



Recent Experience of the United States on Nanotechnology

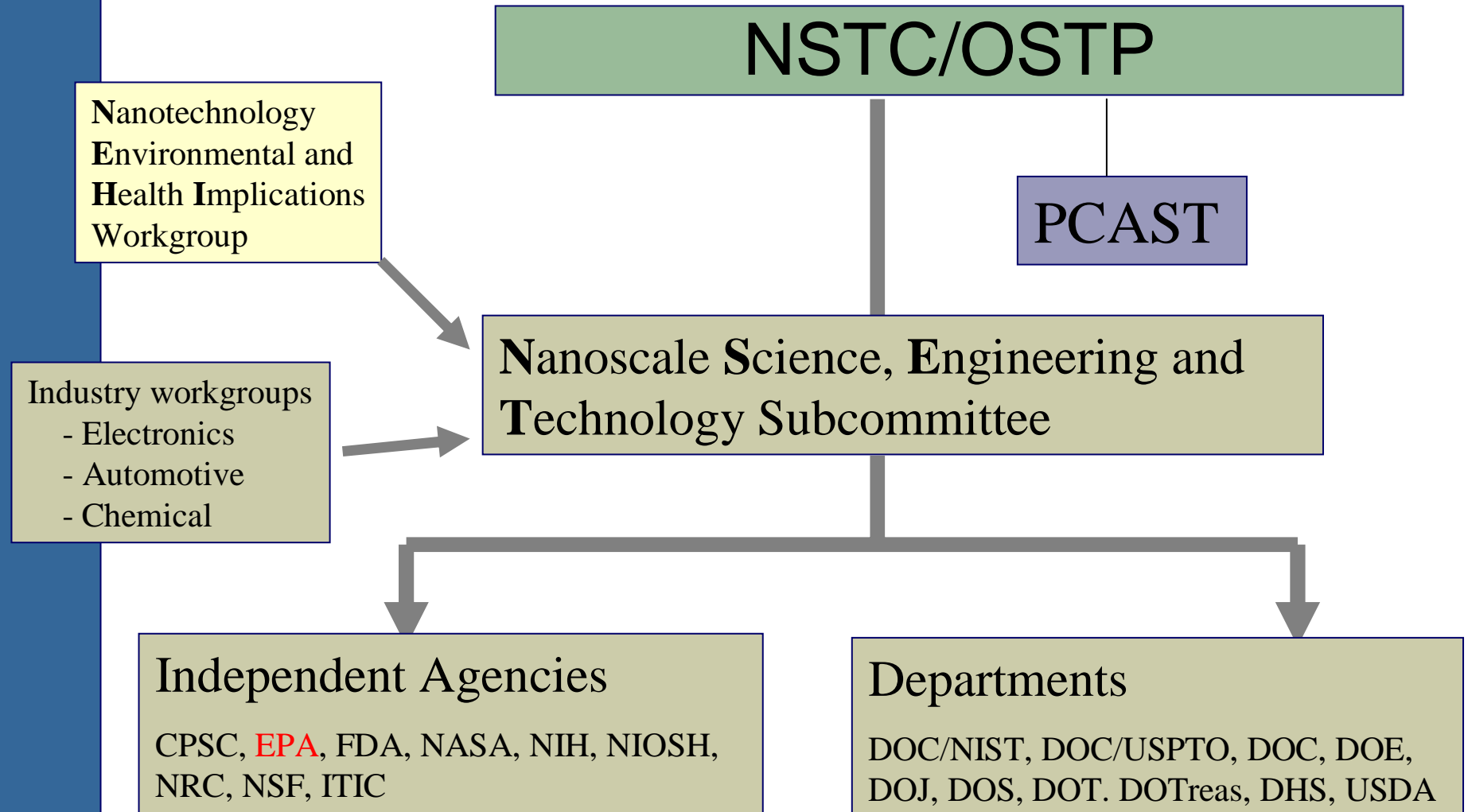
Office of Pollution Prevention and Toxics

U.S. EPA

December 7, 2005



Federal Coordinating Structure for NNI





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**



Approaches for Nanoscale Materials (NM) under Toxic Substances Control Act

- Requirement for new chemical notification depends on whether chemical substance is on the US Inventory
 - **New Chemicals:** Pre-Manufacture Notice (PMN) required before commencement of manufacture
 - **Existing Chemicals:** Notification not required
- Need for a clear distinction between “new” and “existing” chemicals that are nanoscale materials
- Need for an approach to evaluate “existing” chemicals that are produced at the nanoscale



TSCA New Chemicals Program

- 1 Low release, low exposure exemption granted (carbon nanotube)
- A number of PMN submissions under review
- Limits to use of standard assessment approaches
- Developing assessment and control approaches
- Considering testing strategies/methods



TSCA New Chemicals Program

- Developing interim decision logic for review and decision-making on NMs
 - Identification of potential concerns (workers, environment, consumers)
 - Testing recommendations (upfront, tiered)
 - Exposure controls (monitoring, PPEs)
 - Life-cycle analysis (unintended exposures)
- Need to identify and develop possible reporting approaches to better accommodate NM issues/understanding



Consideration of Voluntary NM Program

- EPA initiated effort to obtain public input on potential voluntary program for NMs
- Public meeting held June in Washington, DC
- General convergence of views in a number of areas and encouragement for EPA to proceed in an open and transparent manner
- EPA request for TSCA Advisory Committee to provide additional input (June).



Advisory Committee Consideration of Voluntary NM Program

- Advisory Committee initiated dialogue through an open process, with 3 public meetings in September, October and November
- Included consideration of voluntary and regulatory issues for both new and existing chemical NMs
- “Overview Document” forwarded to EPA for its review/consideration (November)



Advisory Committee Consideration of Voluntary NM Program

- Scope of program
 - Engineered NMs in commerce and “soon to enter commerce”
 - Participation available to new and existing NMs
- Two programmatic levels of commitment
 - **Basic:** Report material characterization info and implement basic risk management practices
 - **In-Depth:** development of additional detailed information (e.g., hazard and exposure/mitigation)



Advisory Committee Consideration of Voluntary NM Program

- Key Elements
 - Public scientific peer consultations
 - Basic set of material characterization information
 - Basic risk management practices
 - Timing and staging of Basic and In-Depth programs
 - Program evaluation
 - Robust, transparent
 - Consideration of reporting regulations to develop more comprehensive understanding
- Incentives
 - Small business outreach
 - Guidance for navigating regulatory system
 - Branding or other recognition for participation



EPA's Consideration of NM Stewardship Program

- Appreciates Advisory Committee and Public input
- Currently considering Stewardship Program based on Advisory Committee's approach
 - Possible role in complementing new chemicals requirements for NMs
 - Provides basis for additional dialogue ofor Stewardship Program on existing chemical NMs
- Timing of next steps: early in 2006



EPA White Paper

- EPA Science Policy Council (SPC) established an Agency workgroup to examine the applications and implications of nanotechnology for the consideration of Agency risk managers.
- Submitted for SPC consideration on November 23 and released for external peer-review on December 2.
- <http://www.epa.gov/osa/nanotech.htm>
- Publication (January 2006)



White Paper Draft Recommendation Areas

- Pollution Prevention and Stewardship
- Research
 - chemical identification and characterization
 - environmental fate
 - environmental detection and analysis
 - potential releases and human exposures
 - human health effects assessment
 - ecological effects assessment
- Risk Assessment
- Cross-Agency Workgroup
- Collaboration
- Training



Information Exchange

- U.S. Technical Advisory Group to Technical Committee on Nanotechnology of the International Standards Organization (US TAG to ISO TC 229)
- “Approaches to Safe Nanotechnology: An Information Exchange with NIOSH”
www.cdc.gov/niosh/topics/nanotech/nano_exchange.html
- “NIOSH web-based Nanoparticle Information Library (NIL)”
www.cdc.gov/niosh/topics/nanotech/NIL.html



Next Steps

- Development of interim NM decision logic for New Chemicals Program
- Development of Inventory guidance distinguishing between “new” and “existing” chemical substances that are nanoscale materials
- Decisions on/initiation of next steps for NM Stewardship Program
- Issuance of Agency White Paper