turning knowledge into practice

Risk and Regulatory Issues Associated with the Disposal of Nanomaterials

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Will regulations designed to deal with end-of-life issues work for nanotechnology?

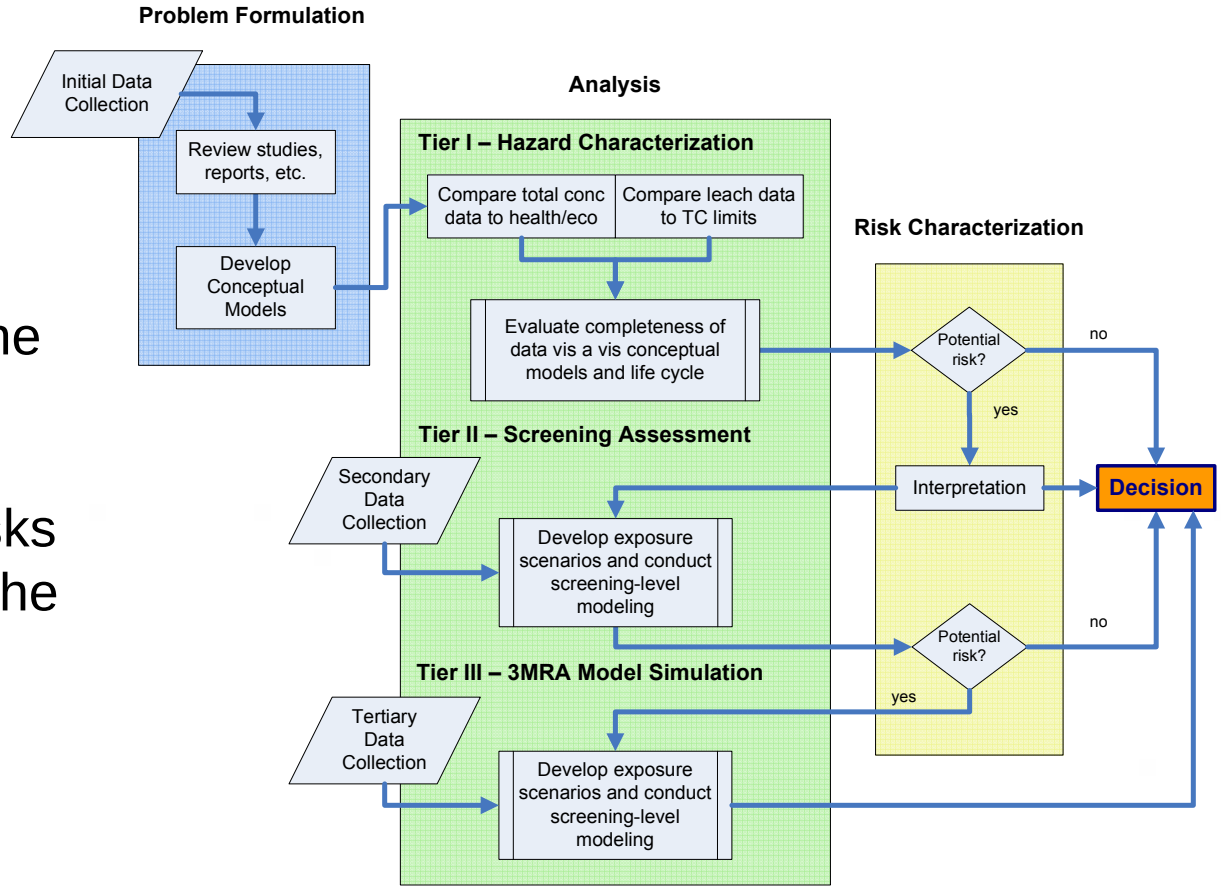
- In US, EPA has primary responsibility for safe and effective disposal of materials and products at the end of the life cycle
- Two key EPA-administered laws that provide the regulatory framework for end-of-life management strategies
  1. Resource Conservation and Recovery Act (**RCRA**)
  2. Comprehensive Environmental Response, Compensation and Liability Act (**CERCLA**)
- Other laws such as the Clean Water Act (**CWA**) and Toxic Substances Control Act (**TSCA**) also regulate the disposition of chemicals
- In terms of "disposal," however, **RCRA** is unquestionably the most important regulatory authority that determines how materials are managed at the end of the life cycle

Why focus on RCRA?

- RCRA regulates the handling, reuse, recycling, storage, treatment, and disposal of solid and hazardous wastes
- Relatively little research on the environmental, health, and safety issues associated with how NMs are managed at the end of the product life cycle
- Recent studies suggest that the risk of release of NMs will be highest during disposal, destruction, or recycling (Breggin & Pendergass, 2007)
- *RCRA requires EPA to characterize the risks to human health and the environment associated with the management of potentially hazardous wastes*

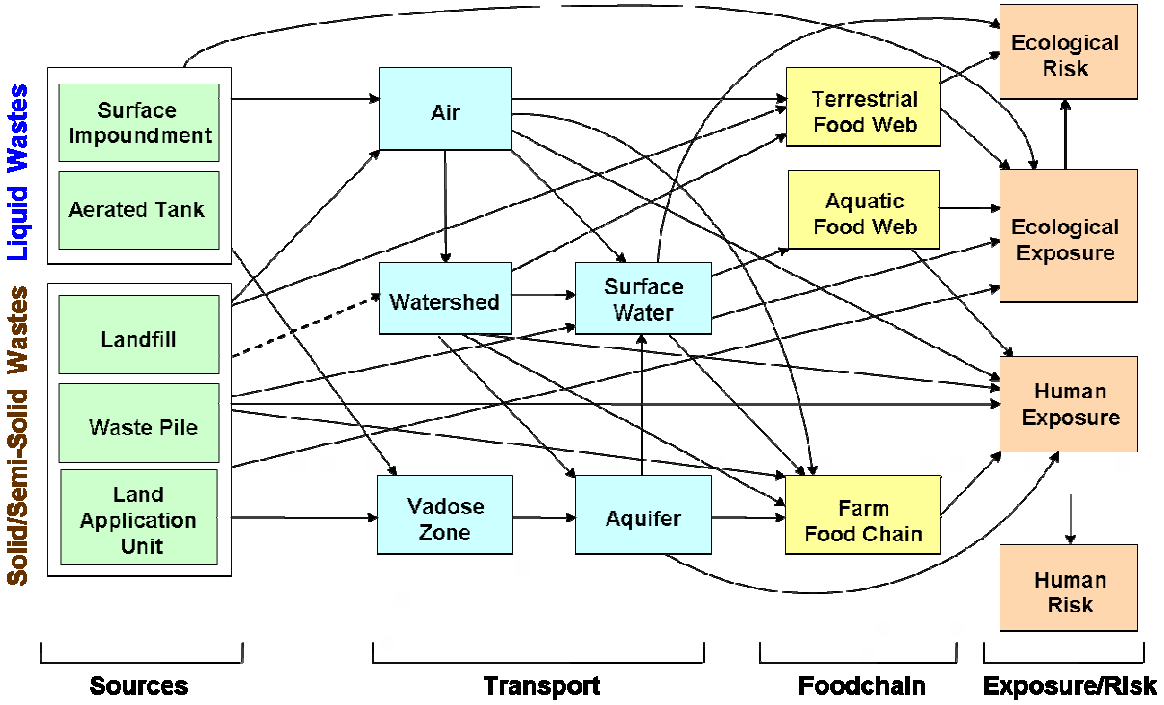
How are management options determined for a "new" chemical, waste, or material under RCRA?

A risk assessment is conducted to determine whether potential management options pose unacceptable risks to human health and the environment



What are the basic data needs for predictive quantitative risk assessments under RCRA?

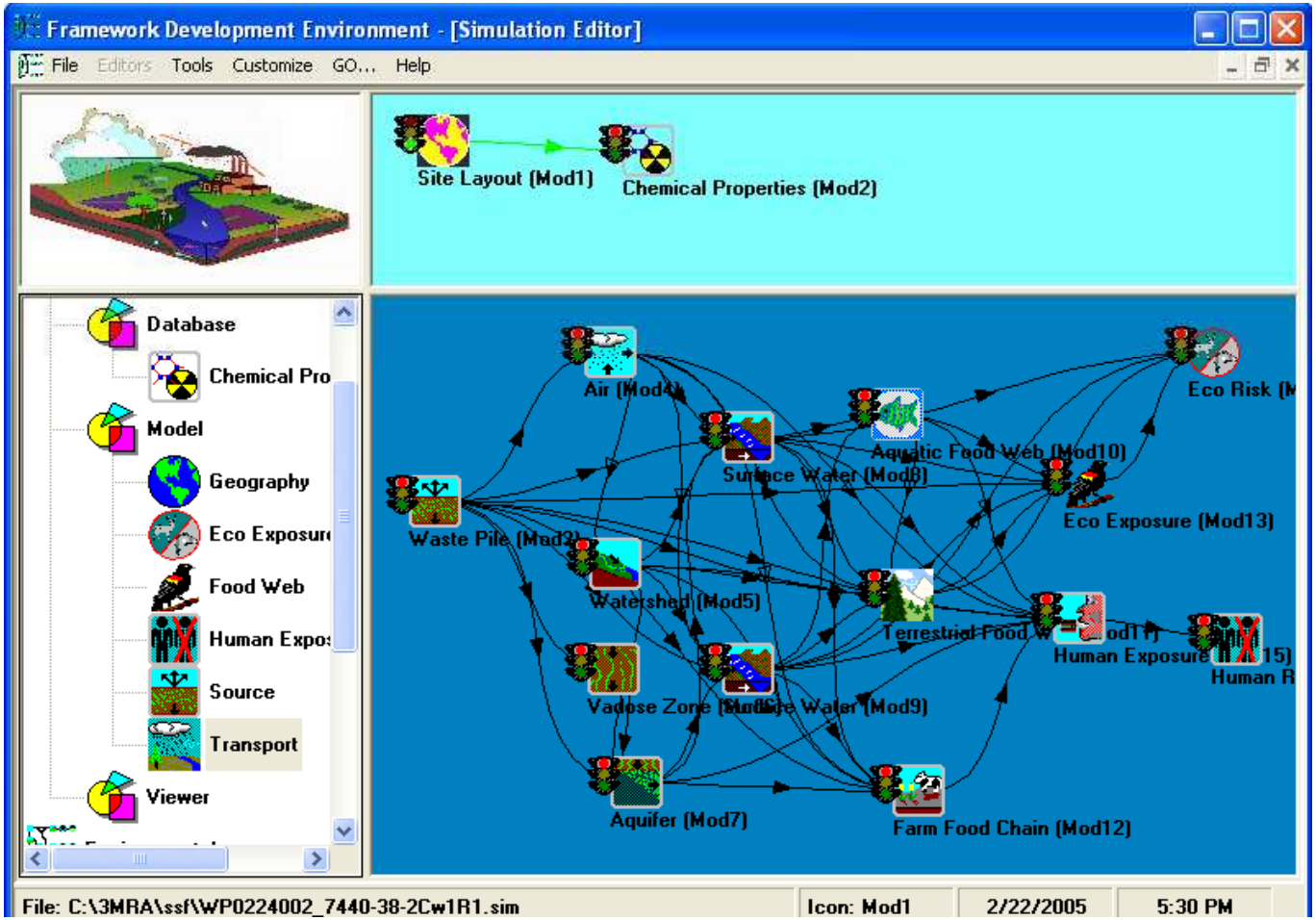
- Partition coefficients
- Biodegradation rates
- Solubility
- Particle sizes
- Bioaccumulation factors
- Biotransfer factors
- Food ingestion rates
- Water consumption rates
- Meteorological data
- Soil characteristics
- Hydrogeologic regions
- Human health toxicity
- Ecological toxicity



Are sufficient data available for *any* NM to support quantitative risk assessment? (hint: no)

- In *The known unknowns for nanomaterials: describing and characterizing uncertainty within environmental, health, and safety risks,* Grieger, Hansen, and Baun (2009) make a compelling case regarding NM data deficiencies
- Authors reviewed 31 recent reports and articles describing the state-of-the-science with regard to NMs and risk assessment
- Methodology divided the uncertainties into four "locations" including (1) Testing, (2) Characteristics of NM, (3) Exposure Assessment, and (4) Effects Assessment
- Authors concluded that "Given these data, it is unclear if quantitative risk estimates including most quantitative uncertainty analyses are able to provide meaningful results."

Can existing risk assessment modeling tools be used for NMs if data are available? (hint: no)

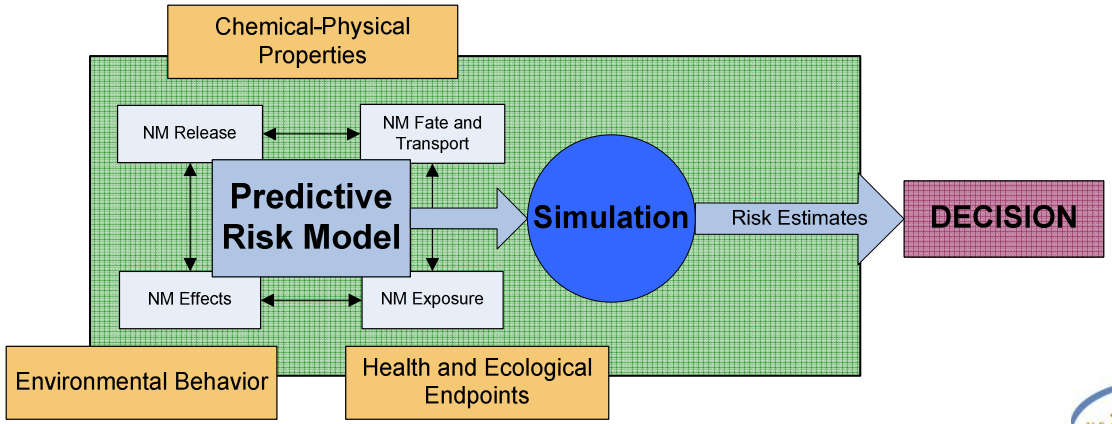


How can we think about risk assessment given the uncertainties associated with NMs?

Lower Cost
Simpler Models
Limited Data Requirements
Higher Uncertainty

Higher Cost
More Complex Models
Greater Data Requirements
Lower Uncertainty

Perhaps we should focus on developing an answer to the question: “what level of research and data are needed to develop a predictive model that can reliably be used to support waste management decisions under RCRA?”



Potential keys to the path forward for assessing end-of-life risks under RCRA?

- RCRA, in its current form, contains sufficient regulatory breadth to cover nanomaterials (e.g., EPA can add NMs under RCRA); however, some changes will likely be needed
- In the absence of reliable tools/data to perform predictive, quantitative risk assessments, alternative approaches such as multi-criteria decision analysis may provide a transparent method to determine the most appropriate management option
- Other structured approaches managing uncertainty in environmental modeling may provide a sound basis for the development of simple models that incorporate new research data as it becomes available (e.g., Koprogge, van der Sluijs, and Peterson, 2009)

A few references of interest ….

- Grieger, K.D., S.F. Hansen, and A. Baun (2009). The known unknowns for nanomaterials: describing and characterizing uncertainty within environmental, health, and safety risks. *Nanotoxicology. 3:3.*
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