

EPA's Nanoscale Materials Stewardship Program and the OECD Working Party on Manufactured Nanomaterials

**Nanotechnology: The Future of EHS Regulatory Policy
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Description

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



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)
- Some NMs 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



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 7/28/08
- 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://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 first submission under the basic program



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



WPMN

- Established in September, 2006
- Three meetings to date:
 - **October 26-27, 2006**
 - **April 26-28, 2007**
 - **November 28-30, 2007**
 - **Next meeting: 11-13 June 2008**
 - **5th meeting: 4-6 March 2009**
- Objective: *To promote international co-operation in health and environmental safety related aspects of manufactured nanomaterials, in order to assist in their safe development*
- Works through the implementation of (8) projects



Who attends the WPMN?

Countries:

Australia, Austria, Belgium, Canada, Denmark, European Commission, Finland, France, Germany, Italy, Japan, Korea, Netherlands, New Zealand, Norway, Poland, Slovakia, Spain, Sweden, Switzerland, United Kingdom, United States

Observers:

- Argentina, China, Israel, Thailand, Brazil, India, Russia
- ISO, WHO, UNEP
- BIAC, eNGOs (ED and FOE), TUAC, WWIC (past)
- ICAPO request

US Workgroup members:

- EPA (OPPT, OPP, ORD), CEQ, OSTP, State, NIH, FDA, NIOSH, OSHA, USDA, NIEHS, USPTO, DOC, CIA, NIST, CPSC



Project 1: OECD Database on Safety Research

- Objective: *to develop a global resource, which identifies research projects that address environmental, human health and safety (EHS) issues associated with manufactured nanomaterials. This will include research projects which are planned, underway or completed.*
- Chair: Australia
- Status:
 - Prototype database available January, 2008
 - Data entry -10 weeks ~ March-May
 - Rollout on or before WPMN-4



Project 2: Research Strategies on Manufactured Nanomaterials

- Objective: *to exchange information and identify common research needs to address human health and environmental safety issues associated with manufactured nanomaterials, and to undertake to meet those research needs.*
- Chair: Germany
- Status:
 - Initial research matrix complete
 - Next steps to focus on strategies



Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

- Objective: *to agree and test a representative set of manufactured nanomaterials (MN) using appropriate test methods.*
- Co-Chairs: USA and European Community
- Status:
 - Testing program agreed encompassing 14 nanomaterials and a range of endpoints.
 - Sponsorship program agreed to/guidance manual under development



Project 4 : Manufactured Nanomaterials and Test Guidelines

- Objectives:
 - *To review existing OECD Test Guidelines for adequacy in addressing manufactured nanomaterials.*
 - *To identify the need for development of new or revision of existing test guidelines.*
- Co-chairs: USA and European Commission
- Status:
 - Reviewing existing guidelines for potential applicability
 - Working in 4 subgroups
 - Physical-Chemical Properties
 - Biotic Effects
 - Bioaccumulation and Degradation
 - Health Effects



Project 5: Co-operation on Voluntary Schemes and Regulatory Programmes

- Objectives:
 - *To identify common elements of the various information gathering initiatives, in place or planned.*
 - *To identify applicable current and proposed regulatory regimes and how they address information requirements, hazard identification, risk assessment and exposure mitigation/ risk management of manufactured nanomaterials.*
 - *To share information on existing or proposed guidance documents on practices to reduce occupational or environmental exposure to or releases of manufactured nanomaterials .*
- Chair: Canada
- Status:
 - Initial comparisons conducted
 - Developing a model “template”
 - Developing a clearinghouse for “International Sharing and Comparison of Data on Manufactured Nanomaterials”



Project 6: Co-operation on Risk Assessment

- Objective: *to evaluate risk assessment approaches for manufactured nanomaterials through information exchange and identify opportunities to strengthen and enhance risk assessment capacity.*
- Chair: UK
- Status: Reviewing results of survey.



Project 7: Alternative Methods in Nano Toxicology

- New project to evaluate and, where applicable, validate in vitro and other methodologies
- Chair: UK
- Status:
 - Invitation to has been circulated
 - Needs to integrate with SG3 and SG4
 - Testing needs to be considered during sponsorship.
 - Report on available methods expected by WPMN-4



Project 8: Exposure measurements and Exposure Mitigation

- New project to develop guidance on exposure measurements and exposure mitigation, with an initial focus on occupational settings.
- Chair: USA
- Status:
 - Invitation to participate has been circulated



For Further Information

NMSP

<http://www.epa.gov/oppt/nano/>

or

www.regulations.gov

(epa-hq-oppt-2004-0122)

OECD

<http://www.oecd.org>