission, made by DuPont, reported a lung toxicity rat study on single-walled carbon nanotubes.