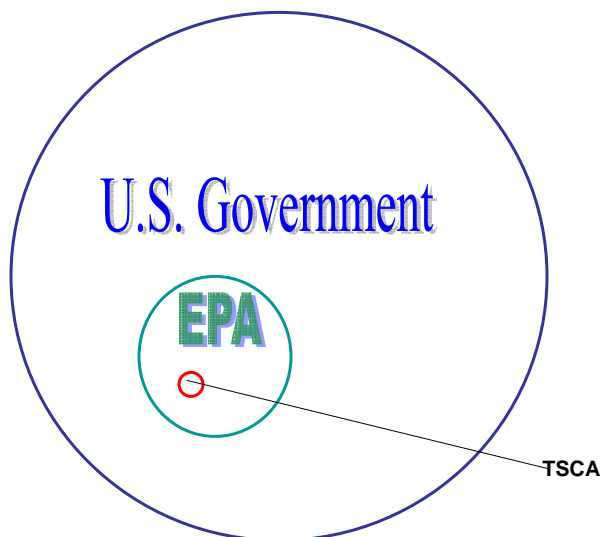


# Regulation of Nanotechnology: A TSCA Perspective

Office of General Counsel  
U.S. EPA

ELI/VCEMS Nanotechnology Governance Symposium - May 19, 2006

## Where I Sit





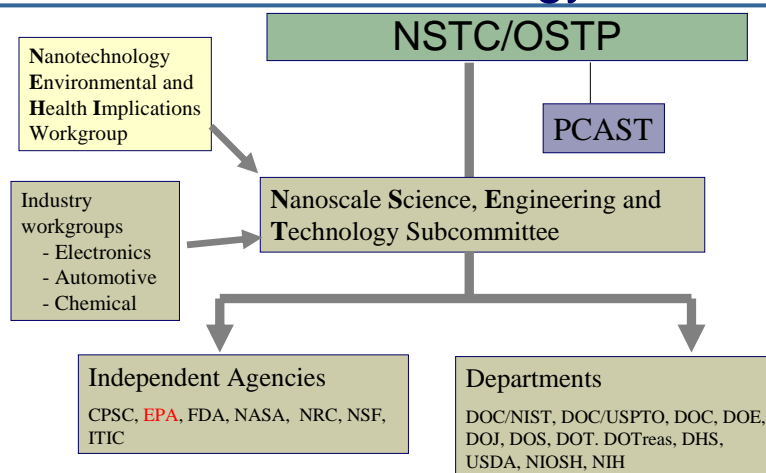
## National Nanotechnology Initiative (NNI)

- Federal R&D program
  - Supports fundamental and applied research
  - Creates university and government nanoscale R&D centers and laboratories
  - Supports activities to address societal implications
  - Helps to educate workforce
- Coordination of federal efforts in nanoscale science, engineering and technology
- Managed within the framework of the National Science and Technology Council (NSTC)

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## Federal Coordinating Structure for National Nanotechnology Initiative



Federal Nanotechnology R&D in the U.S. is coordinated by the NNI

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## Nanotechnology: EPA's Role

- **Provide leadership** to the U.S. and global community in environmental applications and implications of nanotechnology
- **Support research** directly and in collaboration with other agencies through the inter-agency work groups established under the NNI
- Help to **build a research community** with knowledge in nanotechnology
- Address nanotechnology as appropriate under EPA's statutes to **protect human health and the environment**
- Proactively work with industry and NGOs to **facilitate responsible development and realize potential environmental benefits** of nanotechnology

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## Assessing and Addressing Risks: Statutes

- **Clean Air Act**
- **Clean Water Act**
- **Resource Conservation and Recovery Act**
- **Comprehensive Environmental Response, Compensation and Liability Act**
- **Federal Insecticide, Fungicide and Rodenticide Act**
- **Toxic Substances Control Act (TSCA)**

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## TSCA as Vanguard

- **Little opportunity to date for consideration of regulatory issues under pesticide, air, water and waste statutes**
- **TSCA was designed to provide a holistic look at chemical risks**
- **The first vehicle the Agency is using to screen, and if necessary regulate, products of nanotechnology**

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## Early Stage Challenges

- **Defining and characterizing the substances to be evaluated and/or regulated**
- **Determining what products and attributes need the most scrutiny and control**

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## Building Capacity

- **New chemical review**
- **Nanotechnology Stewardship Program**

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## New Chemical Review of Nanoscale Materials under TSCA

- New vs. existing chemicals and the TSCA Inventory
  - **New Chemicals:** Pre-Manufacture Notification under Section 5(a)(1) required before commencement of manufacture
  - **Existing Chemicals:** notification not required
- Need for a clear distinction between “new” and “existing” chemicals that are nanoscale materials
- Low volume and low exposure/release exemptions

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## EPA Consideration of NM Stewardship Program

- A Stewardship Program
  - Would help EPA understand issues and provide guidance needed by industry during the early stages of commercialization
  - Could serve as **umbrella** providing a consistent approach for both new and existing chemical nanomaterials
  - Would help to accelerate early development of test data needed to improve scientific understanding
- Public scientific peer consultations and data collected in program
  - Inform EPA/public
  - Establish sound science basis for EPA's approach

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## Stewardship Program Milestones

- NPPTAC "Overview Document" forwarded to EPA (Nov. 22, 2005)
- OPPT Workgroup; initiation of ICR development (Nov. 2005)
- Intra-agency Workgroup (Mar. 2006)
- Public scientific peer consultations (spring 2006):
  - materials characterization
  - management practices
- Submission of ICR for approval (spring 2006)
- Approval of ICR; publication of FRN (fall 2006)
- Agency decision on initiation/implementation (fall 2006)
- Public scientific peer consultations (spring 2007):
  - risk assessment
  - risk management

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