

Nanotechnology – An EPA Perspective

**NEWMOA Web Conference on
Environmental Health and Safety for
Nanotechnology**

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Definition

- Scale of approximately 1 -100 nm
- Size dependent properties and new functions of matter at the nanoscale
- Manipulate or control material at the nanoscale



White Paper

- Issued as Agency document in February 2007
- Communicate nanotechnology science, science policy, and research issues of importance to EPA. (Not designed to address regulatory issues.)
- Identify potential to prevent, solve, identify environmental problems
- Opportunity to support development of the technology in an environmentally safe and sustainable manner
- Understand potential impacts of nanomaterials and nanoscale products on human health and the environment



Research Activities

Extramural Grants

- Through 2007, 86 grants awarded for approx. \$30 million
- Information available online at www.epa.gov/ncer/nano

In-house Research

- EPA's scientists have done research on toxicity of ultrafine particulate matter and are gathering info on various environmental applications.
- Budget proposal for 2008 provides funding for EPA in-house research

Agency Research Strategy



Research Directions

2007 and 2008

- Environmental fate, transport, transformation, and exposure
- Monitoring and detection methods

Resulting data would be used to inform and develop effects and exposure assessment methods, and identify important points of releases for potential management.

2009 – 2012

- Health and ecological effects, understanding toxicity of the altered materials (as identified in 2007-2008). To be informed and refined by case studies, to be initiated in 2007, to elicit information on how to address high-exposure-potential nanomaterials.
- By 2011-2012, develop systematic and integrated approaches to assess, manage, and communicate any identified risks associated with nanomaterials



Activities to Advance These Directions

- Requested \$10.3 million under President's budget for nanotechnology research in FY 08, including \$4.7 million for an in-house nanotechnology research program.
- Developing research strategy focusing on fate, transport, transformation, and measurement/detection from a life-cycle perspective. To undergo peer review in March 2008.
- Participating with other agencies (through NEHI) to develop a national prioritized research plan.
- Participating on OECD working party on the Health and Environmental Safety Implications of Manufactured Nanomaterials.
- Continuing collaborations with federal agencies, industry, professional societies, academia, and international communities.



Nanoscale Materials (NMs)

- Chemical substances as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are new chemicals and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture (e.g., fullerenes, carbon nanotubes)
- NMs that are existing chemicals, i.e. already on the TSCA inventory (e.g., some metal oxides)
- TSCA definition of new chemical based on molecular identity, not on other properties



General Approach

- Both regulatory and voluntary components
- Regulatory:
 - New Chemicals Program
 - Issue targeted SNURs for specific NMs or categories where there is evidence of
 - Risk concerns
 - Significant exposure/release potential
 - Information gathering
 - Section 8(a) – report use and exposure data
 - Section 8(d) – report health and safety studies
 - Section 8(e) – report substantial risk info



Nanoscale Materials Stewardship Program (NMSP)

- Complements regulatory approach
- Increases experience with risk assessment/ mitigation
- Provides insight on test data to be developed
- Generation of test data to provide sound scientific basis for decision-making
- Encourages risk management practices



NMSP Development

- Initial public meeting in June 2005
- National Pollution Prevention and Toxics Advisory Committee developed “Overview Document” and forwarded to EPA for review/consideration November 2005
- Peer consultations
 - risk management practices October 2006
 - materials characterization September 2007
- Concept paper, inventory paper, ICR released for public comment July 2007
- EPA announced program on January 28



NMSP

- Designed for participants who already manufacture, process, use, or import NMs
- Researchers or PMN submitters may also participate
- Did not attempt to limit or define participants or nanoscale materials
- Permit submitted data to be claimed confidential but encourage as much public data as possible



Basic Program

- During the first 6 months participants report existing information – reporting deadline 7/29/08
- Encourage use of optional data submission form but may provide in any format.
- Report physical and chemical properties, hazard, exposure, use, and risk management practices or plans.
- Encourages participants who do not have a risk management plan to consider developing one and submitting it



In-Depth Program

- Sponsors would develop data on a smaller set of representative nanoscale materials
- Entities or consortia with an interest in developing data should notify EPA.
- EPA will facilitate data development process
- EPA will begin in-depth follow-up with interested stakeholders after they identify themselves

<http://www.epa.gov/oppt/nano/nano-contact.htm>



Outreach

- Strategy to encourage early and active participation in the basic program
- Outreach sessions and meetings with stakeholders during the first six months
- Major trade associations have alerted membership and encouraged participation
- Received submissions under the basic program



NMSP Submissions/Commitments

- NMSP submissions under the basic program:
 - DuPont
 - Office ZPI
 - Strem Chemicals
 - Nanophase Technologies Corporation
 - Confidential Submission
- Companies committed to submit information under the basic program:
 - BASF Corporation
 - Bayer MaterialScience
 - Dow Chemical
 - Evonik/Degussa
 - General Electric
 - Nanocyl North America
 - Nantero
 - PPG Industries
 - Sasol North America



Evaluation

- Interim report approximately one year from initiation based on first six months reporting
- Detailed report and program evaluation in approximately two years
- Determine future direction of NMSP at two-year evaluation
- May adjust or decide future steps earlier if experience or data warrant
- Includes considering use of regulatory authorities under TSCA



International

- The Chemicals Committee of the Organization for Economic Co-Operation and Development (OECD) established a Working Party on Manufactured Nanomaterials
- In-Depth portion of NMSP complements OECD project on Safety Testing of a Representative Set of Manufactured Nanomaterials
- U.S. Technical Advisory Group to Technical Committee on Nanotechnology of the International Standards Organization (**US TAG to ISO TC 229**)



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