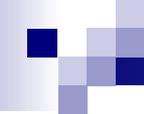


# Nanotechnology: Challenges to the Federal Regulatory System

Mark Greenwood  
Ropes & Gray



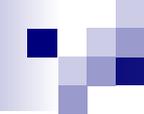
# Agenda

- The Challenges of Nanotechnology
- Issues for the Federal Regulatory System
  - Lead statutes: product vs. facility programs?
  - Principles guiding risk assessment
  - Approach to particulates
  - Monitoring challenge
  - Cross-media tradeoffs
  - Public access to useful information
  - Implementation across programs
  - Engagement of stakeholders



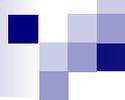
# Challenges of Nanotechnology

- Nanotechnology is not an industry
  - Set of technologies that will spread through multiple industries at differing rates of speed
- Leadership is dispersed
  - No single center of leadership in industry
  - Multiple federal agencies have an interest
    - Regulatory oversight for health, safety, environment
    - Development and promotion of technology



# Challenges of Nanotechnology (con.)

- Presents special issues of toxicology & exposure
  - Size matters: impact of nano-scale particles
    - Exposure potential or inherent toxicity
  - Special physical chemical properties
    - NNI definition of nanotechnology includes creation of novel properties to materials
    - Will these novel properties affect toxicity?
    - Impact of self-replication: analogy to biological material



# Issues for the Federal Regulatory System

- General statutory frameworks are robust
  - Too early to pronounce particular statutes unworkable
- But currently no program is well-suited to address the challenges of nanotechnology
  - Question is how current programs should evolve
- What pressure points does nanotechnology create for federal environmental programs?

# Lead Statutes for Nanotechnology?

- **Product programs: TSCA/FIFRA**
  - History of adapting to new chemical species
  - Weak tools to assure implementation of management practices (product-specific orders/licenses; labels)
  - Woefully under-funded
- **Facility programs: CAA/CWA/RCRA**
  - Bigger programs; strong implementation infrastructure
  - Slow at keeping up with new materials in commerce
  - Dependent on regulating broad categories (VOC, TSS)

# Principles guiding risk assessment

- Backdrop: 10-15 years to clarify toxicology issues, even at a basic level
  - Inadequate resources to test every substance
  - Need for surrogates (e.g., TSCA SAR principles)
- What are the indicators of toxicity?
  - Toxicology of non-nano version of chemical?
  - Particle size, shape, surface area, electrical charge?
- How to define categories of concern (e.g., PBT)?

# Approach to Particles

- EPA has taken differing approaches
  - CAA: particulates are treated as toxics
  - Other programs have distinguished chemical species
    - Small particles migrate widely in body
    - But chemical species can have differing impacts
    - Ex: crystalline silica vs. titanium dioxide, carbon black
- EPA's path on this issue has huge implications
  - Nanotech particles as inherently dangerous?
  - Potential cost to differentiate particles on toxicity spectrum

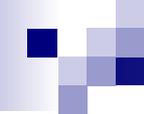
# Challenge of Monitoring

- TSCA/FIFRA don't rely on monitoring
- But monitoring is central to CAA/CWA/RCRA
  - Programs mandate monitoring of “bad” chemicals
- What will be the monitoring protocols for nanoscale materials?
- And can monitoring be cost-effective?
- Monitoring is a central issue that determines viability of various programs



# Cross-Media Tradeoffs

- Nanotechnology as an environmental opportunity
  - Ex: avoiding waste; environmental sensors
- Potential environmental pros/cons
  - Internecine battles among environmental professionals
- Lack of a framework to resolve disputes
  - Criteria for making risk-risk tradeoff decisions
  - Process for dispute resolution



# Public Access to Useful Information

- Debate over significance of toxicology data on nanotechnology is already upon us
- Transparency of data is necessary for compliance, liability protection & public credibility
  - More structured system for sharing data?
- Managing uncertainty: allow science to develop
  - Long road: how to avoid over-reaction to early work?
  - But encourage prudent management responses to credible available evidence



# Implementation Across Programs

- TSCA/FIFRA impose broadly stated controls
  - Ex: no discharge to water, high-temp incineration
  - Minimal specifics (protocols, monitoring, etc.)
- Air/water/waste programs are not watching over implementation of these requirements
  - Not generally aware of such controls
  - Cannot refine controls or assure implementation
- Without coordination, releases of nano-materials will not be controlled



# Stakeholder Engagement

- Range of industries and companies are involved
- Many of the players are not generally engaged in federal environmental policy
  - Ex: Start-up companies, non-US manufacturers
- No single representative for all of these interests
- Important to engage a broader community
  - Real-life scenarios drive policy
  - Missing key players leads to distortion of policy