Improving Information Used in Decisionmaking

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The Need for Improved Information

- What is needed?
  - Development of testing that is quicker and less expensive
- Why?
  - Data on new nanoscale chemical substances reviewed under the Toxics Substances Control Act (TSCA) are often not generated until several years after commercialization
  - Decisions are made on limited information

TSCA - New Chemicals

- TSCA section 5 requires a manufacturer (producer 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

- TSCA requires new chemical manufacturers 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, data on analogs and professional judgment must be utilized by EPA to assess potential risks

TSCA – New Chemicals

- Is the information available to EPA sufficient to permit a reasoned evaluation of the health and environmental effects of the substance?
- In the absence of sufficient information, may the substance present an unreasonable risk of injury to health or the environment?
  - May require testing to provide these data

Use of Analogs

- Given the limited data on nanoscale materials EPA uses analogs
  - Acceptable given the finding is that the chemical "may present an unreasonable risk"
- Respirable, Poorly Soluble Particulates
  - Based on existing data
  - Potential for respirability - particles ≤ 10 μ in diameter
  - Based on test data on 5 different poorly soluble particulates
    - Silica, talc, titanium dioxide, lithium manganese oxide, and carbon black
    - Human and animal data
  - Can be used solely for effects on the lung as a result of inhalation

Physicochemical Characterization

- Characterization of nanoscale materials 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 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 nanoscale analogs

Regulatory Decision

- If the nanoscale materials are respirable then EPA cannot make a determination that the material may not present an unreasonable risk, unless
  - Workers wear personal protective equipment so that they will not inhale the nanoscale materials
  - There are no releases to the environment
  - By a certain product volumes (based on profitability), the company must conduct specified studies, usually including a 90-day inhalation study
- The 90-day inhalation study is almost always only provided when a certain production volume is reached which is typically years after the nanomaterial is first commercialized.

Thank you!