

Assessment and Management of Nanomaterials Under the Toxic Substances Control Act

European Chemicals Agency (ECHA) Topical
Scientific Workshop: Regulatory Challenges in Risk
Assessment of Nanomaterials

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Legislation

- No United States legislation specific to nanoscale materials
- Nanoscale materials managed under existing authorities for
 - Chemicals
 - Pesticides
 - Food and drugs

Toxic Substances Control Act

- Review of new chemicals before they are commercialized
- Review of certain new uses of existing chemicals before they commence
- Collection of information on the manufacturing, import and processing of existing chemicals
- Toxicity and exposure testing
- Limits and other controls on the manufacturing, import processing and use of existing chemicals

TSCA – New Chemicals

Review New Chemicals Before They Are Commercialized

- New chemical notifications must be submitted to EPA for substances not on the TSCA Inventory
- Not a registration program – it is a notification program that provides for EPA review
- After review is complete, the chemical is placed on the TSCA Inventory

TSCA – New Chemicals

New Chemical Reviews

- TSCA requires a manufacturer or importer of a new chemical substance to submit a “premanufacture notice” (PMN) to EPA 90 days before the date of intended start of production or import of the subject substance
- During that 90-day review period, EPA assesses whether the manufacture, processing, distribution in commerce, use or disposal of the substance *presents or may present an unreasonable risk to human health or the environment*

TSCA – New Chemicals

Assessing the Chemical

- Evaluation of risks from new chemicals are considered throughout their product life cycle.
- EPA's focus
 - Potential toxicity
 - Exposure to workers
 - Site-specific assessment of environmental and general population exposure
 - Consumer exposure (using models)

TSCA – New Chemicals

Assessing the Chemical

- TSCA requires new chemical manufacturers and importers to submit only studies/data in their possession or control
 - No minimum set of toxicity or fate studies are required
- No test data are required to be submitted with a notification
 - Predictive models/technical tools and professional judgment must be utilized by EPA to assess potential risks

TSCA – Nanoscale New Chemicals

- Under TSCA, EPA has assessed more than 160 nanoscale materials
 - Primarily carbon-based nanoscale materials
 - Carbon nanotubes
 - Fullerenes and modified fullerenes
 - Quantum dots
 - Assessment based on
 - Information in the possession of industry
 - Consideration of appropriate published data

TSCA – Nanoscale New Chemicals

Review of Nanoscale Materials

- EPA does not have a regulatory definition of nanoscale material for new chemicals
- EPA reviews nanoscale materials in a manner similarly to other new chemicals
- What is assessed is whether the nanoscale material *presents or may present an unreasonable risk to human health or the environment*

TSCA – Nanoscale New Chemicals

Review of Nanoscale Materials

- For the review of nanoscale materials, important considerations, include
 - How the nanoscale material will be manufactured
 - How it will be used
 - Structure
 - Size and size distribution
 - Potential hazards

TSCA – Nanoscale New Chemicals

- What is key to determining whether the nanoscale material “may cause an unreasonable risk”?
 - Proper characterization of the material being reviewed under TSCA
 - Use of published data or analogue data given the lack of a requirement to submit data on the nanoscale material being reviewed by EPA
 - Proper characterization of the material tested in toxicity studies

TSCA – Nanoscale New Chemicals

- Given the lack of data, EPA uses analogs to make determinations
- For many nanoscale materials where there are insufficient data, EPA uses data for the category “Respirable, Poorly Soluble Particulates” to assess potential hazard
 - (see epa.gov/oppt/newchemicals/pubs/npcchemicalcategories.pdf)
- Category is limited to effects on the lung as a result of inhaling particles $\leq 10\mu$ in diameter

TSCA – Nanoscale New Chemicals

- EPA has taken a number of actions to control and limit exposures to these chemicals, including:
 - Limiting the uses of the nanoscale materials
 - Requiring the use of personal protective equipment, such as respirators and impervious gloves
 - Limiting environmental releases
 - Limiting the use to that identified in the submission
 - New uses would need to be reviewed before they could commence
 - Requiring testing after a certain production volume is reached to generate health and environmental effects data
 - 90-day inhalation study

Additional Data Needed

- Identification of Nanoscale Materials
- Physicochemical Characterization
- 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

Distinguishing Nanomaterials

- EPA has been considering how to distinguish among different nanomaterials for the same type of chemical
- EPA is thinking about this for purposes of reporting on different nanomaterials and to include properties beyond size
- The next slide lists several properties and the measured changes that could be used to differentiate nanomaterials for the same type of chemical

Parameters for consideration

- a size variation in the mean particle size of 10% or greater
- a change of 10% or more in one of the following properties:
 - surface charge
 - specific surface area
 - dispersibility/solubility
 - surface reactivity
- EPA is determining how to best characterize each of these properties

Physicochemical Characterization

- Characterization of nanomaterials submitted to EPA for review
 - Physicochemical characterization critical for assessment of nanoscale materials
 - Need accurate identification of materials submitted to EPA
 - Characterization is insufficient
 - Hampered by lack of standards specific to types or groups of nanoscale materials

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 or groups of nanomaterials
 - Important to identify
 - Often not agreed-upon standards for individual types or groups of nanomaterials

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

Exposure - 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 techniques are not applicable when particles are already in the nanoscale

Summary

- For more tailored regulatory determinations
 - Need better characterization of the material subject to review and of materials subject to toxicity studies
- Need standards that are specific to individual types or groups of nanomaterials
- Lack of data makes it more difficult for EPA to determine that the nanoscale material *may not present an unreasonable risk to human health or the environment*
 - May need to take a more conservative approach in the absence of data