

Washington Watch

EPA Considers How Best To Regulate Nanoscale Materials

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As the relentless pace of global investment in all things nano continues, the U.S. Environmental Protection Agency (EPA) has jumped into the murky regulatory waters, trying to decide how best to manage nanotechnology's risks and benefits.

In a May 10, 2005, *Federal Register* notice,¹ EPA announced, in an understated way, its decision to convene a public meeting on "nanoscale materials." The meeting notice represents the Agency's first public foray into harnessing some of nanotechnology's promise within a regulatory framework created almost three decades ago with the enactment of the Toxic Substances Control Act (TSCA).

This column explores some of the regulatory and science policy considerations implicit in EPA's notice, with a view towards forecasting the shape of things to come.

Nanotechnology: The Good, the Bad, and the Uncertain

Nanotechnology is an umbrella term that involves generally the science and technology that enables the manufacture and manipulation of material that has a size of approximately one to 100 nanometers (nm), or 1/100,000 the width of a human hair.

This is not the science of the future. According to *Small Times Magazine*, there are approximately 1,645 nanotech companies now operating in the United States alone. Lux Research, Inc., predicts that, less than a decade from now, 15 percent of global sales will be from products based on nanosciences and nanotechnology. The National Science Foundation (NSF) has estimated that by 2015, nanotechnology applications may be valued at more than \$1 trillion in the global economy.

Part of the allure of nanotechnology is the promise it holds in many commercial areas, as well as the technology's potential to revolutionize applications in the environmental and natural resource arenas. Nanotechnology may offer some key benefits:

- uniquely attractive new tools to detect, monitor, and reduce pollution;
- environmentally benign manufacturing processes; and
- cleaner, less expensive energy.

Friends in Green Places

The appealing potential of nanotech, particularly in the environmental and energy areas, has earned the technology supporters in virtually all camps that participate in the environmental science policy debate.

Environmental Defense (ED), the non-governmental organization (NGO) generally recognized as furthest along in identifying the benefits and potential risks associated with nanotech, readily acknowledges the upsides of the technology. ED's "Getting Nanotechnology Right the First Time" project, however, urges caution to ensure that risks to human health and the environment are identified and managed before nanoscale materials and nanostructures are allowed to cause harm -- assuming, of course, that they potentially are able to do so in the first place.

EPA is another fan. The Agency's "Science to Achieve Results" (STAR) and Small Business Innovation Research (SBIR) programs fund research to develop promising nanotechnologies. The STAR program has already funded 32 grants for more than \$11 million.

Nanotech Unknowns

While much has been written about the inherent promise of nanotechnology, less is known about the human health and environmental effects of nanoscale materials and engineered nanomaterials and structures. Reportedly, there are fewer than 50 publications on nanoparticles.

Generally, poorly soluble nanoscale particulates appear to be more toxic to the lungs of experimental animals than are their bulk counterparts. Additionally, these nanoscale particulates have been shown to be absorbed into the bloodstream and tissue of experimental animals following airborne or waterborne exposure.

Drs. Günter Oberdörster, Eva Oberdörster, and Jan Oberdörster are leading experts on ultrafine particles (UFPs) and respiratory tract toxicity. UFPs are defined as ambient and laboratory-generated nanosized particles (NSP) that are not produced in a controlled, engineered way. The Oberdörsters' studies have shown that NSPs (< 100 nm) are considerably more successful than larger particles in producing an inflammatory response in the lung. UFPs encompass nanoparticles, which are an order of magnitude smaller, at < 0.01 micrometer.

According to a recent article appearing in the National Institute of Environmental Health Sciences' *Environmental Health Perspectives*, the Oberdörsters believe that:

When inhaled, specific sizes of NSP are efficiently deposited by diffusional mechanism in all regions of the respiratory tract. The small size facilitates uptake into cells, transcytosis across epithelial and endothelial cells into the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen, and heart.²

The authors conclude that an “interdisciplinary team approach (e.g., toxicology, materials science, medicine, molecular biology, and bioinformatics, to name a few) is mandatory for nanotoxicology research to arrive at an appropriate risk assessment.”³

Nanoscale Material Research

Nanoscale material research is underway in a variety of venues. Key research projects are discussed below.

National Nanotechnology Initiative

The National Nanotechnology Initiative (NNI) started in fiscal year (FY) 2001. It involves 23 federal agencies managed under the Nanoscale Science, Engineering and Technology (NSET) Subcommittee of the National Science and Technology Council (NSTC), which is appointed by the President.⁴ The NNI coordinates research and development by its constituent agencies, provides funding to university laboratories, and supports U.S. companies that are pursuing commercial applications of nanotechnology.

Since FY 2001, the federal government has spent over \$4 billion on research and development in nanotechnology, and the President has called for an additional \$1 billion in his FY 2006 budget.⁵

The 21st Century Nanotechnology Research and Development Act, passed in 2003, recognized and defined the role of the National Nanotechnology Coordination Office as the secretariat of the NSET Subcommittee managing its day-to-day activities. The act also required that a National Nanotechnology Advisory Panel (NNAP) be created to review periodically the work of the NNI.⁶ The President’s Council of Advisors on Science and Technology (PCAST) was designated to serve as the NNAP, and has recently released its first review.⁷

EPA Research Programs

EPA, through grants from its STAR and SBIR programs, funds research to develop nanotechnology applications that protect the environment. The Agency, along with the National Institute for Occupational Safety and Health and NSF, also funds grants to institutions for studying the potential harmful effects of nanotechnology.⁸ EPA’s Science Policy Council is currently in the process of developing a white paper addressing the various issues related to nanotechnology and the environment.

ICCEC-Recommended Research

Additionally, the National Toxicology Program (NTP) Interagency Committee for Chemical Evaluation and Coordination (ICCEC) in July 2003 recommended one or more types of toxicological studies for 14 substances, including nanoscale materials.⁹

Rice University’s Center for Biological and Environmental Nanotechnology (CBEN) nominated nanoscale materials for study because, given the “[i]ntense current and anticipated

future research and development focus," they believed that "further studies and development of appropriate toxicological methods are needed to adequately assess health effects."¹⁰ The ICCEC nominated studies for nanoscale materials in several areas:

- size and composition-dependent biological disposition of nanocrystalline fluorescent semiconductor materials;
- toxicological characterization of high aspect ratio carbon nanomaterials;
- role of particle core and surface composition in the immunotoxicity of the above-listed materials; and
- phototoxicity of representative metal oxide nanoparticles.

In anticipation of broader research activities in this area, NTP established the Nanotechnology Working Group (NWG) to the NTP Board of Scientific Counselors in order to enhance public participation and input into NTP's nanotechnology research program.

On June 3, 2005, NTP announced the first meeting of the NTP NWG, which was convened on June 24, 2005.¹¹ The NTP NWG is evaluating the toxic and carcinogenic potential of quantum dots and nanotubes in research animals via the inhalation exposure route.

EPA Program Offices That Deal with Nanomaterials

EPA's interest in nanotechnology and nanoscale materials spans across several Agency program offices. The Office of Research and Development has been closely following the developments in nanotechnology and, as noted above, is actively participating in research and development through STAR and related grant programs.

EPA's Office of Air and Radiation is interested in various aspects and health effects of UFPs. In addition, EPA's Office of Transportation and Air Quality regulates (among other aspects of clean fuels and technology) fuel additives, including metal additives, some of which have been classified as a form of nanotechnology.

Other EPA program offices, including the Office of Water and the Office of Solid Waste and Emergency Response, would appear to be well suited to address the regulatory implications of nanomaterials. Given the relatively nascent stage of information gathering on the commercialization of nanoscale materials, however, none of these offices is very far along in these areas.

EPA's Office of Pollution Prevention and Toxics (OPPT) is further along in exploring the regulatory implications of the manufacture, use, distribution, and disposal of nanoscale materials.

TSCA and Nanotechnology

The legal authority relied on by OPPT is the Toxic Substances Control Act (TSCA), which authorizes EPA to review and, if appropriate, establish limits on the manufacture of new and existing nanoscale materials consisting of chemical substances.

In the May 10, 2005, *Federal Register* notice, EPA notes that nanoscale materials consisting of new chemical substances are subject to the notification requirements of TSCA Section 5. Under this section, the manufacturer of a new chemical substance must submit a pre-manufacture notice (PMN), including toxicity and other data, to EPA at least 90 days before production of the chemical is to begin. New chemicals generally are those not already listed on the TSCA Chemical Substance Inventory, which is maintained under TSCA Section 8(b).

Proposed Voluntary Pilot Program for Nanoscale Materials

In the *Federal Register* notice, the Agency acknowledges that nanoscale materials made of existing chemical substances “may enter commerce without notification to EPA.”¹² The Agency seeks comment on its proposal for a “voluntary pilot program” for nanoscale materials that are considered to be already existing chemical substances.

EPA's Request for Comment

EPA asks for comment on the kinds of information that are relevant to several issues, including the evaluation of potential risks from exposure to nanoscale materials, the chemical characterization and nomenclature of nanoscale materials for regulatory purposes, and identification of interested stakeholders.

The Agency believes comment would be “particularly helpful” on certain issues, including:

- the feasibility and value of a voluntary pilot program,
- the scope and design of such a program, including the following elements: pilot program purpose (e.g., research and development, use involving environmental release, and any commercial use), administration, outcomes, duration, and next steps;
- information useful in evaluating potential effects on human health and the environment from exposure to nanoscale materials;
- size, dimensions, and shapes of chemical substances that should be considered nanoscale materials;
- types of information that would be useful (e.g., unique and novel properties) for purposes of informing the voluntary pilot program, and helping to name and

characterize nanoscale materials (including features that distinguish them from otherwise similar chemical substances that do not involve nanoscale structures);

- manufacturing processes for nanoscale materials and how they relate to identities of products from the nanoscale manufacturing sector; and
- identification of interested stakeholders.¹³

Potential Pilot Program Parameters

The Agency believes that information derived from a pilot program “will allow EPA and the affected industry to better understand the issues with respect to potential risks” and will help the Agency “to gain experience in the evaluation of such types of chemical substances.”¹⁴

In this regard, EPA expects that questions about certain “parameters” of the potential voluntary pilot program will be important, such as:

- What should be the scope of a voluntary pilot program?
- What information should be included in a voluntary pilot program?
- What information regarding the properties of the particular nanoscale material would be relevant to consider?
- How long should a voluntary pilot program last?
- How should participants in a voluntary pilot program be identified?
- What should trigger a voluntary submission under the pilot program?
- How likely would companies be to volunteer for such a program, and what incentive structure might encourage participation?
- Should participation in a voluntary pilot program have TSCA Inventory consequences?¹⁵

Implications of EPA's *Federal Register* Notice on Nanoscale Materials

EPA's *Federal Register* notice is interesting for several reasons, as discussed in the sections that follow.

A Good Start by EPA

First, EPA is to be commended for initiating a process that will help explore the risks and benefits presented by the commercialization of nanoscale materials, and for seeking the views of interested parties.

It is also commendable that the Agency is requesting information on the manufacture of nanoscale materials from a wide range of stakeholders, particularly small and medium-sized enterprises. EPA is aware that non-traditional businesses (including the smaller entities that drive innovation) are especially important constituencies in this case. They must be part of the nanotech dialogue, but may be less sophisticated about TSCA-related and other regulatory matters.

TSCA Existing Substances -- or Not

Implicit in the *Federal Register* notice is the idea that nanoscale materials consisting of chemical substances already listed on the TSCA Inventory are themselves existing substances for TSCA purposes. Not everyone would agree with this premise.

Environmental Defense expressed a different view in a letter dated September 2, 2004, to Susan Hazen, Acting Assistant Administrator of the Office of Prevention, Pesticides and Toxic Substances. In the letter, the organization urged EPA to take several actions with respect to chemical substances produced “via nanotechnology.”¹⁶ ED recommends, among other things, that EPA treat as “new substances” for TSCA purposes nanomaterials that have a molecular structure identical to substances already on the TSCA Inventory.

Doing so would mean that such substances are “subject to TSCA’s PMN provisions unless the nanomaterial’s chemical and physical properties are demonstrably identical to the conventional substance.”¹⁷ According to ED:

By definition, an engineered nanoparticle or nanofilm comprised of substances already on the Inventory is being developed precisely because it has “novel properties” that differ significantly from those of the conventional material. Hence its molecular identity can and should be considered “new,” regardless of whether its molecular formula or structure is “new.” Significantly, TSCA defines a chemical substance as one that has “a particular molecular identity” (TSCA section 3, 15 USC section 2602(2)). EPA thus has discretion to interpret the term “molecular identity” to have a meaning encompassing more than just molecular formula or structure, in order to ensure that novel substances are in fact identified as “new” and hence receive the careful review they warrant by being subject to PMN requirements.¹⁸

No TSCA Section 8 Requirements, For Now

In soliciting comments on some type of “voluntary pilot program,” EPA seems to be signaling a decision to forego other, more traditional, TSCA tools at its disposal for addressing nanoscale materials and nanoengineered structures, such as TSCA Section 8.

Under section 8(a), the Agency could require manufacturers and processors of chemical substances and mixtures to report and keep records on production, use, release, and exposure information.

In addition, under TSCA Section 8(d), EPA is authorized to require submission to the Agency of unpublished health and safety studies from persons who manufacture, import, process, or distribute chemical substances or mixtures in commerce.

Reliance upon either or both of these rules would provide significant information to EPA on the manufacture and use of nanoscale materials.

That EPA is not availing itself of these TSCA provisions at this time could be the result of several factors. Rules are much more structured than voluntary programs, and thus take longer to develop. They also require approval from the White House Office of Management and Budget (OMB) -- approval that may or may not be forthcoming. Additionally, it is not clear that traditional TSCA tools would access the diverse constituencies that EPA seeks to engage through a voluntary program.

TSCA SNUR: The Option Not (Yet) Taken

Another option that EPA reportedly has considered, but found unappealing, is the issuance of a significant new use rule (SNUR) under TSCA.

The Agency could define "new use" broadly to include the first time a chemical is manufactured at the nanoscale level. EPA might take the position that any nanoscale version of an existing chemical substance is a "significant new use," and issue a SNUR. Once a SNUR were in place, a Significant New Use Notice (SNUN) would have to be submitted by entities that intend to manufacture SNUR-designated chemicals in a manner restricted by the SNUR.

While this option may hold some appeal, it also invites resolution of the sticky question of what is a "new" chemical substance as opposed to an "existing" one -- a debate that could require enormous resources to resolve, with results of questionable value. Additionally, SNURs are a form of rulemaking. They take years to issue and, of course, are subject to judicial challenge.

No Rules Anticipated under TSCA Sections 4 and 6

EPA's authority under TSCA also extends to other provisions of the Act. Most would agree, however, that the Agency lacks authority to issue any kind of test rule (under TSCA Section 4) to compel the development of new data on nanoscale materials. It appears unlikely that EPA could make the sort of specific legal findings required to propose a Section 4 test rule -- at least in any defensible way.

TSCA Section 6 probably also will not yield any rules in the foreseeable future. This section allows EPA to regulate the manufacture, processing, distribution, use, and/or disposal of a chemical substance or mixture when there is a reasonable basis to conclude that the chemical substance or mixture presents, or will present, an unreasonable risk of injury to health or the environment.

Unreasonable risk findings are notoriously hard to make and require “substantial evidence” through TSCA Section 6(a) rulemaking. Moreover, EPA has been unsuccessful in defending past TSCA Section 6 rulemakings.

For these and other reasons, EPA is understandably reluctant to move forward with more traditional TSCA rulemaking at this time, despite the Agency's interest in obtaining information on nanoscale materials.

The Future of Nanotechnology Regulation

There currently is much ongoing discussion regarding whether -- and, if so, how -- nanoscale materials and structures should be regulated.

On the one hand, some take the view that regulation will stifle innovation and delay the commercialization of innovative nanotechnology products. On the other hand, many also believe that the public's confidence and trust will only be won if the government affirmatively reviews and assesses the safety of nanoscale materials.

A Voluntary Program for Nanotech?

EPA's public meeting on nanoscale materials is a useful first step in striking a balance between the need for government involvement and the potentially chilling effects that traditional regulatory controls could have on these developing markets.

The Agency is being quite open in seeking comment on the type of “pilot program” in which stakeholders may wish to participate. EPA offers as examples of other pilot programs the High Production Volume (HPV) Challenge Program and the Voluntary Children's Chemical Evaluation Program (VCCEP), indicating that they are illustrative of programs designed to provide information efficiently on certain groups of chemicals.

Following the public meeting, EPA asked the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), a Federal Advisory Committee Act (FACA) national advisory body, to consider providing input to EPA by October 25, 2005 (the next NPPTAC meeting date), on options for elements of EPA's approach to a voluntary pilot program for existing chemical nanoscale materials under TSCA, and consideration of other relevant issues raised at the public meeting. EPA requested that NPPTAC establish an ad hoc interim workgroup to provide input to NPPTAC for Committee consideration.

Whether the evaluation of nanoscale materials is well suited for the type of program exemplified by HPV is unclear. Many believe, however, that the opportunities for achieving success are more probable in an HPV-like framework than in a more traditional rulemaking context.

There are several issues with which EPA and interested stakeholders must deal in considering a “voluntary” program, as discussed below.

- ***Potential Legal Challenges***

The HPV program has been subject to several legal challenges. People for the Ethical Treatment of Animals (PETA), along with the Physicians Committee for Responsible Medicine (PCRM), have brought two legal challenges to the program.

In May 2000, after EPA denied their TSCA Section 21(a) rulemaking petition,¹⁹ PETA and PCRM, among others, filed an action in the U.S. District Court for the District of Colorado under TSCA Section 21(b).²⁰ The parties sought a judicial order directing the Agency to issue rules under TSCA Sections 8(a) and 8(d) for all of the approximately 2,800 chemicals on the HPV chemical list. In an unpublished decision, the district court declined, and instead granted EPA's motion for summary judgment.²¹

In September 2002, PETA and PCRM brought a new case against the HPV program, this time in the New York federal district court.²² With PCRM taking the lead, the two parties, among others, challenged the manner in which the HPV program had been developed and implemented, arguing that EPA had made *de facto* substantial release and substantial exposure findings under TSCA Section 4. In an unpublished decision, the district court disagreed, concluding that the HPV program does not amount to *de facto* rulemaking under TSCA.²³ PCRM has appealed this decision to the U.S. Court of Appeals for the Second Circuit.²⁴

Against this backdrop, it is unclear whether PETA or others would similarly challenge any voluntary program designed to obtain information on nanoscale materials along the lines contemplated in EPA's May 10th notice.

- ***The CBI Problem***

Issues involving confidential business information (CBI) are especially tricky for any voluntary program on nanoscale materials. EPA and others have thought about how best to ensure CBI is maintained, but no clear answers have emerged. The public meeting held by the Agency helped identify some approaches to address this concern.

- ***Ensuring Participation by Non-Traditional Stakeholders***

Given the number and importance of small and medium-sized enterprises that are involved in nanotechnology, it will be critically important to ensure that non-traditional stakeholders take part in any voluntary program.

The chemical community is very familiar with the HPV and VCCEP programs. By contrast, small startup businesses are likely to be unfamiliar with such programs -- and indeed may be unfamiliar in general with the regulatory requirements that arise under TSCA and related authorities.

Likely Future Efforts by EPA and Other Governmental Agencies

EPA is actively looking for new ideas and innovative ways to ensure that the benefits of nanotechnology flourish, while the risks are identified and managed appropriately.

The Agency's efforts so far are likely to be the first of many activities that will be initiated in the months and years ahead. Federal (and, increasingly, state) regulators are being challenged to assess nanoscale materials and other products of nanotechnology, and to do so in innovative, non-traditional ways. Moreover, they are being challenged to undertake these reviews with limited resources.

This reality makes it all the more important for the business community to participate actively and creatively in the ongoing dialogue, and to work with EPA and other federal and state agencies to build the public's confidence in nanotechnology. It is in the interest of business organizations to ensure that any risks nanotechnology might present are identified and managed early and comprehensively.

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Notes

- ¹ 70 Fed Reg. 24574.
- ² Oberdörster, G., Oberdörster, E., & Oberdörster, J. (2005, July). Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. *Environmental Health Perspectives*, 113(7), 823-839. Available online at <http://ehp.niehs.nih.gov/members/2005/7339/7339.pdf>.
- ³ Id.
- ⁴ For more information on the NNI, see <http://www.nano.gov>.
- ⁵ President's Council of Advisors on Science and Technology (2005). *The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel 6 (PCAST Report)*. See <http://www.ostp.gov/html/PCASTNanoReport5-17-05.pdf>
- ⁶ 21st Century Nanotechnology Research and Development Act of 2003, Pub. L. No. 108-153, 117 Stat. 1923 (2003).
- ⁷ PCAST Report, note 5 above, at 1.
- ⁸ For more information on EPA's activities in nanotechnology, see <http://es.epa.gov/ncer/nano/index.html>.
- ⁹ 68 Fed. Reg. 42068 (July 16, 2003), available at <http://ntp.niehs.nih.gov/ntp/htdocs/liason/03JunICCECFR.pdf>.
- ¹⁰ Id. at 42070. The nomination describes titanium dioxide as a "potent photocatalyst[] because of the generation of OH radicals through light absorption." See Letter from Vicki Colvin, Director, Center for Biological and Environmental Nanotechnology, Rice University, to NTP Nominations Faculty, National Toxicology Program/NIEHS (May 19, 2003) at 6, available at http://ntp.niehs.nih.gov/ntp/htdocs/Chem_Background/ExSumPdf/Nanoscale.pdf.
- ¹¹ 70 Fed. Reg. 32638.
- ¹² 70 Fed. Reg. 24574.
- ¹³ Id. at 24576.
- ¹⁴ Id. at 24575.

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- 15 Id.
- 16 Letter from Richard A. Denison, Ph.D., Senior Scientist, and Karen Florini, Senior Attorney, ED, to Susan B. Hazen, Acting Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances (September 2, 2004).
- 17 Id. at 3.
- 18 Id.
- 19 See 65 Fed. Reg. 18097 (April 6, 2000), available at <http://www.epa.gov/chemrtk/sec21frn.htm>.
- 20 People for the Ethical Treatment of Animals v. Browner, No. 00-D-1090 (D. Colo., filed May 30, 2000), available at <http://www.epa.gov/chemrtk/cmpldoc.htm>.
- 21 Telephone interview with Donald A. Sadowsky, EPA Office of General Counsel (May 31, 2005). See generally BNA Daily Environment Report at A-2 (December 17, 2001).
- 22 Physicians Committee for Responsible Medicine v. Leavitt, No. 02-7049 (S.D.N.Y., filed September 5, 2002).
- 23 See generally BNA Daily Environment Report at A-4 (August 30, 2004).
- 24 Telephone interview with Donald A. Sadowsky, EPA Office of General Counsel (May 31, 2005).