University of Wisconsin-Madison
NSEC
Nanoscale Science & Engineering Center

Regulatory Issues and Capacity

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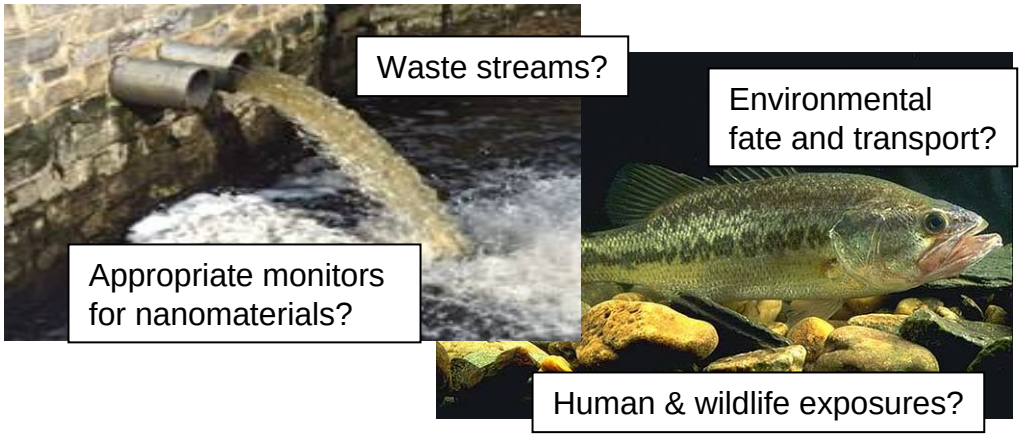
THE UNIVERSITY of WISCONSIN MADISON

Research Activities Related to Regulatory Issues and Capacity

- Delineate key environment and safety risk assessment and regulatory data gaps
- Assess federal and state level regulatory capacities
- Research on the environmental fate and toxicology of engineered nanomaterials

Risk & Regulation Gap Analysis



- Workgroup: Powell, Tai, Kanarek, Griffin (WDNR)
- Research Questions
  - What are the most critical nanotechnology environmental risk data gaps?
  - How do data gaps challenge federal and state regulatory agencies?
  - What social, technical and economic factors influence these gaps?
  - Do government agencies have the capacity to address these issues?
- Methods
  - Content analysis of government, legal, and scientific documents
  - Grounded theory (interviews with government staff and scientists)
  - Participation-based approaches
  - Historical-institutional analysis
  - Collaboration with WI State agencies, UW Health & Safety

Key Risk Assessment Data Gaps

- Few experimental data
- Environmental levels unknown

Environmental Fate and Transport

- Few exposure scenarios characterized

Human and Wildlife Exposures

- Not characterized

Emission to Environment

- Few toxicity studies
- Numerous uncertainties
- Relevant materials and doses not known

Toxicology

- Production levels & locations not well understood

Nanomaterial Sources

Risk Assessment

- Toxicity and exposure data lacking

Policy Development

Risk Communication Citizen Engagement

- Regulations hinge on risk assessments, monitoring and control techniques

- What risks to communicate?
- Whom to communicate with?

Based on Powell & Kanarek. *Wis. Med. J. 2006a, 2006b*; Powell, Griffin, Tai. *Environ. Manage.* (in prep.)

Case Study: WDNR Regulatory Capacity

Economic
Under-funded
Understaffed

Communication
Lack info and training on nanotech risk issues

Prioritization
Overwhelmed with known problems

WDNR Capacity to Address Nanotech Risks

Air
Hazardous NPs emitted?
Emission locations?

Waste
Are nano-wastes hazardous?
Locations of emissions?
Environmental fate?
Do spill laws apply?

Water
NMs used for water treatment?
Emissions? Fate in water?
How/when to issue permits?

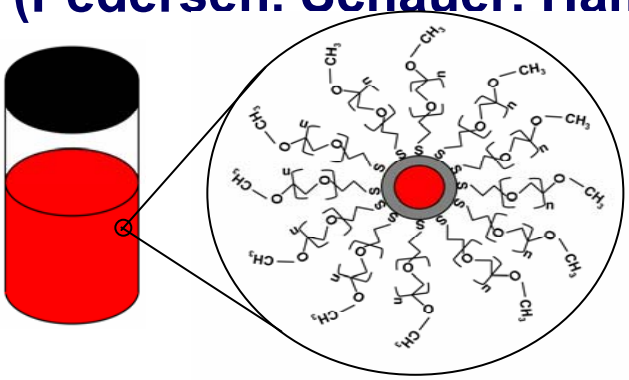
Remediation
Regulatory approval needed for clean-ups using NMs?

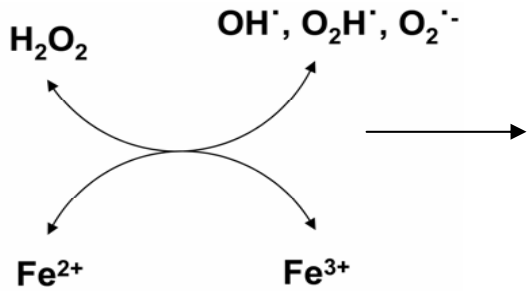
Griffin et al. *Nanotechnology and Natural Resources: Preparing the Department for the Present & the Future*. WDNR, 2007.

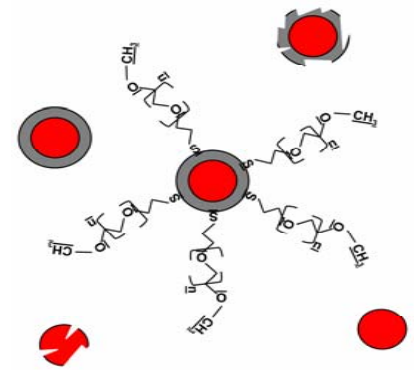
Challenges in Risk Data Gap and Regulatory Research

- Interdisciplinary, collaborative work is time-intensive and unpredictable
- Differing agendas and responsibilities of research scientists and government agencies
- Few incentives to promote collaboration among nanotech scientists and government agencies
- Political, social, cultural, risk perception, and communication barriers to discussing and addressing potential risks

Environmental Stability of Nanomaterials
(Pedersen. Schauer. Hamers)







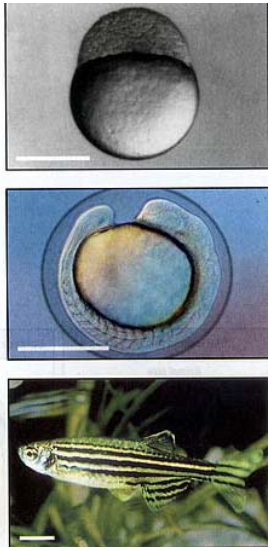
Water-soluble Quantum Dots

CdSe/ZnS-PEG-*R*

R = $-NH_3$ (+), $-OCH_3$ (n), -COOH (−)

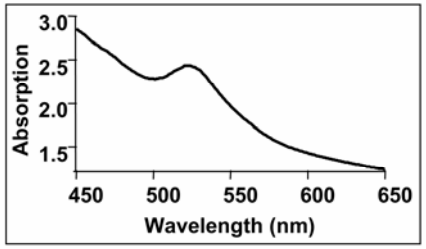
Simulated environmental conditions

Numerous possible by-products



Characterization and Toxicity Assessment

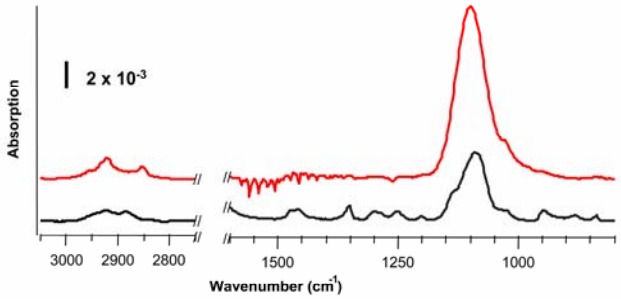
UV-Vis Spectra



Core size

QD concentration

FTIR Spectra



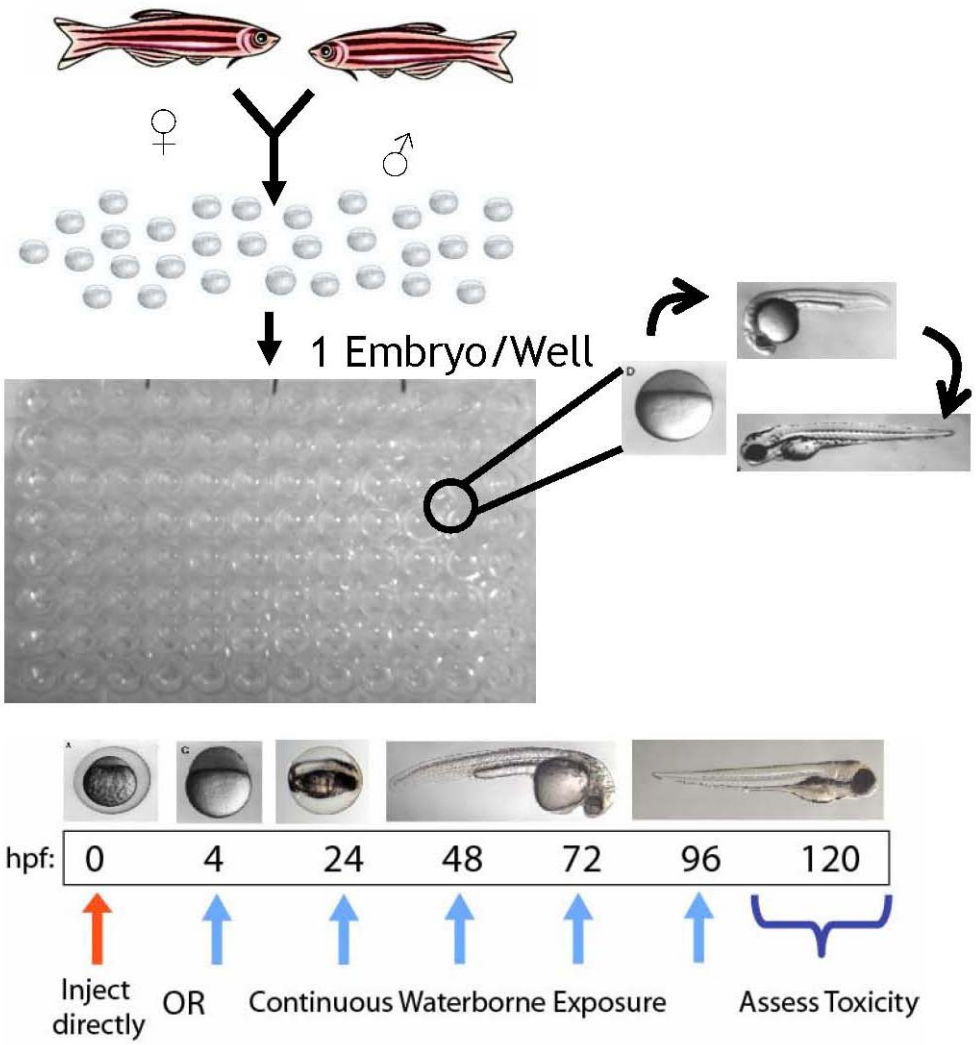
Surface chemistry

Characterization of "weathered" QDs

Toxicity of "weathered" QDs

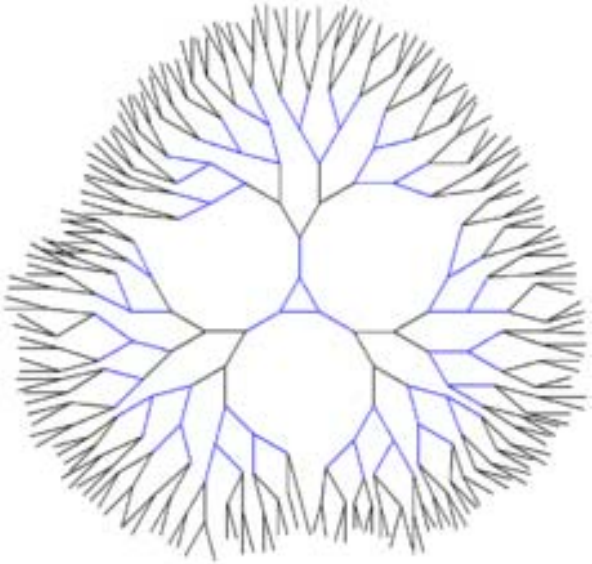
Toxicology of Engineered Nanomaterials

- Workgroup
  - Peterson, Heideman
- Goal: Develop low-cost, medium throughput, whole animal assay to screen for toxicity
- Objectives
  - Assess types of toxic responses produced by NPs
  - Correlate uptake, bioavailability and toxicity with NP characteristics
  - Determine effect of NP exposure on gene expression
  - Develop methods to classify NPs by toxicity and likely exposure routes

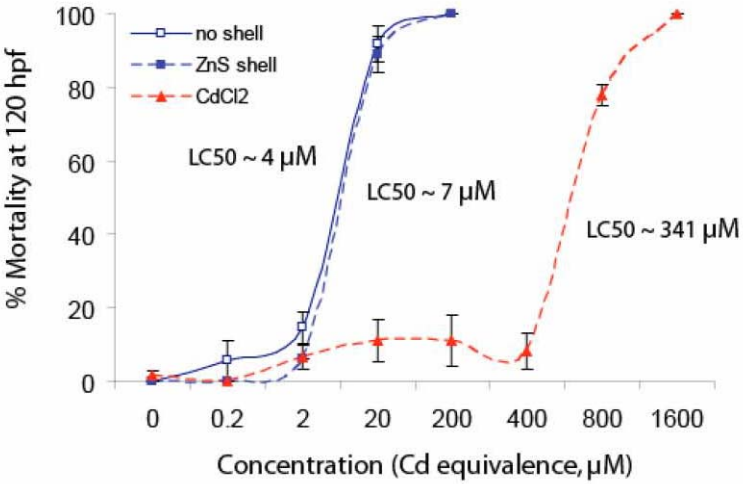


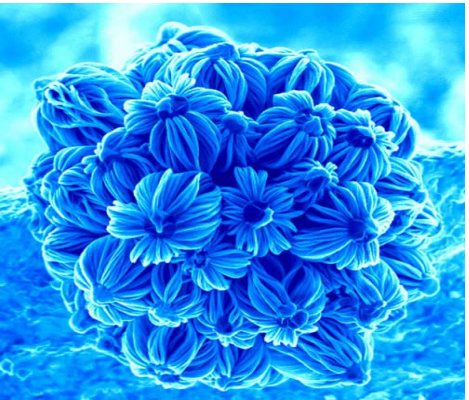
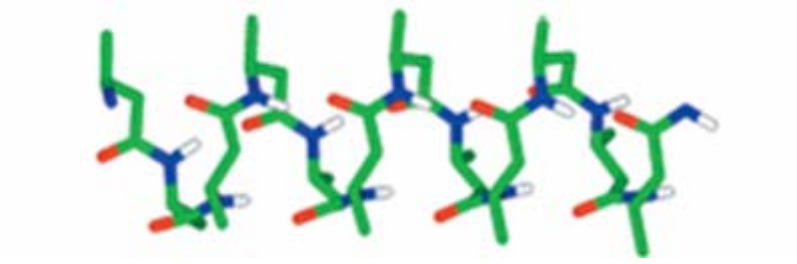
Preliminary Toxicology Findings

- Dendrimers (low-generation PAMAM)
  - Generation influenced toxicity
  - Conjugation with tripeptide targeting cellular receptors decreased toxicity (King Heiden et al., *Toxicol. Appl. Pharm.*, in review)



- Functionalized quantum dots
  - Toxicity not solely Cd-induced
  - QD functionalization influences toxicity
  - Now examining effect of surcae chemistry on toxicity



Challenges in Environmental Fate and Toxicological Research

- Measurement of NPs and their degradation products in environmental and biological matrices
- Determining relevant exposure levels and toxicological endpoints