

**International Workshop on
Challenges to
Increased Use of Documentary
Nanotechnology Standards
December 13-14, 2011**

Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention

Toxic Substances Control Act

- The Toxic Substances Control Act (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
 - Nanoscale materials are subject to TSCA

Toxic Substances Control Act

- Under TSCA, EPA has assessed more than 120 nanoscale materials
 - Carbon nanotubes, fullerenes, quantum dots, and titanium/silica based compounds
 - Information provided by industry
 - Consideration of appropriate published data
- No specific regulatory requirements, including standards, for the data that must be submitted
- In the future, EPA plans to assess under TSCA
 - Other metal oxides and metals
 - Nanoclays

Federal Insecticide, Fungicide, and Rodenticide Act

- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires:
 - All pesticides to be “registered” (licensed) before they may be sold or distributed in commerce
 - Applicants for registration are required to provide information showing proposed use of the pesticide will not “cause unreasonable adverse effects on the environment” – the safety determination
 - EPA to weigh the potential risks and benefits of use when deciding whether to register a pesticide

Federal Insecticide, Fungicide, and Rodenticide Act

- Mandatory information and methods required as part of application to register pesticide
 - Product Identity and Composition
 - Physical and Chemical Properties
 - Health Effects (Toxicology)
 - Ecological Effects
 - Human Exposure
 - Found in 40 CFR 158 & 161

Federal Insecticide, Fungicide, and Rodenticide Act

- On Dec 1., EPA conditionally registered a product containing nanosilver (*i.e.*, HeiQ AGS-20)
 - Safety finding based on toxicity data for analogous forms of nanosilver
 - Four years to develop data to confirm EPA's safety finding
 - EPA has immediate need for standards!

Characterization

- Specific standards are necessary for each aspect of assessing and managing potential risks from nanomaterials.
 - Identifying nanoscale materials subject to regulations or reporting
 - Characterizing nanomaterials that are being tested for exposure or hazard, including particle size determination
 - Identifying other relevant parameters such as shape or surface area

EPA Areas of Interest for Standards

- Identification of Nanoscale Materials
- Physicochemical Characterization
- Environmental Fate
- Exposure Assessment for Humans and the Environment
- Toxicity Testing Guidelines

Identification of Nanomaterials

- No standardized nomenclature
- General terminology for science and technology can be helpful for describing nanomaterials
 - Not usable in a regulatory context
- Need standardized terminology and nomenclature

Physicochemical Characterization

- Physicochemical characterization critical for assessment of nanoscale materials
- Need accurate identification of materials submitted to EPA
- While under FIFRA, EPA requires the submission of product-specific information, in assessments under TSCA, EPA often relies on analogs

Physicochemical Characterization

- Characterization of nanomaterials in toxicity studies
 - Physicochemical characterization is critical to understanding what has been the subject of toxicity studies
 - Poor physicochemical characterization of nanomaterials limits the usability of many studies
 - Partially due to lack of standards
 - Partially because many researchers have not been aware of the importance of characterization and the aspects of nanoscale materials that should be characterized
 - Limits the usability of toxicity data on analogs

Physicochemical Characterization

- Existing standards
 - Often not specific to nanomaterials, *or*
 - Cannot be used for nanomaterials, *or*
 - Are not specific to individual types of nanomaterials
 - Important to identify
 - Often not agreed-upon standards for individual types of nanomaterials

Environmental Fate

- Removal during wastewater treatment
 - EPA guideline was recently found not appropriate for estimating removal efficiency of nanomaterials
- Determining impact of nanomaterials on wastewater treatment processes
 - Differences among countries on impacts and test conditions that should be used

Exposure Assessment

- EPA partnering with International Life Sciences Institute on the NanoRelease Project
 - Release measurement for multiwalled carbon nanotubes embedded in polymers
- Life Cycle
 - Interested in end-of-life issues such as stability of nanocomposites to light
- FIFRA requires rate of release from materials preserved with nanomaterial pesticides

Example - Dustiness

- Assessing potential exposure by measuring dustiness
 - For some materials one exposure technique is to measure how dusty the material is – *i.e.*, how likely is handling and transport of the material to cause exposure to particles
 - For carbon nanotubes and other nanomaterials this type of test cannot be easily conducted because existing test protocols and technique are not applicable when particles are already in the nanoscale

Example - Carbon Nanotubes

- Applicability of results of 90-day Inhalation Study for carbon nanotubes (CNT)
 - 90-day inhalation studies of have been conducted to meet certain TSCA requirements
 - In order to test CNT it is necessary to physically break down the agglomerates or aggregates to dose the animals
 - Without characterization standards comparing the CNT form tested to the CNT form humans are exposed to risk assessment is uncertain

Toxicity Testing Guidelines

- Some existing guidelines are applicable to testing of certain nanoscale materials
- EPA is working with other stakeholders within the OECD Working Party on Manufactured Nanomaterials (WPMN) to evaluate existing test guidelines and develop guidance for testing nanomaterials
- OECD WPMN is looking to ISO for standards that can be used to modify test guidelines so that they can be applicable for nanomaterials

Other Standards Development

- Use NIOSH data and techniques for evaluating worker exposure
- Working with Chemical Abstract Services to develop nomenclature for CNTs
- Protocols between EPA and companies for purposes of FIFRA will reference standards

Do Current Standards Meet Needs?

- No - Several examples have noted toxicity, exposure, and characterization tests that have been conducted but conclusions from that testing have either been not usable or uncertain
- The current situation is that EPA is not always certain if test results are accurately assessing potential risks or characterizing nanomaterials

Summary

- Standards broadly applicable to all types of nanomaterials often not useful or even feasible in a regulatory situation
- Need standards that are specific to individual types of nanomaterials
- New metrics may be needed
- Need to specify categories, particle sizes, or other characteristics applicable to new or existing metrics