Towards Regulating Engineered Nanomaterials: A Framework as a Tool for Overcoming the Existing Limitations

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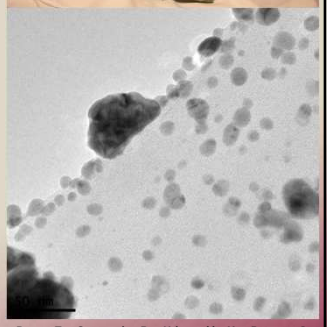
Nanotechnology Trends

Nanomaterials are here!!!

- Rapid increase
  - Production
  - Diversity
  - Commercialization
  - Nano-enabled products
- Increasing Public Concern
- Need for Regulations
- Problem

  Simple Implementation of Existing Regulations May NOT Work



Benn, T., Cavanagh, B., Hristovski, K., Posner, J., Westerhoff, P. (2010) The Release of (Nano)Silver from Consumer Products into Water, Air and Landfills, *Journal of Environmental Quality, 36*, 1875-1882

WHY?

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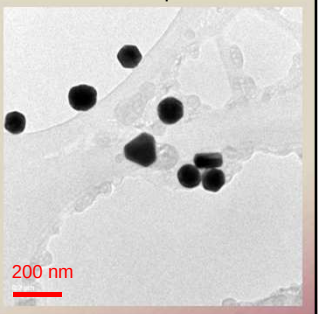
Novel Materials = Novel Challenges

NEW PROPERTIES → NEW RISKS → NEW REGULATIONS

Nanomaterials:

- **Unlike existing chemicals**
- **Unlike bulk materials**
  - **"exhibit new physical, chemical and biological properties which are not present in bulk materials."**

Gold Nanoparticles



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Novel Materials = Novel Challenges

NEW PROPERTIES → NEW RISKS → NEW REGULATIONS

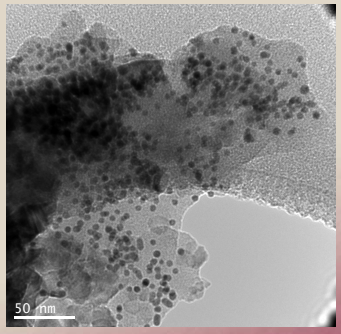
NEW RISKS ?!?

Uncertainty exists in predicting and managing NANORISKS!

Risks Depend:

- **(Nano)Hazard**
  - **(Nano)toxicity**
- **Exposure**

Titanium dioxide nanoparticles found in treated effluent



Westerhoff, P., Song, G., Hristovski, K., Kiser, A., (2011) Occurrence and Removal of Titanium at Full Scale Wastewater Treatment Plants: Implications for TiO_2 Nanomaterials. *Journal of Environmental Monitoring*.

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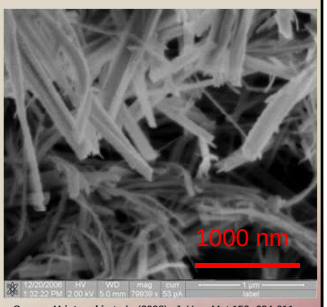
Nano-Hazard and Nano-Toxicity

- How do we quantify nano-hazard?
- How do we measure nano-toxicity?

- Nano-toxicity depends on:
  - Transport of nanomaterials
    - Routes of exposure
    - Cellular uptake
  - Nanomaterial surface properties
    - Size & Shape
    - Surface area
  - Nanomaterial chemical properties
    - Chemical Composition
    - Crystallinity
    - Material Chemistry/Reactivity
    - Functionalization
  - Number Concentration - Dose

Titanate Nanofibers



Source: **Hristovski** et al.. (2008), *J. Haz. Mat.156*, 604-611.

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Nano-Toxic Challenge

- Current Limitations or Barriers:
  - Limitations with existing tools, protocols and methods
    - e.g. SP-ICP-MS does not detect very small ENPs (Dp < 20 nm)
  - Environmental or product matrices affect the properties of engineered nanomaterials

    NANOMATERIALS MAY BE TRANSFORMED !
    - e.g. most of toxicity tests are conducted with pristine ENMs

From: Fillmore Gazette. http://www.fillmoregazette.com/humor/finally-answer

Things tend to get Complicated!

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How do We Overcome These Barriers?

- Is Focusing on Exposure the Right Approach?
  - In need of a Framework that recognizes
    - the relationships among different elements of the environmental and anthropogenic systems
    - the effects that these elements may have on transformation and transport of engineered nanomaterials across their boundaries
  - Borrowing from the multiple barrier concept?!?

Knowing the framework helps us establish barriers between systems

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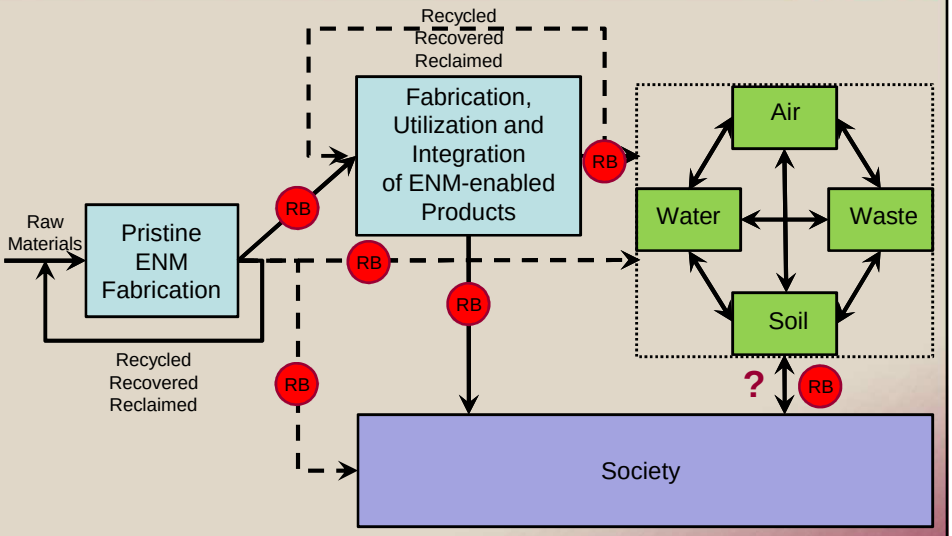
A Simplified Framework



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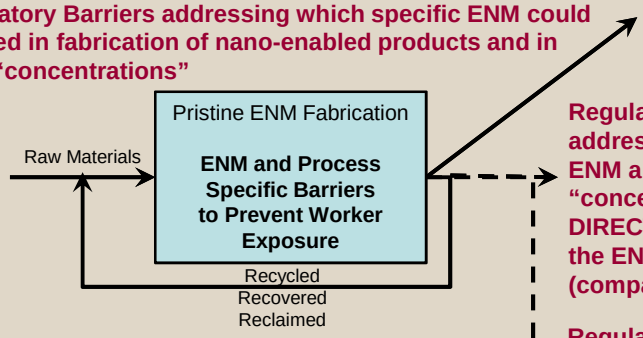
A Simplified Framework

Regulatory Barriers addressing which specific ENM could be used in fabrication of nano-enabled products and in what "concentrations"



Regulatory Barriers addressing which specific ENM and in what "concentrations" could DIRECTLY discharged in the ENVIRONMENT (compartment specific)

Regulatory Barriers addressing which specific ENM and in what "concentrations" could be used DIRECTLY in SOCIETY

Possible Approach Similar to:
- RCRA;
- CAA;
- CWA;
- OSHA (PEL, TLVs)

PROCESS and ENM Specific!

MANUFACTURERS Carry the Burden!!!
Determined on Case-By-Case Basis
Similar to the Globally Harmonized System

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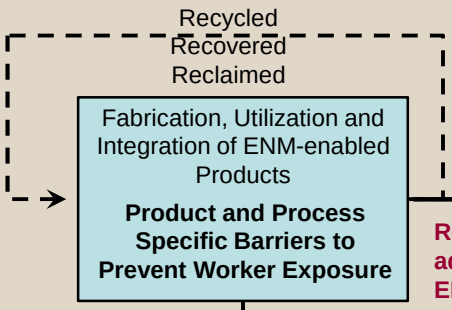
A Simplified Framework



Environmental compartment specific

Regulatory Barriers addressing which specific ENM and ENM-enabled products could be DIRECTLY discharged in the ENVIRONMENT

Regulatory Barriers addressing which and how much of specific ENM could be used in nano-enabled products released DIRECTLY in SOCIETY

MANUFACTURERS Carry the Burden!!!

Determined on Case-By-Case Basis – Similar to the GHS Approach

Possible Approach Similar to:
- RCRA;
- CAA;
- CWA;
- OSHA (PEL, TLVs)

PROCESS and PRODUCT Specific!

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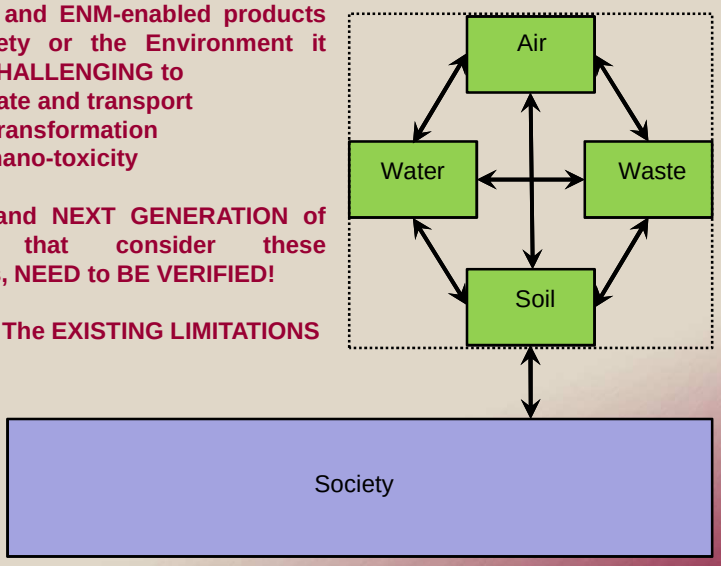
A Simplified Framework

Once ENM and ENM-enabled products enter Society or the Environment it becomes CHALLENGING to

- Assess fate and transport
- Assess transformation
- Assess nano-toxicity

EXISTING and NEXT GENERATION of MODELS, that consider these dimensions, NEED to BE VERIFIED!

PROBLEM: The EXISTING LIMITATIONS



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Epilogue

- The path of developing nanomaterial regulations is COMPLEX!
- It is UNCHARTED TERITORY!
- Having a Framework that
  - Elucidates the Challenges & Limitations
  - Helps utilize existing regulatory concepts

  is a necessary tool!

- Is the proposed simplified framework the right approach?

  Maybe Yes, Maybe No!

  But…

  IT IS A MOVE FORWARD IN SOLVING A PERTINENT MAJOR PROBLEM!

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Thank You!

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