



Approaches for 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 and a Pre-Manufacture Notice (PMN) is required before commencement of manufacture
- Presently no similar requirement for NMs that are existing chemicals, i.e. already on the TSCA inventory
- Limited information currently available indicates that NMs may have different toxicity and/or exposure characteristics than their "macro" counterparts
- Program needs include:
 - A mechanism to collaboratively generate data needed to provide a sound scientific foundation for assessments
 - An appropriate interim approach to obtain better informed decision-making on new chemicals and a better understanding of "existing" chemical NMs
 - An appropriate degree of industry stewardship in the manufacture and use of new and existing chemical NMs

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Stewardship Program

- Stewardship Program:
 - Complements new and existing chemicals regulatory approach
 - Develops a consistent and informed approach for NMs
 - Increases experience with risk assessment/mitigation of NMs and provides insight on what test data needs to be developed
 - Accelerates generation of test data to provide sound scientific basis for decision-making

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Public Engagement

- OPPT held a public meeting in June 2005 to obtain public input on how it might best fill its role in assessing/managing the risks of NMs
- OPPT requested its Federal Advisory Committee group, the National Pollution Prevention and Toxics Advisory Committee (NPPTAC), to provide additional input via a public process
- NPPTAC "Overview Document" forwarded to EPA for its review/consideration (Nov, 2005)
- Agency Workgroup established in May 2006 to explore the concept of a stewardship program using the above to inform discussion
- EPA announced a collaborative public process to develop a program in October

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Program Design

- Launch open and transparent engagement with stakeholders
- Release Agency documents for public comment and discussion at public meetings, e.g.,
 - Determination of Inventory status for NMs,
 - Concept paper on Stewardship Program,
 - Information Collection Request (ICR)
- Hold public scientific Peer Consultations on key elements of Stewardship Program
 - Basic risk management practices
 - Characterization information for NMs
- Consider comments/input and finalize approach

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These are the NPSG



Implementation

- Industry Sign-up
 - "Basic" commitment by companies to the elements of Stewardship Program and to provide data on new and existing chemical NMs
 - "In-Depth" commitment by companies/consortia to develop more detailed test data on representative NMs

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2 level commitment

small & large companies have indicated interest.

Evaluation

- EPA will evaluate the Stewardship Program after two years in an open and transparent process:
 - Consider need to use TSCA information collection authority to supplement information submitted under Stewardship Program
 - Consider all other data developed for NMs (includes Regulatory component)
 - Consider and identify needed next steps; e.g.
 - Continue or modify program
 - Take regulatory steps (e.g., revisions to PMN reporting form)

Next Steps

- Documents the NPCG will see for review before public release:
 - TSCA Inventory Status of Nanoscale Substances: General Approach
 - A Concept paper describing key elements of the Stewardship Program,
 - ANNEX B of the Concept Paper will contain a description of the data elements in the proposed Information Collection Request EPA will issue for the Stewardship Program
- After NPCG review EPA will release the Inventory Document, Concept Paper and proposed ICR for public review and comment.

2 weeks for review of changes of text.

Consensus of OSHA, but will discuss w/ EPA.

- Companies can sign up for... information... that... will be... etc
- Is there a difference between what EPA needs vs OSHA or FDA? And closer to OSHA.
- TSCA exemptions... report... volume, ...
- Definition of new? Defined by TSCA or Stewardship program? EPA needs... but TSCA isn't... doesn't differ...
- Does FDA, OSHA... unclear.
- TSCA... OIR, Technical, ...
- Integration of OIR...