

TSCA Nanotechnology Regulations at EPA

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Jim Alwood
Chemical Control Division
Office of Pollution Prevention and Toxics



General Approach Under the Toxic Substances Control Act (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



Nanoscale Materials (NM) under TSCA

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



TSCA New Chemicals Program

- More than 90 new chemical notices for NM 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)

- 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



Other Examples

- Carbon-, Silica-, Titania- derivatives are handled on a case-by-case basis
 - Personal protective equipment
 - Use/formulation limitations
 - Fractional restrictions on particles $<100\text{nm}$
 - 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 \ll 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



Existing Chemicals

- Issued Interim Report for the Nanoscale Materials Stewardship Program (NMSP) on January 12, 2009
- Issue final report in 2010
- SNUR to require reporting of new nanoscale materials that are existing chemicals
- Section 4 rule to require testing
- Section 8(a) rule to require reporting of available use, production volume, exposure, and toxicity data