http://www.epa.gov/oppt/nano/
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Pollution Prevention and Toxics

Nanotechnology under the Toxic Substances Control Act

On this page:

Highlights

On January 12, 2009, EPA released its interim report on the Nanoscale Materials Stewardship Program (NMSP) (PDF) (38 pp, 872K).

Learn about EPA's NMSP and current participants. EPA welcomes new participants and submissions. Please submit your contact information or comments on the interim report.

Chemical Nanoscale Materials

Many nanomaterials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). This law provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects against unreasonable risks to human health and the environment.

For example, TSCA requires manufacturers of new chemical substances (i.e., those not on the TSCA Chemical Substances Inventory) to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can require reporting or development of information to assess existing chemicals already in the marketplace. Additionally, EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled.

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One of the key questions for manufacturers and importers is determining whether a given nanoscale material is already listed on the TSCA Inventory or if it is a new chemical requiring premanufacture notification to the Agency. On January 28, 2008, EPA released the TSCA Inventory Status of Nanoscale Substances – General Approach (2008) (PDF), (7 pp, 37K), describing EPA's current thinking regarding whether a nanoscale material is a "new" or "existing" chemical substance under TSCA.

EPA has received and reviewed numerous new chemical notices under TSCA for nanoscale materials including carbon nanotubes. The Agency has taken steps to control or 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, and
- limiting environmental releases.

The Agency has also required testing to generate health and environmental effects data where appropriate. EPA has permitted limited manufacture of new chemical nanoscale materials through the use of administrative orders or Significant New Use Rules 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).

To complement and support EPA's new and existing chemical programs under TSCA, the Agency developed a Nanoscale Materials Stewardship Program (NMSP). The NMSP will help provide a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and contribute to an improved understanding of risk management practices for nanoscale chemical substances (nanoscale materials).

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

EPA is actively participating in the Working Party and contributes to all of the projects. Of particular relevance to the in-depth portion of the Agency's Nanoscale Materials Stewardship Program (NMSP) is the project on Safety Testing of a Representative Set of Manufactured Nanomaterials. The WPMN has identified a representative list of manufactured nanoscale materials for environmental health and safety testing, including:

- fullerenes (C_{60})
- 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

The WPMN has launched a Sponsorship Program for Testing Manufactured Nanomaterials. The OECD Secretariat has asked delegations about their willingness to sponsor, or co-sponsor, one or more nanomaterials and endpoints. The OECD will act as a clearinghouse for the sponsorship program and will prepare a guidance manual for sponsors. EPA is sponsoring environmental effects and fate testing of fullerenes, single walled carbon nanotubes, multiwalled carbon nanotubes, silver nanoparticles, and cerium oxide. EPA encourages U.S. entities to participate in the OECD's work in addition to the in-depth portion of the NMSP.

Resources and Related Links

- Federal Register Notice regarding the TSCA Inventory status of carbon nanotubes, October 31, 2008
- Interim Ad Hoc Work Group on Nanoscale Materials, National Pollution Prevention and Toxics Advisory Committee Overview Document (PDF) (13 pp., 1.1 MB)
- Risk Management Practices for Nanoscale Materials Public Meeting Summary (PDF) (75 pp., 464K) October 19-20, 2006
- Meeting Summary Report (PDF) (35 pp, 119K) of the August 2, 2007, Public Meeting for the Nanoscale Materials Stewardship Program
- Meeting Summary Report (PDF), (83 pp, 333K) Material Characterization of Nanoscale Materials (September 6-7, 2007, Peer Consultation Meeting)
- Pollution Prevention Through Nanotechnology Conference, September 25-26, 2007
- Pesticide issues in the works: nanotechnology, the science of small
- Nanotechnology for Waste and Cleanup
- Research on Nanotechnology
- EPA Nanotechnology White Paper, February 2007 (PDF), (136 pp, 4.1MB) describes why EPA is interested in nanotechnology across its programs, the Agency's statutory mandates, and risk assessment issues specific to nanotechnology across media.