

The background of the slide is a solid blue color with a large, faint, circular seal of the United States Environmental Protection Agency (EPA) centered behind the text. The seal features a central emblem with a sun, a tree, and a water drop, surrounded by the words "UNITED STATES ENVIRONMENTAL PROTECTION AGENCY".

# Nanotechnology at EPA

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**Jim Alwood**  
**Chemical Control Division**  
**Office of Pollution Prevention and Toxics**



# Nanomaterials (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”



# 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 (ToxCast)
  - Material characterization
  - Use restrictions
    - Must be embedded in a polymer/metal matrix and/or
    - Personal protective equipment for workers
- Compliance focus in March 2009



## Current Activity: 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, these PMNs have been regulated by a SNUR



# Examples

- Carbon-, Silica-, Titania- derivatives are handled on a case-by-case basis
  - Personal protective equipment
  - Use/formulation limitations
  - Fractional restrictions on particles  $<100\text{nm}$
  - 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 (previous slide)
- Emerging complex nanomaterials in the  $\ll$ one gram production volume range



# General 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
- Nanoscale Materials Stewardship Program (NMSP) for existing-chemical based nanomaterials
  - Basic reporting
  - In-depth program
  - Backstopping through 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
- Section 8(e) – notices of substantial risk



# 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 NMSP participation
- Issue final report in early 2010
- Pursue In-depth testing
- Pursue possible TSCA section 8(a)/4 rules to help fill data gaps



# 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 (final peer review comments received Dec. 10, 2008)
  - 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



# NATIONAL NANOTECHNOLOGY INITIATIVE

The National Nanotechnology Initiative (NNI) provides a multi-agency framework to ensure U.S. leadership in nanotechnology that will be essential to improved human health, economic well being and national security. The NNI invests in fundamental research to further understanding of nanoscale phenomena and facilitates technology transfer.

Leading to a Revolution in Technology and Industry

[www.nano.gov](http://www.nano.gov)

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

- 2001: NNI created as a federal initiative
- 2003: 21st Century Nanotechnology Research and Development Act (Public Law 108-153)
- 26 Agencies (13 with R&D budgets)
- The goals of the NNI are to:
  - Maintain a **world-class research and development program** aimed at realizing the full potential of nanotechnology
  - Facilitate **transfer of new technologies** into products for economic growth, jobs, and other public benefit
  - Develop **educational resources, a skilled workforce, and the supporting infrastructure** and tools to advance nanotechnology
  - Support **responsible development** of nanotechnology



# 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



# TSCA Website and Docket

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

[www.regulations.gov](http://www.regulations.gov)

**epa-hq-oppt-2004-0122**