



Nanoscale Materials Stewardship Program

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Definition

- Scale of 1 -100 nm
- Size dependent properties and new functions of matter 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)
- NMs that are existing chemicals, i.e. already on the TSCA inventory (e.g., 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



General Approach

- 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
- Federal 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 to 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 limit/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 of program participants report existing information
- 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.
- After participants are identified EPA will facilitate data development process



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
- 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



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