

Briefing to NATO Advanced Research Workshop

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Overview

- Toxic Substances Control Act
- Regulatory Framework for Nanoscale Materials (NMs)
 - New v Existing NMs under TSCA
 - TSCA Regulatory Oversight of NMs
- Voluntary Nanoscale Materials Stewardship Program
- International Collaborations
- National Nanotechnology Initiative (NNI)
- EPA Research and Development

Toxic Substances Control Act -- TSCA

- Passed in 1976
- Filled gaps in existing chemical regulation
- Responded to public concerns about chemical exposures
 - PCB's in the environment
 - Kepone contamination
- EPA Administrator given power to regulate
 - Chemicals in commercial use with risk or potential risk to environment

Toxic Substances Control Act -- TSCA

- TSCA provides EPA number of regulatory mechanisms
 - Inventory of chemical substances
 - New chemical review
 - Testing of existing chemicals
 - Direct regulation of chemicals
 - Reporting/record-keeping requirements
 - Import/export requirements

Nanoscale Materials under TSCA

- Many nanoscale materials (NMs) are “chemical substances” as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are “new” chemicals
 - TSCA definition based on molecular identity, not other properties
 - New chemical examples include fullerenes & carbon nanotubes
- NMs already on the TSCA Inventory are “existing” chemicals
 - Some metal oxides
- EPA paper on TSCA Inventory status of NMs

TSCA Regulatory Oversight of NMs

- Pre-manufacture notice (PMN) is required before manufacture of new chemical NMs
 - Over 35 PMNs on NMs received since 2005
- Significant New Use Rules can be applied to specific NMs or categories of NMs
- Information collection authorities can be used to obtain needed information
 - Use & exposure data
 - Health & safety studies
- Substantial risk reporting requirements keep EPA promptly informed of new information

Nanoscale Materials Stewardship Program (NMSP)

- Encourage responsible development
- Complement TSCA regulatory program
 - NM manufacturers, processors, users, or importers
 - Researchers or PMN submitters can also participate
- Increase experience with risk assessment/mitigation
- Provide firmer scientific basis for decision-making
- Encourage risk management practices to reduce potential exposures/releases

NMSP: Basic Program

- Requests participants to submit existing information on NMs by 7/28/08
 - Physical & chemical properties, hazard, exposure, use, & risk management practices or plans
- Encourages use of optional data submission form but may provide data in any format
- Encourages participants who don't have risk management plans to develop & submit them

NMSP: In-Depth Program

- Sponsors commit to develop data on a smaller set of representative NMs over a longer time period
- EPA will facilitate data development process
- Entities or consortia with an interest in developing data should notify EPA at: <http://epa.gov/oppt/nano/nano-contact.htm>

NMSP Outreach & Recognition

- EPA strongly encourages early and active participation in the basic program
 - Submission before 7/28/08
 - EPA outreach via letters, stakeholder meetings, & conferences
- Major trade associations have notified members & encouraged participation
- EPA will publicly recognize participants

NMSP Evaluation

- Interim evaluation & report
 - Approximately one year from initiation based on reporting during first six months
- Detailed program evaluation & report
 - Approximately two years from initiation
 - Determine future direction of NMSP
- EPA will adjust or decide future steps as needed during or at the end of the NMSP
 - Includes TSCA regulation to obtain data or take other actions

International Collaboration on NMs

- Organization for Economic Cooperation & Development (OECD) Working Party on Manufactured Nanomaterials Projects:
 - Development of an OECD Research Database
 - Environmental Health & Safety Research Strategies on Manufactured Nanomaterials
 - Safety Testing of a Representative Set of Manufactured Nanomaterials
 - Manufactured Nanomaterials & Test Guidelines
 - Cooperation on Voluntary Schemes & Regulatory Programs
 - Cooperation on Risk Assessments
 - Alternative Methods in Nanotoxicology
 - Exposure Measurement & Exposure Mitigation
- International Organization for Standardization (ISO)
 - Technical Committee on Nanotechnology (TC 229)
 - Standards for terminology, nomenclature, metrology & instrumentation

NATIONAL NANOTECHNOLOGY INITIATIVE



The National Nanotechnology Initiative (NNI) provides a multi-agency framework to ensure U.S. leadership in nanotechnology that will be essential to improved human health, economic well being and national security. The NNI invests in fundamental research to further understanding of nanoscale phenomena and facilitates technology transfer.

Leading to a Revolution in Technology and Industry

www.nano.gov

Federal Nanotechnology R&D in the U.S. is coordinated by the NNI.

- 2001: NNI created as a federal initiative
- 2003: 21st Century Nanotechnology Research and Development Act (Public Law 108-153)
- 26 Agencies (13 with R&D budgets)
- The goals of the NNI are to:
 - Maintain a **world-class research and development program** aimed at realizing the full potential of nanotechnology
 - Facilitate **transfer of new technologies** into products for economic growth, jobs, and other public benefit
 - Develop **educational resources, a skilled workforce, and the supporting infrastructure** and tools to advance nanotechnology
 - Support **responsible development** of nanotechnology

EPA Research and Development -- Applications and Implications

- Applications address existing environmental problems and prevent future problems.
- Implications address the interactions of nanomaterials with the environment and any possible **risks** that may be posed by nanotechnology

Examples of Environmental Applications

<i>Air</i>	sensors; nanofiber filters
<i>Water</i>	sensors; treatment
<i>Waste</i>	waste minimization, remediation
<i>Toxics</i>	green chemistry; treatment
<i>Homeland Security</i>	chemical/biological/radiological sensors; decontamination

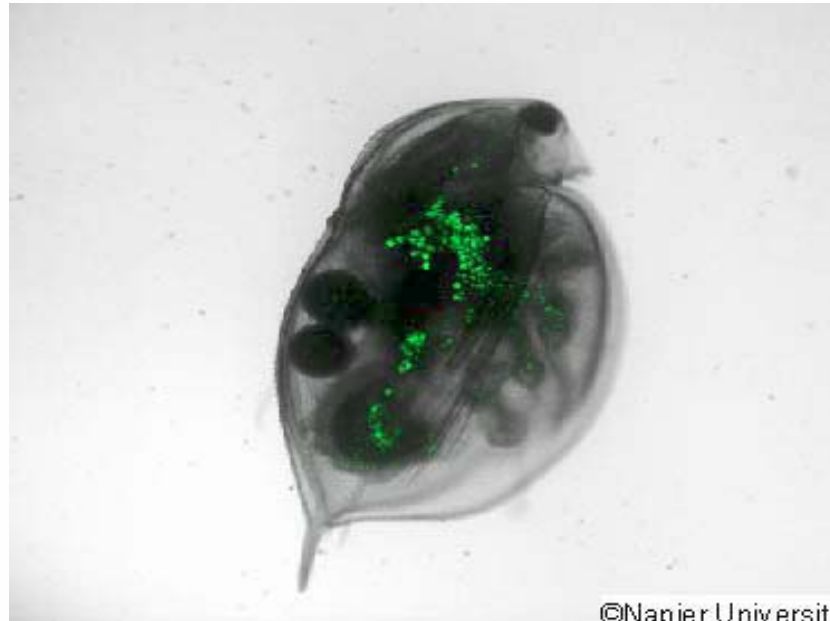


Nanorust Cleans Arsenic from Drinking Water.
Image courtesy of CBEN/Rice University

Environmental Implications

- Unique properties of nano-scale particles
- Many unknowns:
 - toxicity,
 - exposure
 - transport
 - bioaccumulation
 - persistence
 - Transformation
- Potential toxicity through inhalation and skin exposure routes

Implications Example: Nanoparticles in *Daphnia*



Fluorescent nanoparticles in a water flea (*Daphnia magna*). Adult and neonate *Daphnia* were exposed to 20nm and 1000nm fluorescently tagged carboxylated nanospheres for up to 24 hours. Nanoparticles were observed in gut and fatty lipid storage droplets using laconfocal microscopy. (Image courtesy of Teresa Fernandes and Philipp Rosenkranz, Copyright Napier University)

EPA's Role in Nanotechnology

- Provide leadership under the NNI on the environmental applications and implications of nanotechnology.
- Work in collaboration with other federal agencies and other organizations to identify research priorities to support safe development of nanotechnology.
- Support research directly and in collaboration with other agencies to address research priorities.
- Address nanotechnology as appropriate under EPA's statutes to protect human health and the environment.