

Perspectives on Regulating Graphene Products under the Toxic Substances Control Act

ANSI

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Discussion Points

- How the existing regulatory chemicals framework is used to manage risks of emerging nanotechnology-related materials and products entering the market.
- Example of how nanomaterials are currently assessed.

Toxic Substances Control Act (TSCA)

- 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
 - Coordinate with other Federal agencies

Nanomaterials (NMs) under TSCA

- NMs are “chemical substances” as defined by the Toxic Substances Control Act (TSCA)
- NMs not on the TSCA Inventory are “new chemicals”
- TSCA “chemical substance” definition based on molecular identity, not on other properties
- NMs on the TSCA Inventory are “existing chemicals”

New Chemicals Program (TSCA §5)

- Chemicals not on the TSCA Inventory are “new chemicals”
- Manufacturers or importers of new chemicals submit premanufacture notices (PMNs)
- Regulation Pending Development of Information
 - Consent Orders
 - Significant New Use Rules (SNURs)

TSCA New Chemicals

- More than 190 new chemical notices for NMs have been received since 2005
- Most notices have completed EPA review, are regulated, but allowed in commerce.
 - Requirements to prevent human and environmental exposure
 - Requirements to develop data

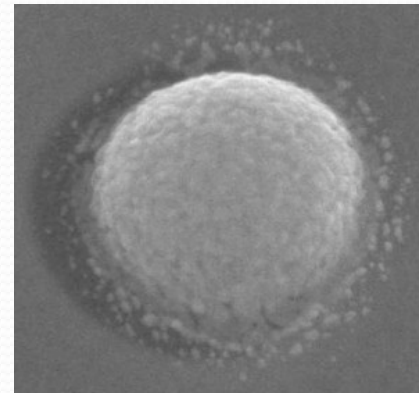
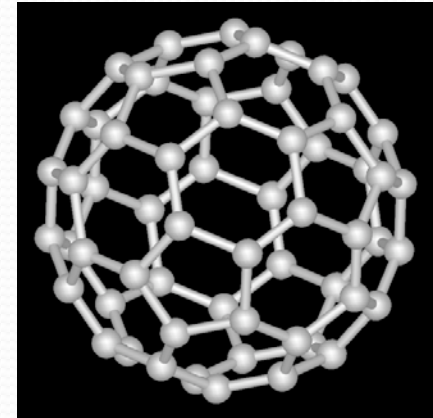
New Chemical Risk Management

- 100% of potential NMs receive further review and are usually regulated but allowed in commerce.
- The review and ultimate regulation of NMs can take 6 – 24 months per substance.

Some types of nano-PMNs

(assessed as “respirable, poorly soluble particulates”)

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



Risk assessment challenges

Stage of the RA

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

Challenges

- 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

Risk assessment challenges

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Challenges

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

Risk assessment challenges

Stage of the RA

- Material
Characterization AND P-
Chem properties
- Exposures
 - Occupational
 - **Environmental**
 - General public
- Hazards
 - Eco
 - Human health

Challenges

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

Risk assessment challenges

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 - **General public**
- Hazards
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Challenges

- General public
 - Are they chemically bound in composites or just embedded?
 - Exposures from incineration/landfilling?

Risk assessment challenges

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 - Eco
 - Human health

Challenges

- Eco:
 - No acute effects at saturation due to low solubility?
 - Sample prep/test methods
 - what about the possibility of chronic effects, especially on transformed products?

Risk assessment challenges

Stage of the RA

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Characterization AND P-
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 - General public
- Hazards
 - Eco
 - **Human health**

Challenges

- Human health:
 - Relevance of aerosols and material characteristics from tox studies compared to occupational exposures
 - Dose metrics/sample prep
 - What is the right tox paradigm ?

Risk Assessment

- Typical assessment for new chemicals would establish an exposure limit, based on best the available analogue.
- Due to the uncertainty of hazard and exposure data, EPA considers risks to be inconclusive.
- Needs better data on human and environmental exposure for a more conclusive risk assessment.

Public Comments for CNT SNURS

- EPA did not adequately identify CNTs
- EPA did not make an adequate risk finding
- Changing reviews as new data becomes available
 - one company specifically requested that EPA include latest data/findings
- When does a CNT become a different chemical
- Applicability of regulation when bound in a polymer matrix and other forms
- Applicability of SNUR to R&D activity

Contact Info

<http://www2.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under>

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