



Pollution Prevention and Toxics

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Control of Nanoscale Materials under the Toxic Substances Control Act

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Highlights

February 19, 2010 -- EPA is developing a Significant New Use Rule (SNUR) and other regulations to address potential health and environmental risks from nanoscale materials.

March 15, 2010 -- EPA is for the first time providing free access to the consolidated Toxic Substances Control Act (TSCA) Chemical Substance Inventory on its Web site. Also for the first time the Inventory is available at Data.gov as a dataset and as an extraction tool, which makes the data easier to manipulate. News release: EPA providing easy access to TSCA Inventory.

Nanoscale Materials

Many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). To ensure that nanoscale materials are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, EPA is pursuing a comprehensive regulatory approach under TSCA. This four-pronged approach includes: Premanufacture notifications; a Significant New Use Rule; an information gathering rule; and a test rule.

Premanufacture Notifications

TSCA requires manufacturers of new chemical substances to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled. Manufacturers are encouraged to contact EPA if they need assistance determining whether their nanoscale materials are subject to new chemical notification requirements.

Since 2005, EPA has received and reviewed over 100 new chemical notices under TSCA for nanoscale materials, including carbon nanotubes, and that number will increase over time. The Agency has taken a number of actions to control and limit exposures to these chemicals, including:

- limiting the uses of the nanoscale materials,
- requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators,
- limiting environmental releases, and
- requiring testing to generate health and environmental effects data.

EPA has permitted limited manufacture of new chemical nanoscale materials through the use of administrative orders or Significant New Use Rules (SNUR) under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the protective equipment and environmental release limitations discussed above).

Significant New Use Rule (SNUR)

The Agency is developing a SNUR under section 5(a)(2) of TSCA to ensure that nanoscale materials receive appropriate regulatory review. The SNUR would require persons who intend to manufacture, import, or process new nanoscale materials based on chemical substances listed on the TSCA Inventory to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before commencing that activity. The SNUR would identify existing uses of nanoscale materials based on information submitted under the Agency's voluntary Nanoscale Materials Stewardship Program (NMSP) and other information.

The SNUNs would provide the Agency with a basic set of information on nanoscale materials, such as chemical identification, material characterization, physical/chemical properties, commercial uses, production volume, exposure and fate data, and toxicity data. This information would help the Agency evaluate the intended uses of these nanoscale materials and to take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment.

Information Gathering Rule

As part of the Agency's efforts to ensure a more comprehensive understanding of nanoscale materials that are already in commerce, EPA is also developing a proposed rule under [TSCA section 8\(a\)](#) to require the submission of additional information. This rule would propose that persons who manufacture these nanoscale materials notify EPA of certain information including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data.

Test Rule

Under [TSCA section 4](#) EPA will propose a rule to require testing for certain nanoscale materials that are already in commerce. EPA would be particularly interested in classes of nanoscale materials not already being tested by other Federal and international organizations. The results of the required tests would assist EPA in understanding potential health and environmental effects of the nanoscale materials. The results could also help to establish a correlation between the chemical/physical properties and the effects of the nanoscale materials.

Timing of Rules

EPA anticipates proposing the SNUR, section 8(a) and section 4 rules by the end of 2010.

International Cooperation on Nanomaterials

Fully understanding the environmental applications and implications of nanotechnology requires the concerted efforts of scientists and policy makers across the globe. EPA is working collaboratively with stakeholders both domestically and internationally to address nanoscale materials, to identify and address nanotechnology research needs, and to develop international standards for nanotechnology.

International organizations such as the International Organization for Standardization (ISO) and the Organization for Economic Cooperation and Development (OECD) are engaged in nanotechnology issues.

The ISO has established a technical committee to develop international standards for nanotechnology. This [technical committee, ISO/TC 229](#), [EXIT Disclaimer](#) is working to develop standards for terminology and nomenclature, metrology and instrumentation, including:

- specifications for reference materials,
- test methodologies,
- modeling and simulation, and
- science-based health, safety and environmental practices.

The OECD has established a [Working Party on Manufactured Nanomaterials \(WPMN\)](#) [EXIT Disclaimer](#) that is engaged in a variety of projects to further our understanding of the properties and potential risks of nanomaterials:

- Development of a Database on Environmental Health and Safety (EHS) Research
- EHS Research Strategies on Manufactured Nanomaterials
- Safety Testing of a Representative Set of Manufactured Nanomaterials
- Manufactured Nanomaterials and Test Guidelines
- Cooperation on Voluntary Schemes and Regulatory Programs
- Cooperation on Risk Assessments
- The Role of Alternative Methods in Nano Toxicology
- Exposure Measurement and Exposure Mitigation
- Cooperation on the Environmentally Sustainable Use of Nanotechnology

EPA is actively participating in the Working Party and contributes to all of the projects which help leverage international expertise and resources. The project on Safety Testing of a Representative Set of Manufactured Nanomaterials, in particular, will help address important data gaps. The WPMN has identified a representative list of manufactured nanoscale materials for environmental health and safety testing, including:

- fullerenes (C₆₀)
- single-walled carbon nanotubes (SWCNTs)
- multi-walled carbon nanotubes (MWCNTs)
- silver nanoparticles
- iron nanoparticles
- carbon black
- titanium dioxide
- aluminum oxide
- cerium oxide
- zinc oxide
- silicon dioxide
- polystyrene
- dendrimers
- nanoclays

The WPMN has also published a list of testing endpoints in the following areas:

- nanomaterial information/identification
- physical-chemical properties

- material characterization
- environmental fate
- environmental toxicology
- mammalian toxicology
- material safety

A number of countries and organizations are sponsoring testing. EPA is sponsoring environmental effects and fate testing of fullerenes, single-walled carbon nanotubes, multi-walled carbon nanotubes, silver nanoparticles, and cerium oxide. The United States is also contributing testing for iron, carbon black, titanium dioxide, aluminum oxide, and dendrimers. The outcome of this and other OECD projects will contribute to EPA's efforts to enhance its regulatory oversight of nanoscale materials

Resources and Related Links

- [Federal Register Notice regarding the TSCA Inventory status of carbon nanotubes, October 31, 2008](#)
- [TSCA Inventory Status of Nanoscale Substances -- General Approach \(2008\) \(PDF\)](#) (7 pp, 37K), regarding whether a nanoscale material is a "new" or "existing" chemical substance under TSCA
- [Pollution Prevention through Nanotechnology Conference, September 25-26, 2007](#)
- [Meeting Summary Report \(PDF\)](#), (83 pp, 333K) Material Characterization of Nanoscale Materials (September 6-7, 2007, Peer Consultation Meeting)
- [EPA Nanotechnology White Paper, February 2007 \(PDF\)](#), (136 pp, 4.1MB)
- [Risk Management Practices for Nanoscale Materials Public Meeting Summary \(PDF\)](#) (75 pp, 464K), October 19-20, 2006
- [Interim Ad Hoc Work Group on Nanoscale Materials, National Pollution Prevention and Toxics Advisory Committee Overview Document \(PDF\)](#) (13 pp, 1.1 MB)
- [Nanotechnology for Waste and Cleanup](#)
- [Pesticide issues in the works: nanotechnology, the science of small](#)
- [Research on Nanotechnology](#)