



EPA

United States
Environmental Protection
Agency

Regulatory Priorities and Information Needs Linked to Exposure to Nanomaterials

*Second Quantifying Exposure to Engineered Nanomaterials from Manufactured
Products (QEEN II) workshop*
9-10 October 2018
Department of Labor

Office of Chemical Safety and Pollution Prevention

Overview

- Background on TSCA
- New Chemicals Review Considerations
- New Chemical Categories
- Regulatory Determinations under TSCA
- Issues with Developing a Nanomaterials Category

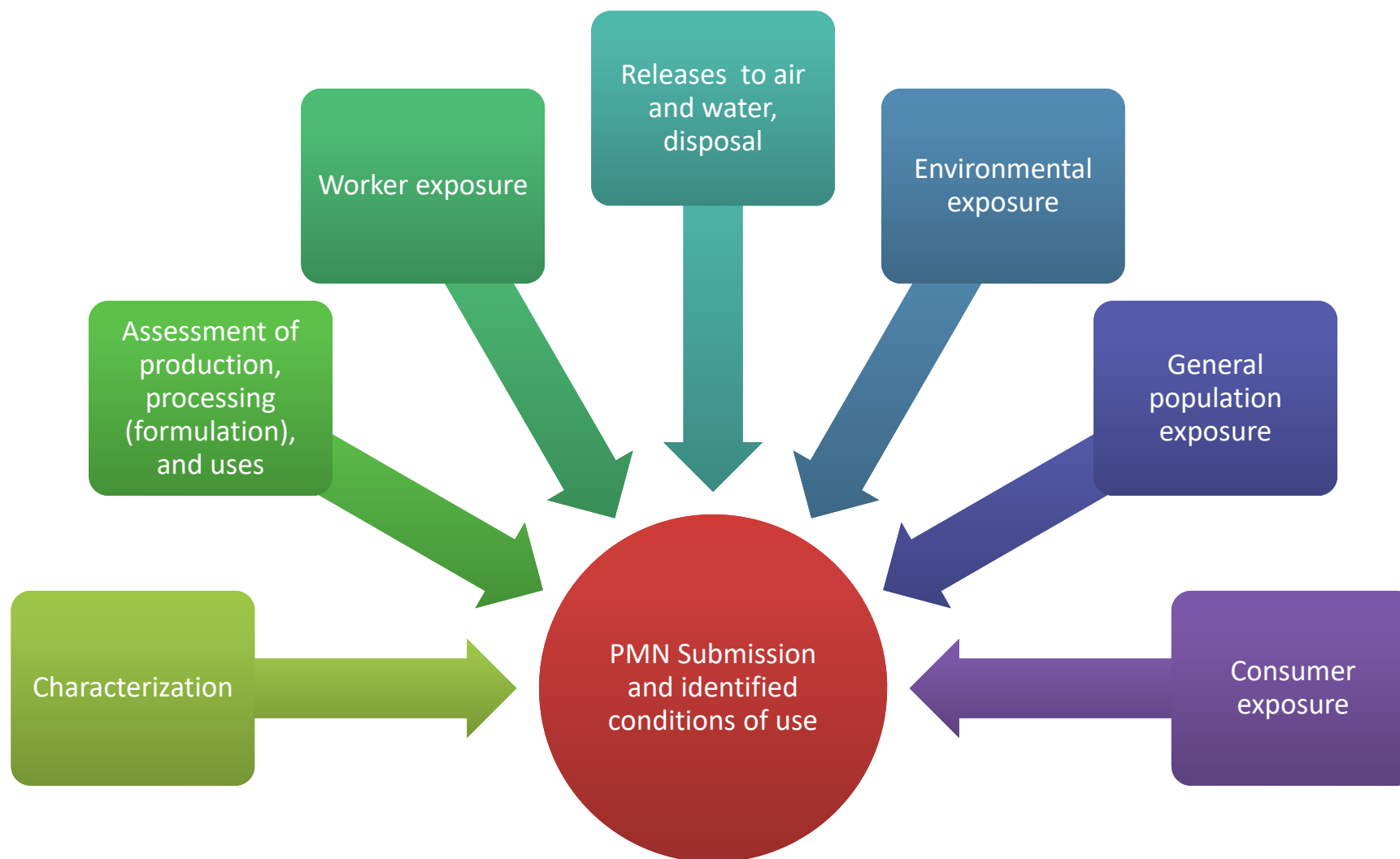
Toxic Substances Control Act (TSCA) - An Overview

- Provides basic authority for chemicals regulation in the U.S.
- TSCA requires EPA to:
 - Evaluate and, where appropriate, control unreasonable risk for new chemicals and new uses of certain existing chemicals
 - Prioritize, evaluate and address risk for existing chemicals that present unreasonable risk to health or the environment
 - Gather information on new and existing chemical substances and mixtures, including requiring testing where needed to fill data gaps
 - Coordinate with other Federal agencies
- Nanoscale materials are managed under TSCA; No U.S. legislation specific to nanoscale materials

TSCA – Information Required to be Submitted for New Chemicals via Premanufacture Notices (PMNs)

- Chemical Identity
 - Includes particle size and particle size range
 - Morphology or shape
- Byproducts and impurities
- Estimated production/import volume
- Proposed uses and amounts for each use
- Human exposure information
- Disposal methods and estimates of releases to the environment
- Existing test data in submitter's possession or control concerning human and environmental effects

TSCA New Chemical Review Considerations



Review of New Chemicals

- EPA reviews ~1000 new chemical submissions annually
- Statutory review period is short – 90 days
- Very few submissions include data (<15%)
- Reviews are typically based on structural analogues and categories

New Chemical Categories

- Chemical Categories are a practical way to extrapolate existing data to analyze related substances
- Category evaluation supports:
 - Greater weight of evidence
 - Increased confidence in conclusions
 - Better basis for establishing biological plausibility
- Category analysis facilitates strategic testing to fill data gaps, where necessary
 - Weight of evidence used for deciding on additional testing
 - Defines the nature and scope of any potential testing needs

Categorization of Nanomaterials

- No category currently exists for nanomaterials specifically
- U.S. focus is on toxicity of components
 - For example, Cd
 - Functionalization of coatings
 - Persistence in the environment
- Nanomaterials may also fit into existing chemical categories, such as “Respirable, poorly-soluble particulates”:
 - Category is based on data for five different poorly-soluble particulates: silica, talc, titanium dioxide, a lithium manganese oxide, and carbon black
 - Use U.S. NIOSH REL for CNT/CNF (1 ug/m³) for risk assessment
 - Physico-chemical properties testing and a 90-day inhalation toxicity test (OECD TG 413+ BAL) are often necessary to evaluate potential health and environmental impacts of nano substances

TSCA Determinations Under Section 5

Presents An
Unreasonable
Risk

Insufficient
Information
and May
Present An
Unreasonable
Risk

Chemical
Substance
Produced In
Substantial
Quantities

Insufficient
Information to
Make A
Reasoned
Evaluation

Not Likely To
Present An
Unreasonable
Risk

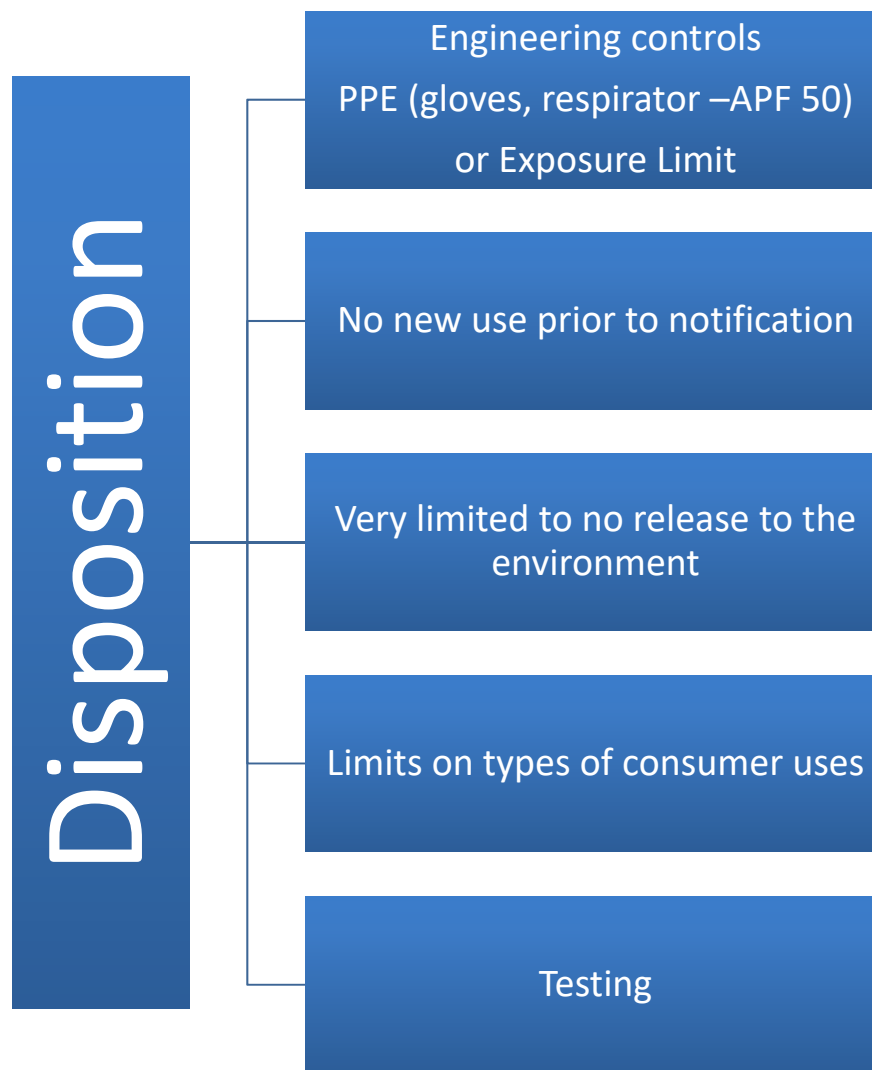


Section 5 Review and Determination

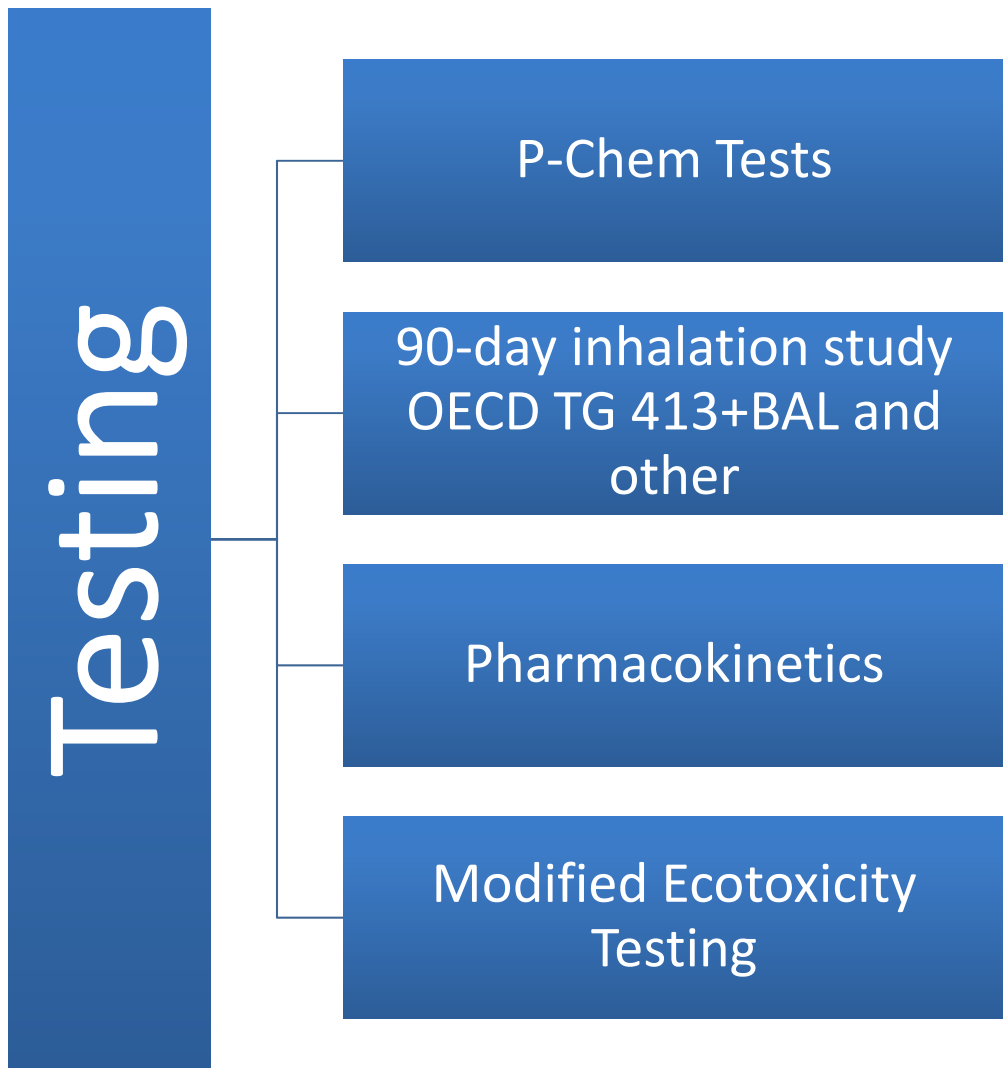
Insufficient Info and May Present An Unreasonable Risk

- As a result of the review, EPA determines that, in the absence of sufficient information to conduct a reasoned evaluation, the manufacture, processing, distribution in commerce, or use, may present an unreasonable risk of injury to health or the environment under the conditions of use.
- Regulation under section 5(e): Regulation Pending the Development of Information
 - Section 5(e) order
 - Testing or other potentially useful information may be required

Disposition



Testing



Nanomaterials under the TSCA New Chemicals Program

- More than 210 new chemical notices for nanomaterials have been received since 2005
- Most notices have completed EPA review, are regulated, but allowed in commerce
 - Requirements to prevent human and environmental exposure (PPE, certain end uses not allowed, no release to water, etc.)
 - Requirements to develop data for fate, ecotoxicity, and/or toxicity
- A limited number of 5-day, 28-day, 90-day, acute, irritation, sensitization, intratracheal instillation, and genetic toxicity studies have been conducted on nanomaterials (many of which have been on CNTs)

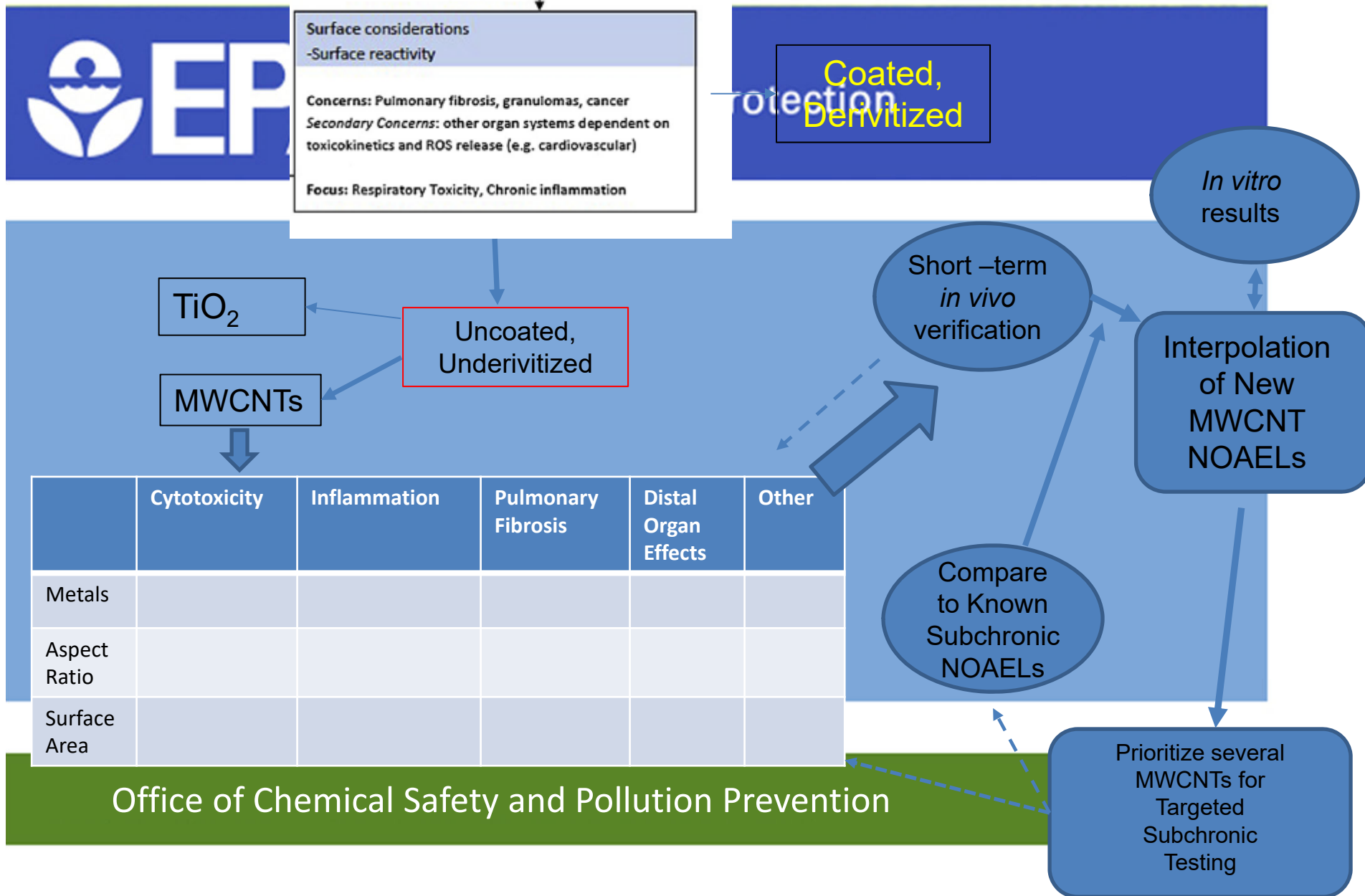
Carbon Nanotubes/Fibers

- EPA has received new chemical notices under TSCA on over **100 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
- Production volumes have ranged from less than 100 kg scale to greater than 100,000 kg

Challenges to Development of Chemical Category for CNTs

- Nanomaterials (and specifically CNTs) are engineered to have particular properties, which is different than functional group-based chemicals (aldehydes, ethers, etc.)
 - How do chemical-structural and material characterization properties correlate with physical-chemical properties?
 - CNTs often do not exist as distinct species; rather the populations of the materials can consist of distinct species and agglomerates and aggregates
 - A broad range of potential CNT forms may affect toxicology
- Insufficient data to identify relevant properties or identify properties key to establishment of a CNT category
- Unclear test methods/relevance of results

Variables in the Building of a Specific MWCNT Category



Environmental Fate of CNTs

- The Agency has insufficient information regarding the fate and transport of CNTs, and makes the following protective assumptions when assessing CNTs
 - 0% removal by a Publicly Owned Treatment Works (POTW) or a Waste Water Treatment (WWT) Plant from either biodegradation or sorption for assessing releases to surface waters
 - 0% removal via incineration
 - Rapid migration to groundwater from landfills
 - High persistence in the environment
 - Rapid transformation to highly dispersible chemical species via reaction with sunlight and natural organic matter

Ecotoxicology

- The Agency has not adopted a concentration of concern for CNTs
- CNT toxicity generally reported in the 10s to 100s ppm for both water- and sediment-borne material
 - Sublethal effects have been noted in rainbow trout at levels 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 (environmentally feasible)
- Uptake studies in whole aquatic organisms indicate that CNT uptake is limited to ingested material
- CNT functionalization, length, capping, and purity may affect ecotoxicology

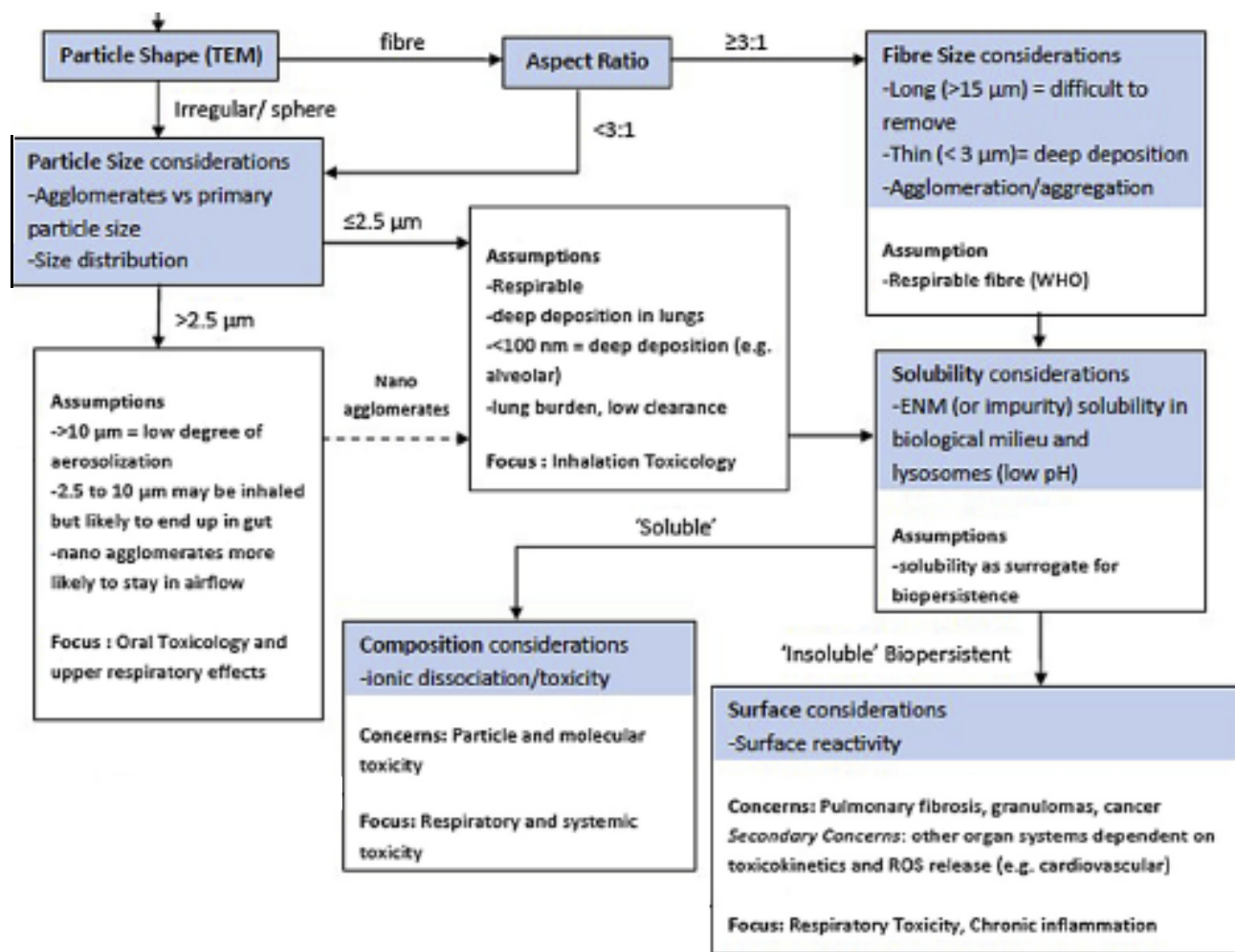
Environmental Risk Assessment

- Development of nanomaterial-specific test guidelines are needed for more appropriate environmental hazard assessment
- Furthermore, due to the transformation potential of CNTs, the Agency would likely require generation of additional data if a company wanted to release CNTs to the environment

Occupational Exposure Challenges

- Large agglomerates – do these break down into respirable and inhalable particles that can reach the deep lung? What metric describes the propensity to break down?
- How do CNTs disperse in lung/other biological fluids? Is there relevance for measuring occupational exposures?
- Occupational inhalation exposures to respirable particles are a key concern
 - No consensus approach within EPA
 - Highly dependent on model and assumptions
 - Unclear how to interpret/utilize experimental data

Physicochemical Factors in Context of Inhalation Toxicity



Consumer Exposure Challenges

- The following forms of CNTs 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;
- Potentially useful information is testing to address the stability of CNTs in composites

For More Information

Reviewing New Chemicals Under TSCA:

<https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>

Control of Nanoscale Materials Under TSCA:

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

Predictive Models and Tools for Assessing Chemicals Under TSCA

<https://www.epa.gov/tsca-screening-tools>

Thank you!

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