

Challenges of Evaluating the Human Health Risks of Nanomaterials

Iris A. Camacho-Ramos, Ph.D. Risk Assessment Division, Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency February 24, 2015

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Manufactured Nanomaterials under the Toxic Substances Control Act (TSCA)

- Manufactures or importers are required to submit a "premanufacture notice" (PMN) to EPA 90 days before the date of intended start of production or import of the new manufactured nanomaterial.
- Information required as part of a PMN: chemical identity, use, anticipated production volume, byproducts, exposure & release information, disposal practices, existing available health & environmental effects test data.
- During the 90-day review period, EPA determines if the manufactured nanomaterial presents or may present an unreasonable risk to human health or the environment.



TSCA New Chemicals Program

New Nanomaterials (NMs)

- > 160 new chemical notices received since 2005
- Most notices have completed EPA review → NMs allowed in commerce, but regulated.
 - Requirements to prevent human and environmental exposure
 - Requirements to develop data



Some Types of Nanomaterials Reviewed under TSCA

- Fullerenes; Modified fullerenes
- Carbon nanotubes (CNTs)
- Quantum dots
- Nanopolymers
- Silica derivatives
- Titania derivatives







Stage of the RA

Challenges

- Material Characterization and P-Chem properties
- Exposures
 - Occupational
 - Environmental
 - General public
- Hazards
 - Human health

- No nomenclature system developed
- Generally, insufficient data to identify relevant properties
- Unclear test methods/relevance of results
- How does material characterization correlate with p-chem



RA= risk assessment

Stage of the RA

Material Characterization and P-Chem properties

- Exposures
 - Occupational
 - Environmental
 - General public
- Hazards
 - Human health

RA= risk assessment

Challenges

Occupational

- Large agglomerates do these break down into respirable and inhalable particles that can reach the deep lung?
- How do NMs disperse in lung/other biological fluids?
- Interpretation of workplace exposure monitoring report



Stage of the RA

- Material Characterization and P-Chem properties
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RA= risk assessment

Challenges

Environmental

- Do releases of NMs escape treatment plants or do they sorb to sludge?
- If they escape the treatment plants, would natural organic matter and sunlight lead to soluble transformation products?



Stage of the RA

- Material Characterization and P-Chem properties
- Exposures
 - Occupational
 - Environmental
 - General public
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 - Human health



Challenges

- General public
 - Are NMs chemically bound in composites or just embedded?
 - Exposures from
 - consumer use (e.g., spray application)?
 - incineration/landfilling?



Stage of the RA

- Material Characterization and P-Chem properties
- Exposures
 - Occupational
 - Environmental
 - General public
- Hazards
 - Human health

<u>Challenges</u>

- Human health:
 - Relevance of aerosols and material characteristics from toxicity studios compare
 - toxicity studies compared
 - to occupational
 - exposures
 - Dose metrics/sample preparation





Future Directions

- Development of chemical categories for NMs
 - OECD Categories Workshop in Sept 2014
 - Regulatory Cooperation Council project
- Development of alternative tests (e.g., screening) and read across properties to support risk assessment and risk management
- Identify criteria of concern/no concern



Conceptual Approach for Toxicity Testing of Nanomaterials





Thank you!

Iris A. Camacho-Ramos camacho.iris@epa.gov 202-564-1229

