Nanotechnology at EPA

Nanotechnology Health and Safety Forum
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Jim Alwood
Chemical Control Division
Office of Pollution Prevention and Toxics

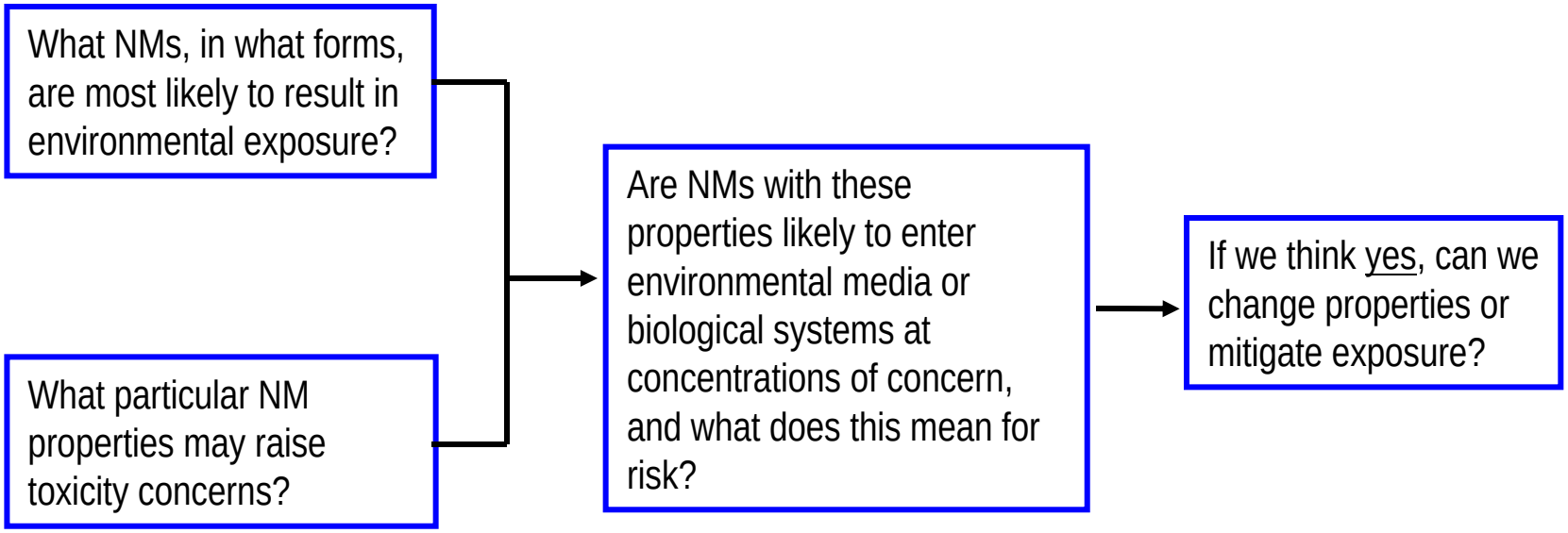
Why the Interest?

- 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.
- New applications will likely lead to new exposure scenarios.
- Potential environmental benefits.

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

ORD - Nanomaterials and Environmental Decision Making: A Few Simple Questions



EPA's Nanomaterial Research Strategy (NRS)

- Integrated extramural and in-house program designed to deliver decision-support information to EPA's program and regional offices
- *Themes:*
  - Sources, fate, transport, exposure
  - Human health and ecological effects
  - Risk assessment methods
  - Risk prevention and mitigation

Issues, Path Forward

- *Near Term*
  - Implementing EPA's nanotechnology research strategy
  - Interagency coordination
    - International coordination; OECD involvement
  - Providing near-term decision support
- *Longer Term*
  - Capacity building
  - Evolving the research program as needs change
  - Developing an integrated, multidisciplinary nanotechnology research team

General Nanoscale Material (NM) Approach Under TSCA

- Address new and existing chemical-based nanomaterials through a combination of regulatory and voluntary components
- New Chemicals Program
  - Pre-manufacture Notices (PMNs)
  - Significant New Use Rules (SNURs)
  - Consent orders where needed
- Section 8(e) – notices of substantial risk

General Nanoscale Material (NM) Approach Under TSCA

- Existing-chemical based nanomaterials
  - Basic reporting
  - In-depth program
  - Regulations if/where appropriate, e.g.,
    - Targeted SNURs for NMs/categories where
      - » Risk concern and/or
      - » Significant exposure/release potential
    - Data Development
      - Section 4 test rules
    - Information gathering
      - Section 8(a) – report use and exposure data
      - Section 8(d) – report health and safety studies

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”

Current Approach: TSCA New Chemicals Program

- More than 60 new chemical notices for NMs have been received since 2005
- Bona Fide Intent Notices are also being received on a regular basis
- Reporting exemptions may be possible in some cases
- A number of PMNs have cleared the 90-day review period
  - Companies have agreed to/taken steps to protect against human and/or environmental exposure where applicable
  - In some cases, data development is necessary
  - Consent orders applied in some cases
  - To date, PMNs have been regulated by a SNUR
- Reviews are becoming increasingly standardized.

Examples

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

Carbon Nanotubes (CNTs) under TSCA

- October 31, 2008 CNT Federal Register Notice regarding chemical identity questions and enforcement
- Allotropes of carbon such as CNT are considered “new”
- Outreach to CNT producers
- CNT consent orders
    - 90 day toxicity studies (to date, inhalation only)
    - 1 gram sample – screening testing
    - Material characterization
    - Use restrictions
        - Must be embedded in a polymer/metal matrix and/or
        - Personal protective equipment for workers
- Close cooperation with California, Canada, Japan and EU on CNTs
- Compliance focus beginning in March 2009

Future Directions
New Chemicals

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

Future Directions
Existing Chemicals

- Issued Interim Report on January 12, 2009
- Continue to encourage participation
- Issue final report in early 2010
- Pursue In-depth testing
- Develop TSCA section 8(a)/4 rules to help fill data gaps

Nanotechnology Benefits

- EPA held a P2 through Nanotechnology conference in Washington in 2007
  - Nearly 250 participants; considerable interest
- EPA, working through the OECD is organizing an international conference on environmental benefits in Paris July 15-17
- ORD STAR grants
- Life Cycle Analysis under development for CNTs/batteries
- Links to climate and energy issues

Other EPA Offices

- OPP
  - Nanosilver antimicrobials
- OAR
  - Fuel additives (e.g. Cerium Oxide)
- OSWER
  - Site remediation (Nanoscale Zero Valent Iron)

16

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 8 projects via “Steering Groups”

OECD WPMN Projects

- **Project 1:** Database on Safety Research
- **Project 2:** Research Strategies on Manufactured Nanomaterials
- **Project 3:** Safety Testing of a Representative Set of Manufactured Nanomaterials
- **Project 4:** Manufactured Nanomaterials and Test Guidelines
- **Project 5:** Cooperation on Voluntary Schemes and Regulatory Programs
- **Project 6:** Cooperation on Risk Assessment
- **Project 7:** Alternative Methods in Nano Toxicology
- **Project 8:** Exposure Measurement and Exposure Mitigation

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 14 nanomaterials and a range of endpoints
  - Guidance manual developed
  - Alternative testing add-ons likely

OECD Sponsorship Arrangements

as of 3 December 2008

	Lead sponsors	Co-sponsors	Contributors
Fullerenes(C60)	Japan, US		China, Denmark
SWCNTs	Japan, US		Germany, Canada, EC, France, China, BIAC*
MWCNTs	Japan, US	Korea, BIAC	Germany, Canada, EC, France, China
Silver nanoparticles	US, Korea	Germany, Canada, Nordic Council of Ministers, Australia	China, EC, France
Iron nanoparticles	China		Canada, US, Nordic Council of Ministers
Carbon black			Germany, US
Titanium dioxide	France, Germany	Canada, Spain, BIAC, Korea, US, Austria	Denmark, China
Aluminium oxide			Germany , US
Cerium oxide	UK/BIAC(NIA), US	Netherlands	Australia, Germany, EC, Switzerland
Zinc oxide	UK/BIAC(NIA)	BIAC(CEFIC), Australia, US	Canada
Silicon dioxide	France, EC	BIAC(CEFIC), Korea, Belgium (awaiting confirmation)	Denmark
Polystyrene			Korea
Dendrimers		Spain	US
Nanoclays			US, Denmark

* Business and Industry Advisory Committee

Contact Info

http://www.epa.gov/oppt/nano/

www.regulations.gov

epa-hq-oppt-2004-0122

alwood.jim@epa.gov

202 564-8974