

Nanotechnology Regulation at EPA

September 22, 2010

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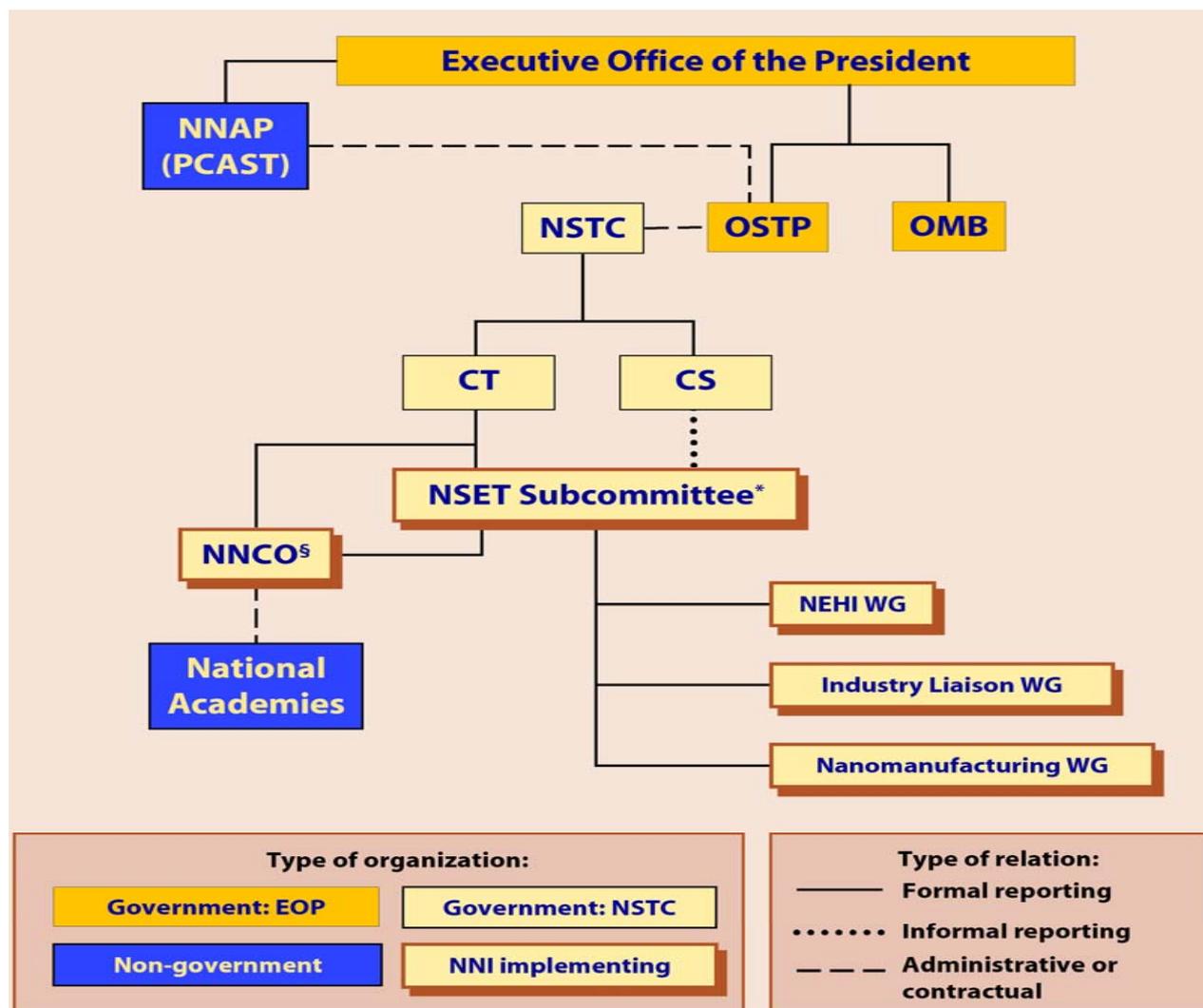


Why the Interest?

- The nanotechnology sector appears poised for considerable economic growth.
- Considerable federal R&D spending has been earmarked for nanotechnology - National Nanotechnology Initiative (NNI).
- The physical phenomenon of “unique properties” lends itself to wondering if there may also be unique toxicological effects.
- Some studies have demonstrated toxic and pharmacokinetics implications of concern.
- There is considerable need for additional environmental, health and safety (EHS) data on nanomaterials including metrics for risk assessment
- New applications will likely lead to new exposure scenarios.
- Potential environmental benefits.



NNI Structure



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 – venue for coordination with 25 NNI agencies

NNCO: National Nanotechnology Coordination Office

NEHI: Nanotechnology Environmental and Health Implications workgroup



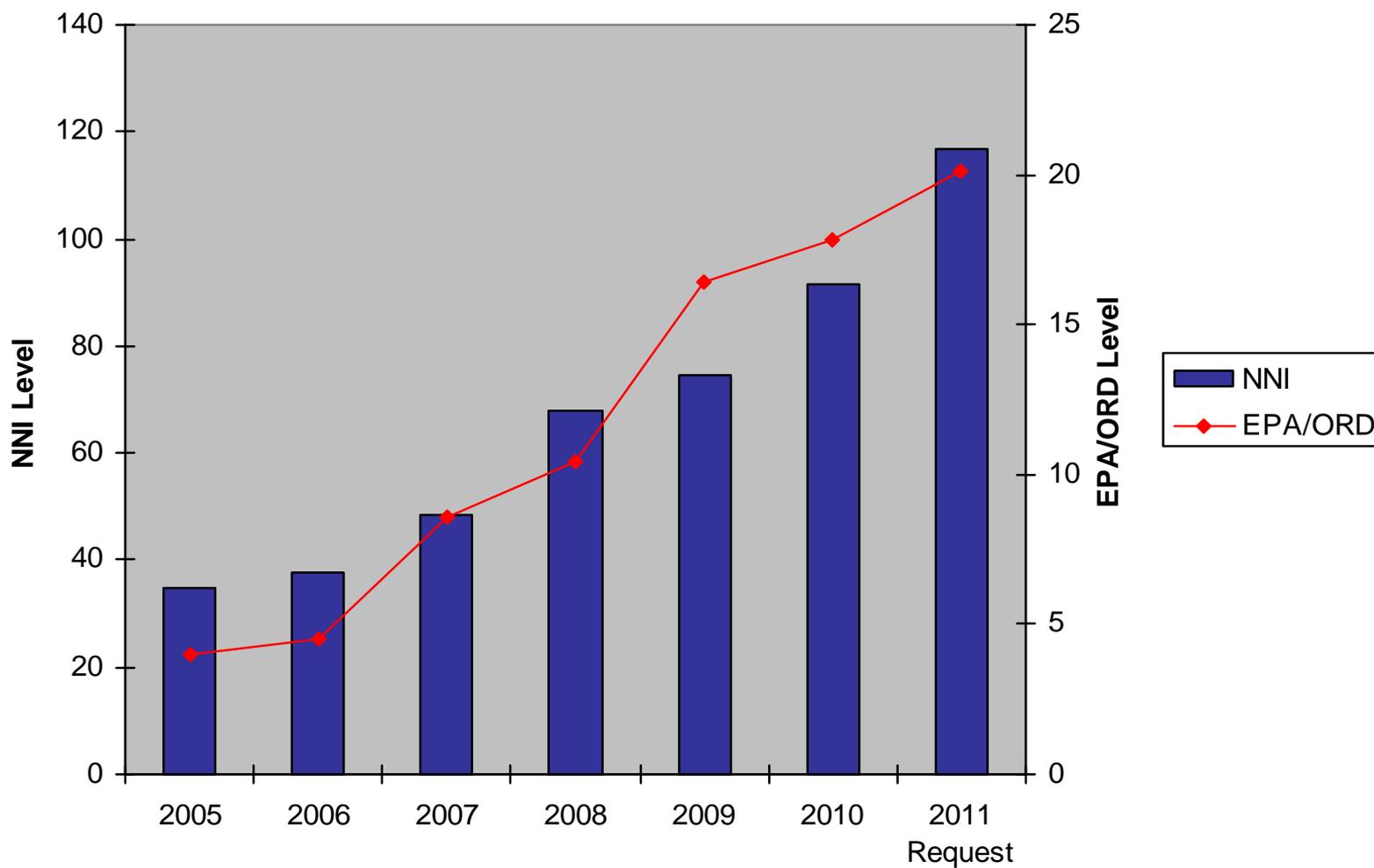
Nanotechnology White Paper: Purpose

- Mandated by the Science Policy Council
- Provide information for EPA managers
- Communicate nanotechnology science, science policy, and research issues important to EPA. (Not designed to address regulatory issues.)
- Focus on describing:
 - the technology
 - internal and external activities
 - potential environmental applications
 - potential human health and environmental implications
 - research needs
- Issued in February 2007



Nanotechnology EHS Budget

Total NNI and EPA (\$ Million)





How EPA is Allocating its Nanotechnology Research Resources

- 50% Sources, Fate, Transport, and Exposure
- 30% Human Health and Ecological Effects
- 10% Risk Assessment Methods and Case Studies
- 10% Preventing and Mitigating Risks

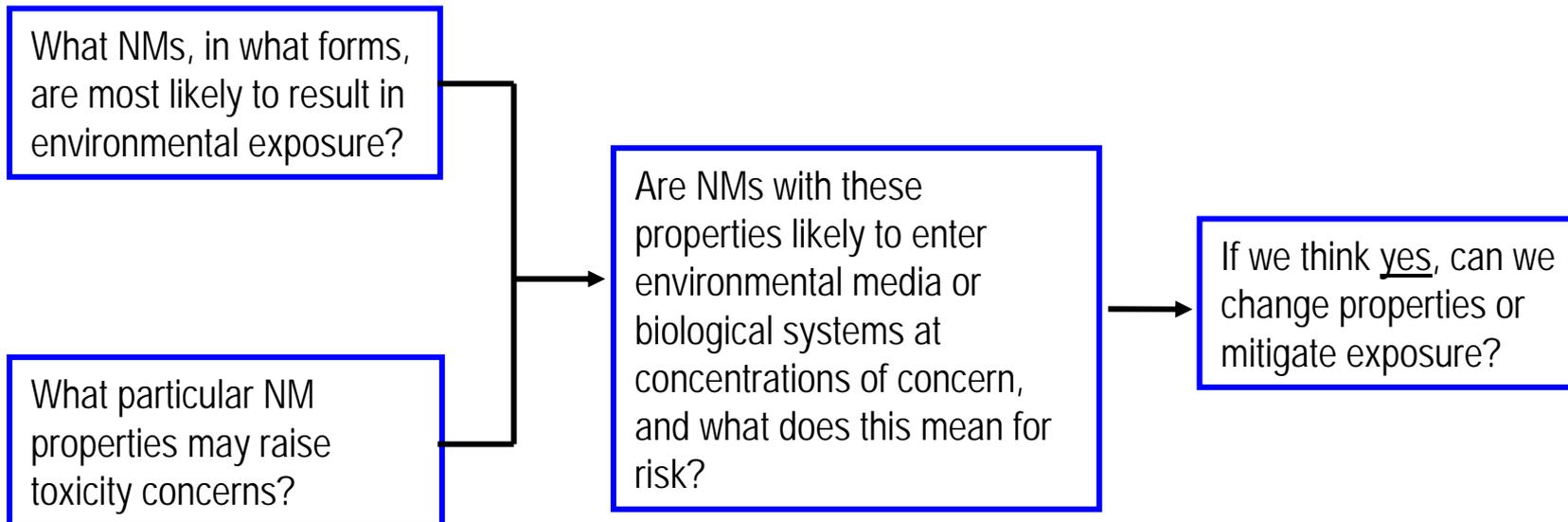
Challenges:

Potential Release and Exposure: How much of what materials are/will be produced for what uses?

Properties: What properties make a material toxic, mobile, persistent, and bioavailable?



Nanomaterials and Environmental Decision Making: A Few Simple Questions





General Nanoscale Material (NM) Approach Under TSCA

- New Chemicals Program
 - Pre-manufacture Notices (PMNs)
 - Low Release/Exposure Exemption (LoREX)
 - Significant New Use Rules (SNURs)
 - Consent Orders
- Existing-chemical based nanomaterials
 - SNURs for Existing NMs
 - Section 4 test rule
 - Section 8(a) – report existing data
 - Section 8(e) – notices of substantial risk



Toxic Substances Control Act (TSCA)

- TSCA provides broad authority to:
 - Gather information on new and existing chemical substances and mixtures
 - Require testing of chemicals
 - Screen and control unreasonable risks of new and existing chemicals
 - Coordinate with other Federal agencies



New Chemicals Program

Chemicals not on the TSCA Inventory

- Manufacturers or importers of new chemicals submit premanufacture notices (PMN) [TSCA §5 (a)]
- Regulation Pending Development of Information [TSCA §5(e)]
- Significant New Use Rules (SNUR) [TSCA §5 (a) (2)]



NMs under TSCA

- Chemical substances as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are “new chemicals”
 - TSCA definition based on molecular identity, not on other properties
 - Fullerenes and carbon nanotubes
- NMs on the TSCA Inventory are “existing chemicals”
 - Some metal oxide particles
- EPA paper on TSCA Inventory status of NMs
- Different tools available depending on whether a chemical is “new” or “existing”



TSCA New Chemicals Program

- More than 100 new chemical notices for NMs have been received since 2005
- Some notices are reporting exemptions
- Numerous PMNs have completed the 90-day review period
 - Requirements to prevent human and environmental exposure
 - Requirements to develop data
 - Consent Orders
 - SNURs – many already published



Carbon Nanotubes (CNT) under TSCA

- October 31, 2008 CNT Federal Register Notice regarding chemical identity questions and enforcement
- Allotropes of carbon such as CNT are considered “new”
- CNT consent orders
 - 90 day inhalation toxicity studies
 - 1 gram sample – screening testing
 - Material characterization
 - Embedded in a polymer/metal matrix
 - Personal protective equipment for workers



Examples

- Carbon-, Silica-, Titania- derivatives are handled on a case-by-case basis
 - Personal protective equipment
 - Use/formulation limitations
 - Fractional restrictions on particles <100nm
 - Require testing
 - Aligned with standing new chemicals policy for respirable poorly soluble particulates
- EPA has received PMNs for fullerenes and modified fullerenes
- Emerging complex nanomaterials in the <<one gram production volume range



Public Comments for CNT SNURS

- EPA did not adequately identify CNTs
- EPA did not make an adequate risk finding
- Changing reviews as new data becomes available
 - one company specifically requested that EPA include latest data/findings
- When does a CNT become a different chemical
- Applicability of regulation when bound in a polymer matrix and other forms
- Applicability of SNUR to R&D activity



Future Directions New Chemicals

- Development of chemical categories for NMs
- Integration of test data into PMN reviews
 - PMNs and consent orders
 - TSCA 8(e) data
 - Academic research
 - ORD and NNI data
 - International (OECD) data
 - NMSP data



Nanoscale Materials Stewardship Program (NMSP)

- In January 2008, OPPT introduced a voluntary reporting program for nanoscale materials based on chemicals on the TSCA Inventory
- NMSP was a limited success
 - 31 companies submitted reports
 - 132 unique nanoscale materials
- OPPT analyzed the interim results and determined that:
 - 2/3rds of the chemical substances from which commercially available nanomaterials are based were not reported
 - 90% of the different nanomaterials that are likely to be commercially available were not reported
 - Completeness of NMSP reporting uncertain
- Issued Interim Report for the Nanoscale Materials Stewardship Program (NMSP) on January 12, 2009



Existing Chemicals

- SNUR to require reporting of new nanoscale materials that are existing chemicals
- Section 4 rule to require testing of certain nanoscale materials
- Section 8(a) rule to require reporting of available use, production volume, exposure, and toxicity data for existing nanoscale materials



Nanotechnology Benefits

- EPA held a P2 through Nanotechnology conference in Washington in 2007
 - Nearly 250 participants; considerable interest
- OECD conducted an international conference on environmental benefits in Paris July 15-17
- OECD WPMN project on Environmentally Sustainable Use of Nanotechnology



Other EPA Offices

- Office of Pesticide Programs
 - Nanosilver Pesticide Applications
 - Scientific Advisory Panel – Nov 2009
 - How to treat active and inert ingredients that are nanoscale materials
 - Data that will be required
- Office of Air
 - Fuel additives (e.g. Cerium Oxide)



OECD WPMN

- Organization for Economic Cooperation and Development - Working Party on Manufactured Nanomaterials
- Established in September, 2006
- Objective: *To promote international cooperation in health and environmental safety related aspects of manufactured nanomaterials, in order to assist in their safe development*
- Works through the implementation of 9 projects via “Steering Groups”



Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

- Objective: *to agree and test a representative set of manufactured nanomaterials (MN) using appropriate test methods.*
- Status:
 - Testing program encompasses 13 nanomaterials and a range of endpoints
 - Guidance manual developed
 - Alternative testing add-ons likely

	Lead sponsor(s)	Co-sponsor(s)	Contributor
Fullerenes(C60)	Japan, US*		China, Denmark
SWCNTs	Japan, US*		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, US*	Korea, BIAC	Canada, Germany, France, EC, China, BIAC
Silver nanoparticles	Korea, US	Australia, Canada, Germany, Nordic Council	France, EC, China
Iron nanoparticles	China, BIAC		Canada, US, Nordic Council
Gold	South Africa		
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, US*, BIAC	China, Denmark
Aluminium oxide			Germany, US
Cerium oxide	US*, UK/BIAC	Australia, Netherlands, Spain	Germany, Switzerland, EC
Zinc oxide	UK/BIAC	Australia, Spain, US, BIAC	Canada
Silicon dioxide	France, EC	Belgium, Korea, BIAC	Denmark
Dendrimers		Spain, US*	
Nanoclays			Denmark, US



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