



Nanoscale Materials under TSCA

Briefing for DoD

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Approaches for Nanoscale Materials under TSCA

- Nanoscale materials (NMs) that are “chemical substances” as defined by TSCA are subject to TSCA controls
- NMs not on the TSCA Inventory are “new chemicals”
 - Pre-Manufacture Notice (PMN) required before manufacture
 - OPPT is reviewing PMNs for NMs
- No PMN required for “existing chemical” NMs, i.e., already on the TSCA inventory
- Limited information on whether some NMs may have different toxicity and/or exposure characteristics than their “macro” counterparts
- NM 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 realize oversight of existing chemical NMs
 - An appropriate degree of industry stewardship in the manufacture and use of new and existing chemical NMs



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 FACA 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
- Administrator approved a collaborative public process to design a NM Stewardship Program (Sept. 2006)
 - Jim Gulliford invited >500 organizations and agencies to participate (Oct. 2006)



Stewardship Program

- **Step 1 – Collaborative Program Design**
 - Launch open and transparent engagement with stakeholders
 - <http://epa.gov/oppt/nano/index.htm>
 - Release Agency documents for public comment and discussion at public meetings, e.g.,
 - Determining the Inventory status of 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 (Oct. 2006)
 - Characterization information for NMs (2007)



Stewardship Program

- **Step 2 – Implement NM Stewardship Program**
 - 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



Stewardship Program

- **Step 3 – Evaluation of Stewardship Program**
 - 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:
 - Continue or modify program
 - Take regulatory action (e.g., revisions to PMN reporting form)



Stewardship Program Development Process

- Agency workgroup reviews/develops documents
- EPA Nanotechnology Policy Committee (Office Director level) reviews documents and addresses issues
- Interagency Nanotechnology Policy Coordination Group (NPCG) reviews documents and forwards comments to EPA
- EPA makes changes and completes Agency processes, as appropriate
- Documents released to the public



Stewardship Documents for Upcoming NPCG Review

- NM Stewardship Concept Paper
 - Describes general approach, issues, and considerations for Stewardship Program
 - Includes TSCA Framework on OPPT approach to oversight of nanotechnology under TSCA
- TSCA Inventory Status of Nanoscale Materials
 - Addresses OPPT approach to determining whether a NM is a “new” or “existing” chemical substance under TSCA
- Information Collection Materials
 - Description of information to be collected via the Stewardship Program