



Nanotechnology an EPA Perspective

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Nine Zeros Breakfast Forum

Office of Pollution Prevention and Toxics



Overview

- 21st Century Nanotechnology Research and Development Act (NRDA)
- National Nanotechnology Initiative (NNI)
- EPA Activities
- Current TSCA activities
- Nanoscale Materials Stewardship Program

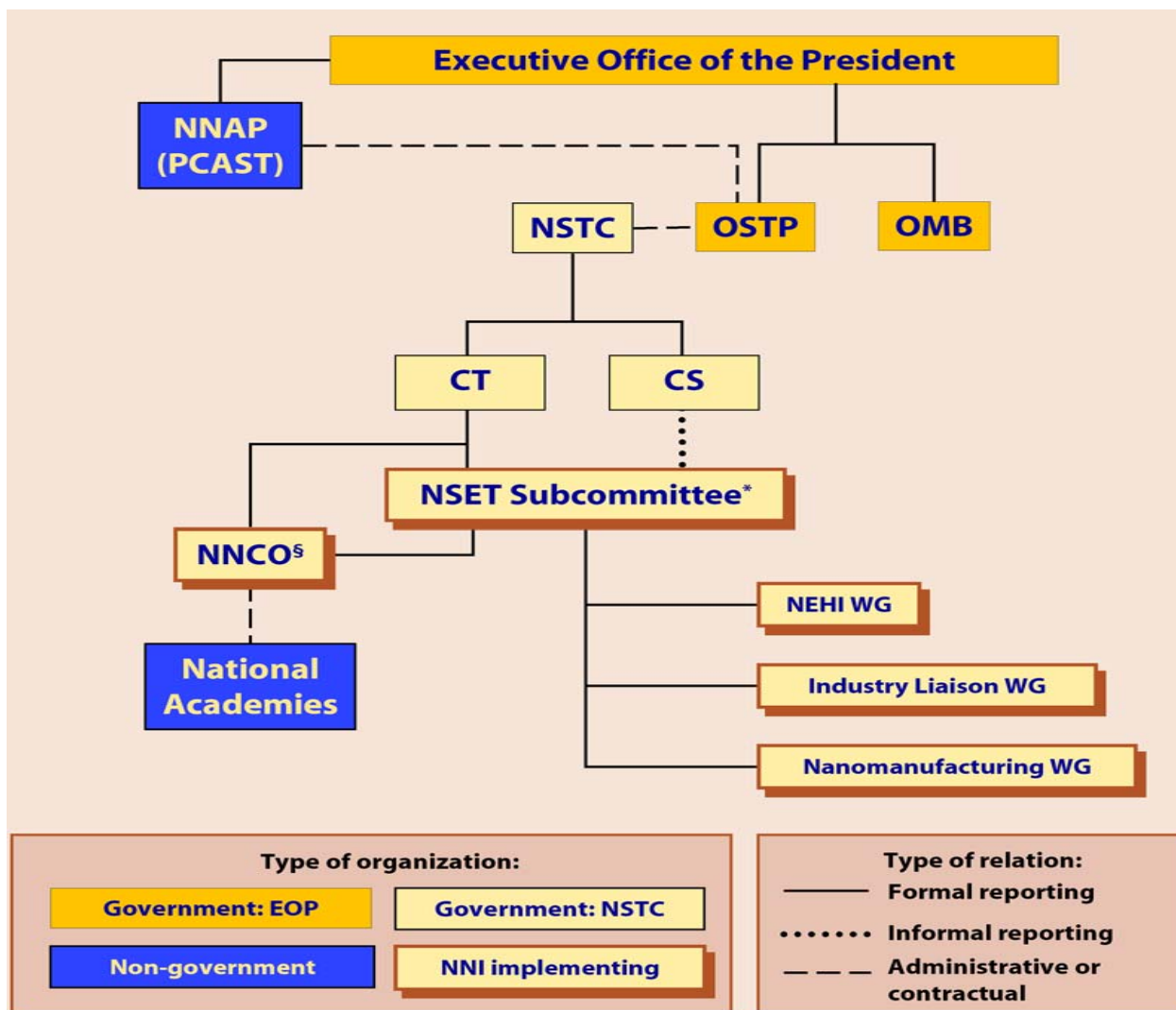


21st Century Nanotechnology Research and Development Act

- The NRDA resulted in implementation of the National Nanotechnology Initiative (NNI) to:
 - establish the goals and priorities for Federal nanotechnology R&D
 - invest in Federal R&D programs in nanotechnology to achieve those goals; and
 - provide for interagency coordination of Federal nanotechnology activities undertaken pursuant to NNI.



NNI Organization



PCAST: President's Council of Advisors on Science and Technology

NNAP: National Nanotechnology Advisory Panel

NSTC: National Science and Technology Council

CT / CS: Committee on Technology / Science

NSET: Nanoscale Science, Engineering, and Technology subcommittee

NNCO: National Nanotechnology Coordination Office

NEHI: Nanotechnology Environmental and Health Implications workgroup



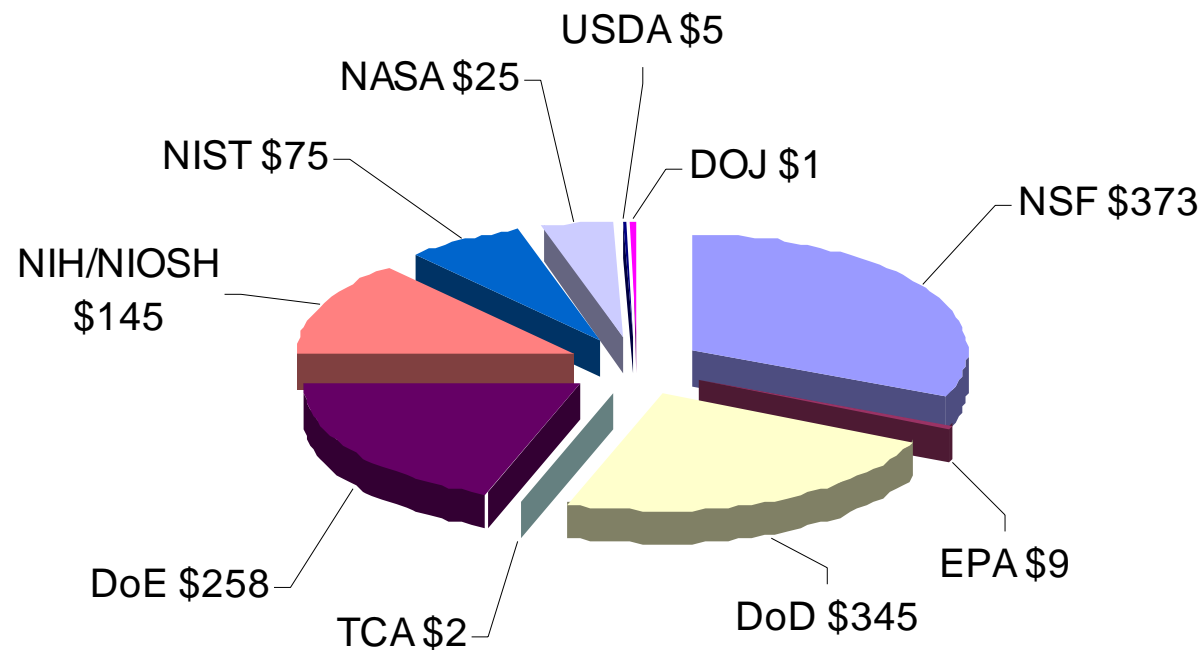
NNI Goals

- Maintain a world class research and development program aimed at realizing the full potential of nanotechnology
- Facilitate the transfer of new technologies into products for economic growth, jobs and other public benefits
- Develop educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology and
- Support the **responsible development** of nanotechnology



Nano in the US

Federal (NNI) funding = \$1.277 billion (2007 Request)*



- Total US spending (Fed, State, private) ~\$3 billion/yr
- ~ \$39 million/yr on EHS research (2006)

*www.nano.gov



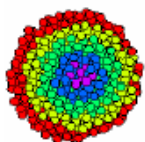
What is Nanotechnology?

Three elements, based on the NNI:

- **Size:** Approximately 1 – 100 nm in one or more dimensions
- **Properties:** Unique phenomena enabling novel applications
- **Control:** Deliberately engineered.



Timeline for beginning of industrial prototyping and nanotechnology commercialization: Four Generations



~2000

1st Passive Nanostructures

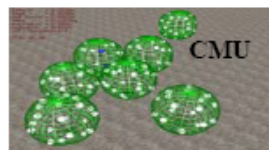
Ex. Coatings, nanoparticles, nanostructured metals, polymers, ceramics



~2005

2nd Active Nanostructures

Ex. 3D transistors, amplifiers, targeted drugs, actuators, adaptive structures



~2010

3rd Systems of Nanosystems

Ex. Guided assembling; 3D networking and new hierarchical architectures, robotics, evolutionary



~2015-2020

4th Molecular Nanosystems

Ex. Molecular devices 'by design', atomic design, emerging functional systems



Products on the Market

- Step assists on vans
- Bumpers on cars
- Metal-cutting tools
- Sunscreens and cosmetics
- Longer-lasting tennis balls
- Light-weight, stronger tennis racquets
- Stain-free clothing and mattresses
- Dental-bonding agent
- Burn and wound dressings
- Ink
- Automobile catalytic converters
- Paints and coatings to protect against corrosion, scratches and radiation
- Protective and glare-reducing coatings for eyeglasses and cars

Estimate 80-90 consumer products on the market*

List from www.nano.gov

**Emtech*



EPA Activities - Research

- Office of Research & Development (ORD)
Grants and Research

Applications – e.g., remediation and sensor products

Implications – e.g., health and environmental safety research on nanoscale materials most likely to be found in commerce

Extramural (STAR) Grants

- Through 2005, 65 grants awarded for approx. \$22 million
- Approx. 50/50 applications and implications research
- Grants for 2006 on implications are in process of final selection/funding by EPA, NSF, NIOSH, NIEHS.
- Information available online at www.epa.gov/ncer/nano



EPA White Paper

- Science Policy Council (SPC) created a cross-Agency workgroup to develop a white paper
 - Input and review by all EPA Offices.
 - Describes the potential environmental benefits of nanotechnology; identifies risk assessment issues and research needs; and provides recommendations for next steps.
 - On February 15 EPA published the White Paper
 - www.epa.gov/osa/nanotech.htm.



EPA Activities

- Office of Air -- reviewing an application under the CAA for registration of a diesel additive that claims to be nanosized cerium oxide.
- Office of Pesticides -- receiving inquiries about nanoscale materials and is forming a workgroup to consider issues
- Office of Solid Waste -- held a workshop July 2006 on nanotechnology and waste management practices
- Office of Pollution Prevention and Toxics (OPPT) -- has received new chemical notifications and is developing a stewardship program



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
- There is presently no similar requirement for NMs that are existing chemicals, i.e. already on the TSCA inventory
- The 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 realize oversight of “existing” chemical NMs
 - An appropriate degree of industry stewardship in the manufacture and use of new and existing chemical NMs



TSCA New Chemicals Program Experience/Issues

- PMN submissions on nanosized chemicals are being received and reviewed but most have not met other elements of NNI definition -- unique properties or deliberately engineered
 - A low release, low exposure exemption has been granted (carbon nanotube)
- There have been several recent company meetings on pending new chemical NMs
- General approach has been to permit limited manufacture of nanosized new chemicals under appropriate controls via use of consent orders and Significant New Use Rules (SNURs)



TSCA New Chemicals Program Experience/Issues

- There are limits to use of standard assessment approaches; information is needed to help guide assessments
- Potential submitters are strongly encouraged to use the pre-notice consultation process to help expedite reviews
- Industry needs clear direction on what is a “new” versus “existing” chemical NM
- Requirement for reporting of **substantial risk** information under Section 8(e)



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
- <http://www.epa.gov/oppt/nano/>



OPPT Approach

- NMs Program under TSCA that includes
 - Both regulatory and stewardship components
 - Encourages responsible development of NMs
- Regulatory:
 - New Chemicals Program
 - Issue targeted SNURs for specific NMs or categories where there is evidence of
 - Risk concerns
 - Significant exposure/release potential
 - Information gathering
 - Section 8(a) – report use and exposure data
 - Section 8(d) – report health and safety studies



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
 - Provides for the responsible development called for in the NRDA and by NNI



Stewardship Program

- **Step 1 – Collaborative 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
 - Public Docket: EPA-HQ-OPPT-2004-0122



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; e.g.
 - Continue or modify program
 - Take regulatory steps (e.g., SNURs, revisions to PMN reporting form)



Related Activities

- **P2 Conferences**
 - ORD/OPPT will jointly hold a conference on the pollution prevention benefits of NMs in 2007
 - ORD will hold a conference on the clean development of NMs in 2007
- **Organisation for Economic Co-operation and Development (OECD)** – the OECD established a Working Party on Manufactured Nanomaterials to consider the environmental health and safety implications of manufactured NMs.
- **Voluntary Consensus Standard Activities**
 - American National Standards Institute- Nanotechnology Standards Panel (**ANSI-NSP**)
 - U.S. Technical Advisory Group to Technical Committee on Nanotechnology of the International Standards Organization (**US TAG to ISO TC 229**)
 - American Society for Testing and Materials Nanotechnology Committee (**ASTM E56**)



Summary/Contact Information

- Responsible Development
- What does Nanotechnology mean to you
- Limited Information
- Open Transparent Process

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