Identifying & Regulating Environmental Impacts of Nanomaterials

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Rationale

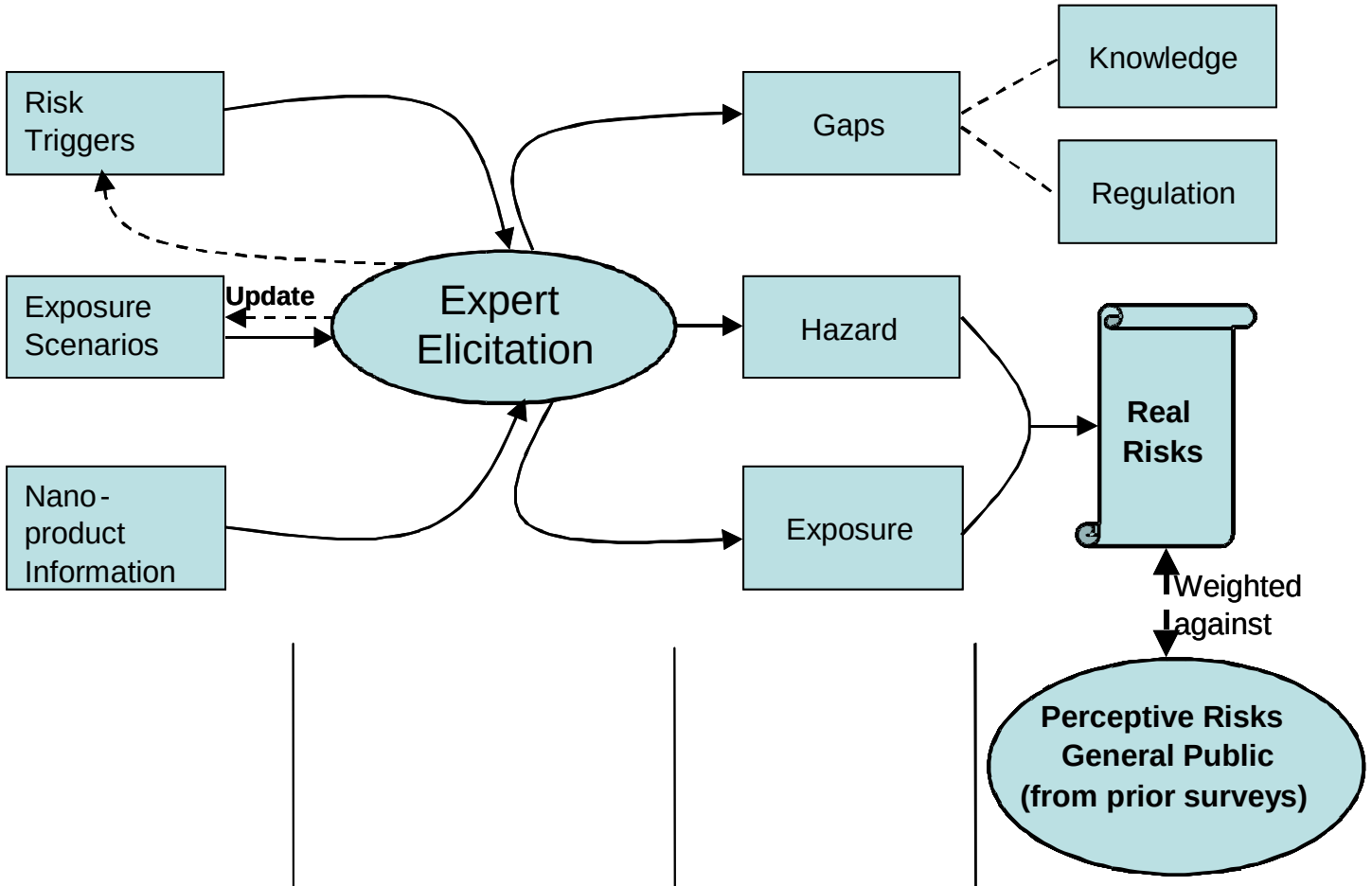
To realize the market potential of nanotechnology, uncertainties need to be characterized through upstream identification of risks & opportunities. Some uncertainties with nanotechnology:

- No real-time monitoring & protection technology
- Toxic effects at cellular or tissue levels
- Classification & Nomenclature for Regulation
- System-level: Cascading, Interactive, Embedded and Autonomous System effects

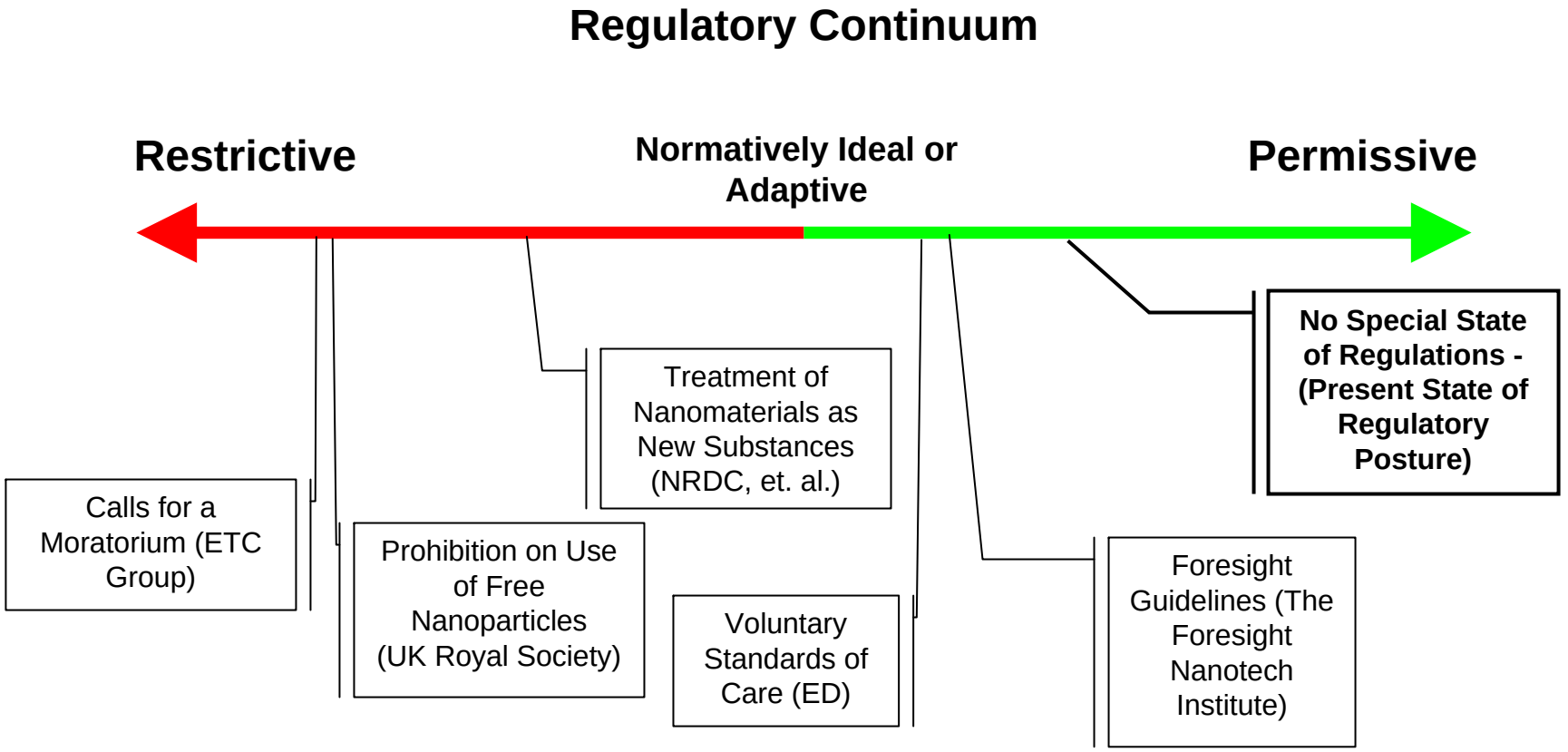
Research Goals

- Framework to identify the risks and impacts:
  - Estimating risks from a study of potential hazards and exposure scenarios
  - Including Regulatory & Knowledge Gaps in risk identification strategy
- Methodology to weigh benefits against risks
- Pathways to risk-based regulation rather than list-based regulation

Methodology: Scenario Analysis & Expert Elicitation



Continuum of Nanotechnology Regulation Proposals



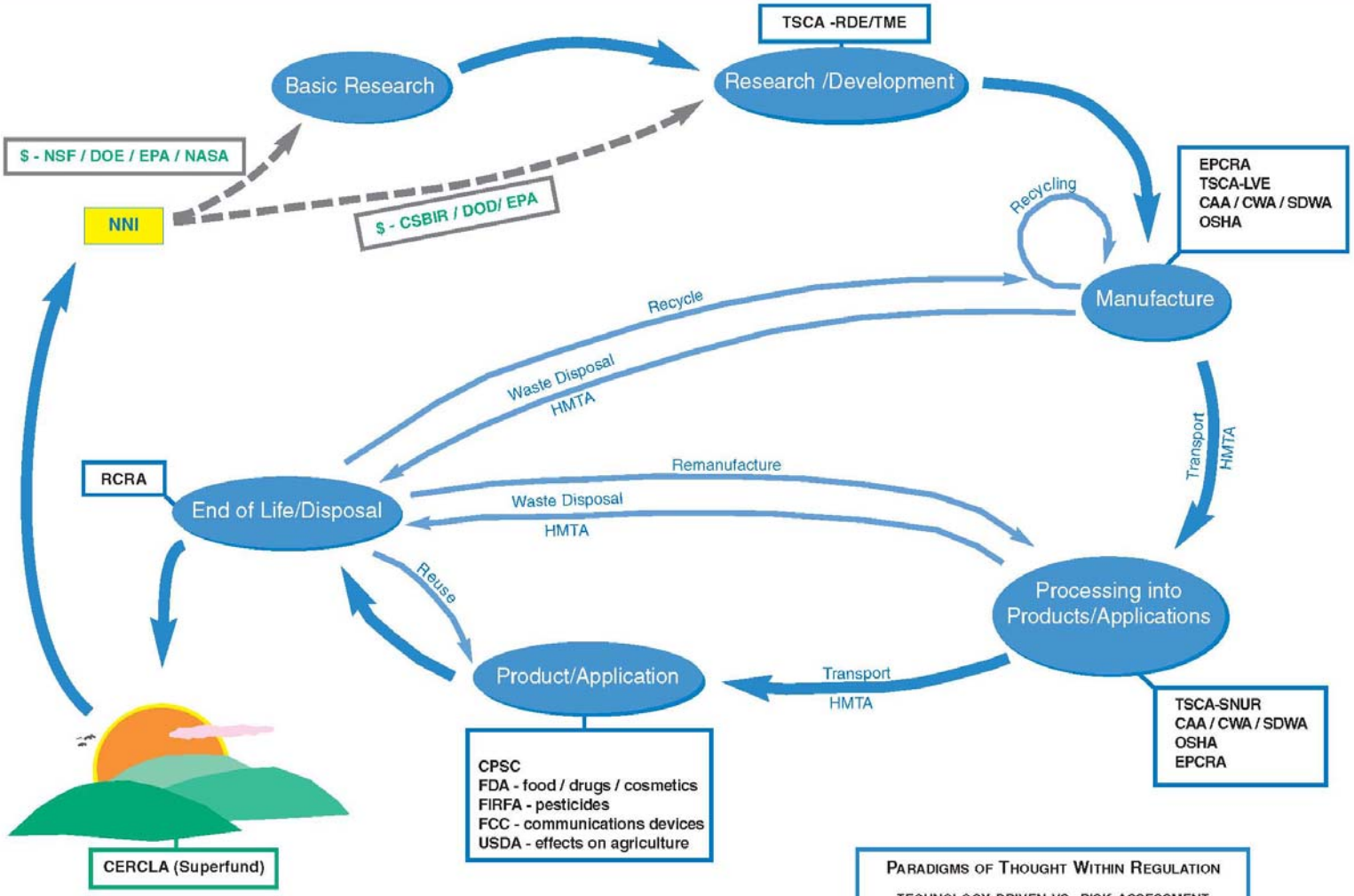
Regulatory Gaps

Nano-products likely to fall through regulatory gaps due to classification and nomenclature issues

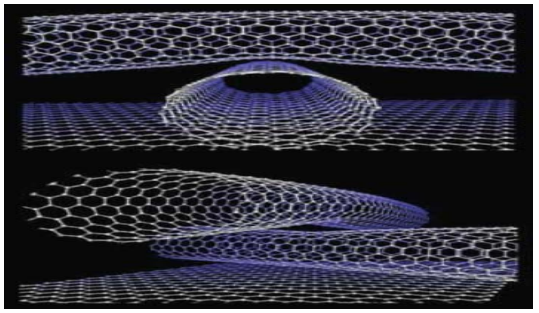
- *Which* regulatory gaps apply to *which* nano-products
- To *what* extent, and *where* in the product life cycle
- Weight the risks that arise from regulatory gaps

Life Cycle Stage	Relevant Risk Triggers	Possible products
R & D, Manufacturing and Application stage		
TSCA: R&D, Test marketing, Low volume exemption		Products that contain carbon nanotubes (Field Emission Displays), perhaps tennis rackets
FDA: Regulatory centers	FDA Nomenclature: Device or a Drug?	Sunscreen, Toothpaste, Food Supplement, MRI contrast agent
FIFRA: Pesticidal or antibacterial effects?	Antibacterial - harm useful bacteria in the environment or the human body?	Toothpaste, Air freshener
End-of-Life & Disposal stage		
RCRA: classification under RCRA?	Multiple Disposal Pathways	Air freshener spray, Battery, MRI contrast agent, Field emission display
Transporting stage		
HMTA	New product - new nano-application or performance enhancement?	Battery, MRI contrast agent, Field emission display
Long Term Environmental Site Implications stage		
CERCLA (Superfund): Long term environmental, health risk	Dispersibility, Photoactive behavior or Catalytic Property, Antibacterial	Air Freshener, Battery, Racquet, Field Emission display

Life Cycle Analysis and Regulation of Nanotechnology



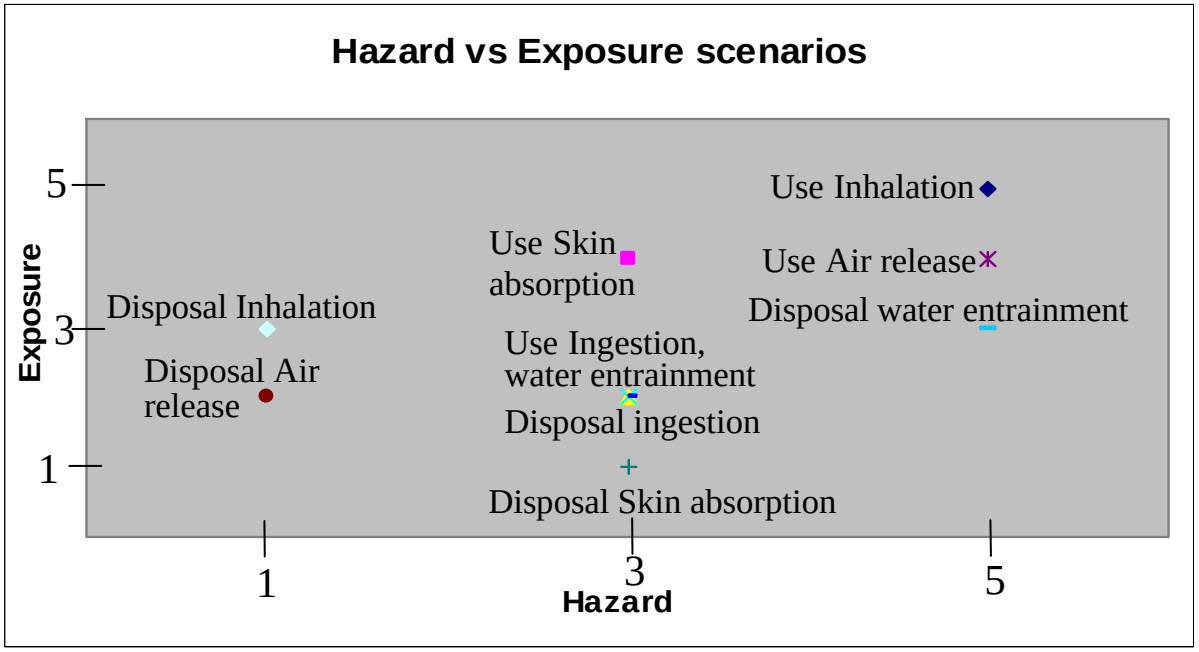
Case Study: Carbon Nanotubes and the Low Volume Exemption



- Life Cycle Stage: Manufacture
- Regulatory Gap: Under TSCA, LVE limits regulation of facilities producing <10,000 kg/year
- Scenario:
  - About 44 carbon nanotube producers (Cientifica), and about 100 metric tons produced per year (UK Royal Society)
  - "A 40 inch computer display uses one-sixth of a gram of carbon nanotube powder (roughly 10,000 nanotubes) (Mann 2004). If all 25 metric tons of carbon nanotubes going to electron emission applications (estimated above) are used for computer displays, they would enter into 150 million displays."
- Implications:
  - Potential environmental impacts are widespread with no attention to risk.
  - Nanomaterials change the risk assessment paradigm. Mass does not correlate risk or exposure.

Risk Identification for Air Fresheners

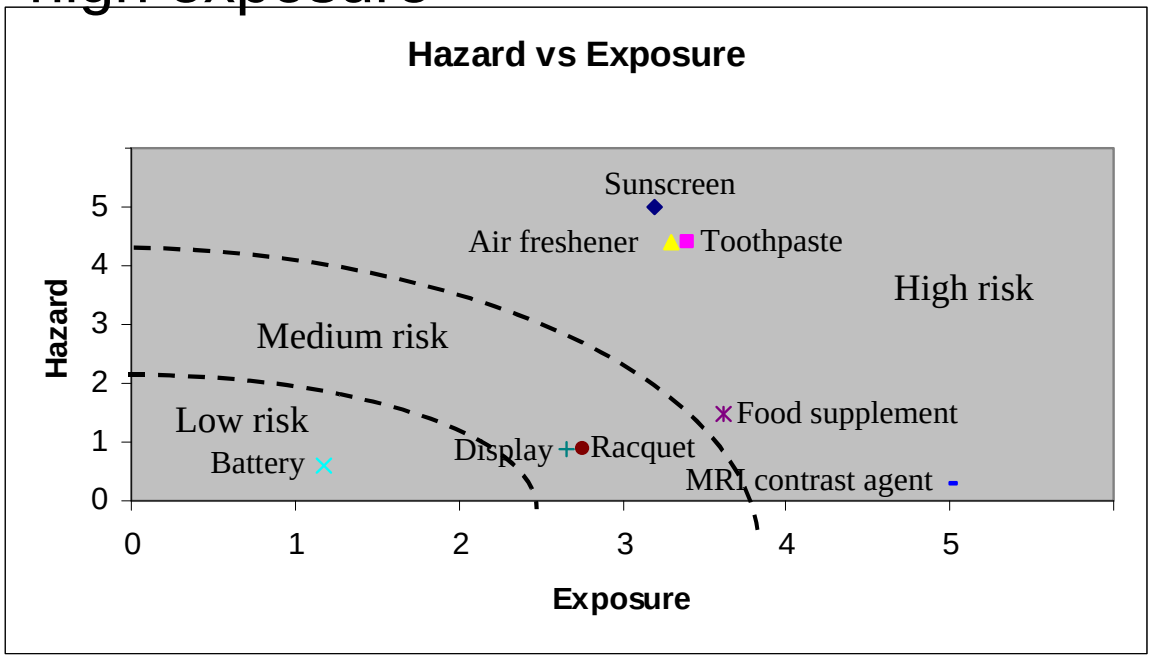
Product Information: 20-50 nm silver nanoparticles in polymer matrix with antibacterial properties (used as spray)
High-risk scenarios: Inhalation and air release during use, water entrainment during disposal
Nano-property risk triggers: Easy bio-availability, anti-bacterial property, ease of dispersion, affect on susceptible populations



Intersection Scenarios:
- Wider bio-availability during air-release or water entrainment
- Anti-bacterial effects outside product cycle
- Susceptible Population (respiratory problems)

Risks from cross-section of products

- Relative risks higher for sunscreens, toothpastes, and air fresheners based on number and weights of both ‘high hazard’ and ‘high exposure’ scenarios
- Food supplements and MRI contrast agents pose some significant scenarios for high-hazard, but few scenarios for high exposure



Risk higher for products where Nanoparticles can be disengaged from the matrix or composite to which they are bound

Challenges & Opportunities

- Risk:
  - Including regulatory and knowledge gaps in framework
  - Criteria to weigh risks arising from various sources
- Regulatory:
  - Statutes regulate products not technologies
  - Dispersed through multiple agencies
- Toxicology:
  - Need standardized methods to collect toxicology data for application within risk context
- Risk versus benefit analysis
- Hazard communication to decrease exposure

Publications

- (In Press). Environmental Regulatory Implications for Nanomaterials under the Toxic Substances Control Act (TSCA), IEEE Technology & Society
- The Product Life Cycle and Challenges to Nanotechnology Regulation, Nanotechnology Law and Buiness, Vol 3, Issue 4.
- (Submitted). Identification of Risks in the Life-Cycle of Nanotechnology-Based Products, Journal of Industrial Ecology.
- Conference Presentations at MRS Fall 2005, NSTI Summer 2007

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