EPA Approach to Regulating Carbon Nanomaterials

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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
- Maintain TSCA inventory

New Chemicals Program

Chemicals not on the TSCA Inventory

- Manufacturers or importers of new chemicals submit premanufacture notices (PMN) [TSCA §5 (a)]
- Regulation Pending Development of Information [TSCA §5(e)]
- Significant New Use Rules (SNUR) [TSCA §5 (a) (2)]

Carbon Nanomaterials (CNMs)

Carbon nanomaterials include pure and functionalized carbon nanotubes (CNTs), carbon nanofibers, and fullerenes.

EPA has received new chemical notices under the Toxic Substances Control Act (TSCA) for over 100 nanoscale materials and, among them, more than 30 for CNMs.

Production volumes of the CNMs range from kg scale to greater than 10,000 kg per year.

EPA regulates CNMs, usually with Consent Orders and Significant New Use Rules.

Carbon Nanomaterials (CNMs)
cont

Each CNM or functionalized CNM is considered a distinct chemical substance.

Each material has different key parameters.

EPA recommends using existing EPA test methods and OECD's test methods for nanomaterials to measure these parameters.

Test methods may not be applicable or non-existent

Carbon Nanomaterials (CNMs)
cont

Key parameters for CNT could include:

- # of walls
- inner diameter, outer diameter and length
- functionalization
- capped or open ended
- straight, branched, or tree structure
- dry particle size distribution
- dustiness

Key parameters for fullerenes could include:

- functionalization
- dry particle size distribution
- dustiness
- water solubility
- surface chemistry

Examples of test methods and techniques for fullerenes and functionalized fullerenes

- **Dry particle size distribution**: Scanning transmission electron microscopy (STEM), using a dry particle counting method with a resolution of less than 1 nanometer and with no counting after dispersion in a solution and evaporating solvent on the form of the substance which has the highest content of particles smaller than 10 microns.
- **Water solubility**: OECD 105 test method
- **Dustiness**: EN 15051 method
- **Surface chemistry**: Electron energy loss spectroscopy (EELS) and/or X-ray photoelectron spectroscopy/electron spectroscopy for chemical analysis (XPS/ESCA), functionalized probe atomic force microscopy (AFM), or Auger electron spectroscopy

Challenges

- No nomenclature system has been developed for CNTs
- Generally, insufficient data to identify relevant properties
- Unclear test methods/relevance of results
- How do chemical-structural and material characterization properties correlate with physical-chemical properties

Addressing Insufficient Data – Consent Orders

Data may include the size particle distribution, certain basic physical –chemical properties, and some health studies.

In the Consent Orders, EPA requires some health tests (mostly, the 90-day inhalation toxicity) and p-chem properties. To protect workers, EPA requires NIOSH-approved full face respirators with N-100, R-100, or P-100 cartridges, impervious gloves and full body coverage.

Addressing Insufficient Data – Consent Orders cont.

Due to the lack of data on the CNMs aquatic toxicity and environmental fate, the Consent Orders have generally required no water releases during manufacturing, processing, and use of CNMs.

No established methods to determine the concentration of the CNMs in water

EPA has allowed very limited releases of CNMs for surface water in one case where the manufacturer provided test data.

Environmental Fate and Exposure

- The Agency does not have models or methods designed to predict the fate of, or exposure to, CNMs in the environment.
- Combined with the lack of test results for nanomaterials, there is uncertainty in estimating removal efficiencies, degradation half-lives, partitioning, and transport of nanomaterials.
- To address this uncertainty, EPA uses a bounding, “what-if” scenario that assumes CNMs are released into the environment, are persistent, bioaccumulate, and are highly mobile until a submitter demonstrates otherwise.

Guideline posted on EPA public website

http://www.epa.gov/oppt/exposure/pubs/guidance.htm

Environmental Exposure

Screening level estimates used to determine if manufacture, processing, or use of nanomaterials result in releases sufficient to warrant control

Two exposure scenarios for nanomaterials:

One simulates **releases to water** (0% wastewater treatment removal)

Second simulates **releases from sludge** (100% adsorption to wastewater treatment sludge followed by 100% desorption from sludge to groundwater)

Purpose of these scenarios is to create bounding estimates for maximum concentrations

Ecotoxicology

No established concern concentration for CNMs:

- toxicity of e.g., CNTs generally reported in the 10s to 100s ppm for both water and sediment borne material

- Sublethal effects of CNTs have been noted in fish as low as 100 ppb.

- The solubility of CNTs is predicted < 1 ppb, but stable dispersions may be created in the presence of natural organic matter or via functionalization (which is environmentally feasible).

- Uptake studies in whole aquatic organisms indicate that CNTs do not cross the gut lumen suggesting uptake is limited to ingested material.

- The broad range of potential CNT forms that may affect ecotoxicology: functionalization; length and end-capping; presence of catalyst metals; level of purity

Environmental Risk Assessment

an example for CNTs

- Based on the framework for other new chemicals, EPA models predict no ecological effects at saturation of CNTs in water which would generally lead EPA to conclude low environmental hazard and risk for CNTs, as manufactured.

- However, due to the transformation potential of CNTs and uncertainty of the relevance of existing data, EPA considers the ecological hazard and risk of CNTs to be inconclusive.

- Generation of additional data would be required if a company wanted to release CNTs to the environment.

Occupational Exposures – Challenges

- Do large agglomerates break down into respirable and inhalable particles that can reach the deep lung?
  - No metric to describe the propensity to break down

- How do CNMs disperse in lung/other biological fluids?

- Occupational inhalation exposures to respirable particles are a key concern
  - No consensus approach
  - Highly dependent on model and assumptions
  - Unclear how to interpret/utilize experimental data

Occupational Exposures - Challenges

- Validated exposure monitoring data
- Early studies focused on identifying and reducing emission hotspots in facilities,
  - did not quantify worker exposures
  - may represent worst case exposure scenarios,
  - but did not identify which particle forms
- What percentage of particle detections are of actual CNMs rather than soot or organic carbon?
- What are the characteristics of the actual CNMs from such exposures compared to the CNMs as manufactured or generated for a toxicity study

Human Health - Consumer Exposure

- The following forms of CNMs may be distributed to consumers:
  - completely reacted (cured);
  - incorporated or embedded into a polymer matrix that itself has been completely reacted (cured);
  - embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing;

Consumer/General Exposure - Challenges

- Are CNMs chemically bound in composites or just embedded? How stable are the CNMs in the composites? What is the material lifecycle?
  - Some consent orders may require testing to help address this issue.
- Thermogravimetric analysis suggests raw CNTs will be easily incinerated.
- What about under actual incineration and composite conditions?

Human Health Risk Assessment

- A typical assessment for other new chemicals would establish an exposure limit based on the best available analogue to estimate potential risk.
- Due to the uncertainty of the relevance of both hazard and exposure data. EPA considers the human health hazard and risk of CNMs to be inconclusive.
- Generation of additional data would be required if a company wanted to manufacture CNMs without the current restrictions found in consent orders.

Regulatory Management of CNMs

EPA needs:

- Identification of parameters to measure
- Measurement methods
- Testing protocols
- Valid data

Contact Information

http://www.epa.gov/oppt/nano/

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