



# **Nanotechnology Update**

## **GlobalChem 2009**

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# Current 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
- Voluntary approach 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



# 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 50 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
- 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  $<100\text{nm}$
  - Testing as appropriate
  - Aligned with standing new chemicals policy for respirable poorly soluble particulates
- EPA has received the first PMNs for fullerenes and modified fullerenes
- Carbon nanotubes (next slide)
- Complex nanomaterials in the  $\ll$ 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 (ToxCast)
  - Material characterization
  - Use restrictions
    - Must be embedded in a polymer/metal matrix and/or
    - Personal protective equipment for workers
- Cooperation with California, Canada, Japan and EU on CNTs
- Focus on CNT compliance after March 2009



# Future Directions for New Chemicals

- Development of new chemical category(s) 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)

- Complements and informs regulatory approach
- Increases experience with risk assessment/ mitigation
- Provides insight on test data to be developed
- Generation of test data to provide sound scientific basis for decision-making
- Encourages risk management practices



# NMSP Components

- Basic Program – participants report existing information on nanoscale materials
  - physical and chemical properties
  - hazard data
  - exposures
  - uses
  - risk management practices
- In-Depth Program - sponsors develop data on representative nanoscale materials



# Basic Program Results

- 29 companies have submitted data
- 123 unique nanoscale materials
- 12 of 14 OECD materials covered by submissions and commitments
- <http://epa.gov/oppt/nano/stewardship.htm>



# In-Depth Program

- Four commitments
  - three for carbon nanotube manufacturers
  - one for a carbon nanoparticle producer
- Companies/consortia can still participate
- EPA working with some additional potential participants
- Initial meeting of participants April 2009



# OECD WPMN Project 3: Safety Testing of a Representative Set of Manufactured Nanomaterials

- Objective: *to agree and test a representative set of manufactured nanomaterials using appropriate test methods.*
- Status:
  - Testing program encompasses 14 nanomaterials and a range of endpoints
  - Alternative testing add-ons likely



# OECD Sponsorship Arrangements

as of 3 December 2008

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

\* Business and Industry Advisory Committee



# General Path Forward

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



# Contact Info

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