

# Assessing and Managing the Risks of Chemical Substances Manufactured as Nanoscale Materials under TSCA

National Consultation on Nanomaterials

January 28, 2016

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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 carbon nanotubes and how they are currently regulated.
- Current steps undertaken to develop regulation for nanomaterials under existing laws and policies.
- Issues identified for regulation of nanoscale materials.

# 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)

- 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 170 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

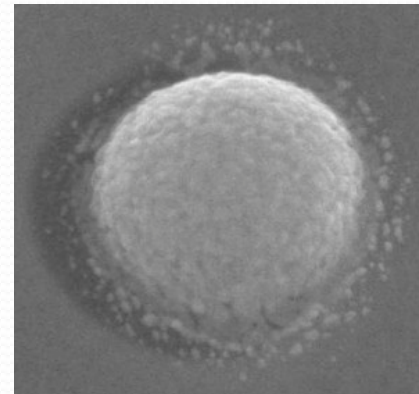
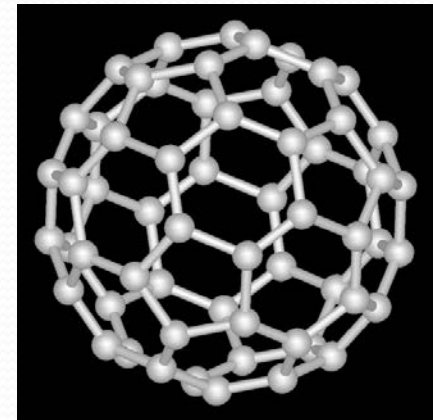
# New Chemical Risk Management

- EPA takes no action on 85%-90% of typical new chemicals.
- 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

(most assessed as “respirable, poorly soluble particulates”)

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





# Identification and Characterization

- EPA has received new chemical notices under TSCA on over **70 carbon nanotubes and fibers**
- Each CNT is considered a distinct chemical substance. Some key parameters:
  - # walls, inner diameter, outer diameter and length
  - functionalization
  - capped or open ended
  - straight, branched, or tree structure
  - particle size and distribution
  - impurities/catalyst incorporation
  - surface chemistry if surface modified
  - surface area and porosity
  - TEM/SEM images that show the morphology of the tubes
- Production volumes have ranged from less than 100 kg scale to greater than 100,000 kg

# Risk Assessment

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

# Example: Respiratory Hazard

- At the current time EPA considers data from numerous CNT studies and the NIOSH Recommended Exposure Limit of 1  $\mu\text{g}/\text{m}^3$  for CNT
  - Uncertainty Factors
    - extrapolation from subchronic to chronic
    - LOAEC to NOAEC
    - interspecies variation
    - intraspecies variation
    - database incompleteness

# Carbon Nanotubes (CNT) under TSCA


- 10/31/2008 CNT Federal Register Notice regarding chemical identity questions and enforcement
- Allotropes of carbon are considered “new”
- 09/17/2010 Final SNUR issued for two specific carbon nanotubes
- Other CNT consent orders and SNURs continue to be issued (in 2013 17 final SNURs for CNTs, fullerenes, and in 2014 19 final SNURs for CNTs)

# 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

# Existing Chemicals - Information Gathering Rule

- TSCA Section 8(a) Proposed Rule for Chemical Substances Manufactured or Processed as Nanoscale Materials
- Proposed April 6, 2015
- <http://www2.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under>



# Goals of Issuing this TSCA Section 8(a) Proposed Rule

- Ensure that EPA has basic information on nanoscale materials currently in commerce to:
  - Increase understanding of what nanoscale materials are in commerce;
  - Inform EPA efforts to characterize risk; and
  - Enhance the ability to assess risks and make appropriate risk management decisions.

# Goals of Issuing this TSCA Section 8(a) Proposed Rule

- EPA would review the data submitted for all nanoscale materials subject to the rule.
- EPA would consider whether further actions or additional data are needed.



# Selected Comments

- EPA does not have authority under TSCA to issue the rule as proposed because TSCA applies to chemical substances not different physical forms or different particle sizes of chemical substances
- EPA needs to better define the terms unique and novel properties and trace amounts
- Withdraw and repropose the rule once there are better definitions

# Selected Comments

- EPA should clarify the number of dimensions for particles of 1-100 nm
- EPA should better define particle and how particle size is to be determined – either weight, count, or volume
- There is not standardized testing for the physical properties in the proposed rule identified for manufacturers and processors to determine if they are subject to the rule
- EPA cannot require this testing until validated protocols are developed



# Selected Comments

- There are numerous suggestions for additional exemptions
- Reporting for chemicals such as carbon black, silica, and titanium dioxide would require reporting for chemicals that are already established in commerce, are well characterized and would duplicate existing chemical data reporting requirements
- Organic dyes and pigments should be excluded because they are well characterized and have limited amounts of particle sizes less than 100 nm
- Polymers should be excluded because of low risk



# Moving Forward

- Classification/categories of nanomaterials based on similarities in chemical composition as a good starting point
- Need to determine what parameters make nanoscale materials “sufficiently similar” to allow for read-across
- Refinement of such parameters will aid in the development of more precise subclasses, which will better guide the use of read across information in risk assessments
  - Additional scientific research and expert input is needed to further refine parameters and classes/subclasses
- Terminology, definitions, and nomenclature need to be further developed within the international community

# Contact Info

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

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