



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