Creating an Effective Oversight System for Nanotechnology

Mark Greenwood
Ropes & Gray
Why this Paper?

- Nanotechnology has arrived in several industries
- Environmental health and safety is an issue
  - Data suggest some materials could be hazardous
- Public is expecting some kind of oversight
- Yet public debate has not focused on the core principles that should guide oversight
  - More focus on research and legal jurisdiction
- Need to “ask the right questions” on principles
  - Then multiple parties can pursue common goals
Why Now?

- Government agencies are making decisions
  - Criteria being used are not transparent
- Industry is developing internal policies for worker protection and product screening
- Insights for research priorities
- Focus on core issues improves engagement
- Guide to technology innovators
- Informs business models that will succeed
Core Building Blocks for Oversight

- Risk Criteria
  - What is and is not a problem?
  - What are acceptable risks?

- Information Needs
  - What information is needed to make a reasonable judgment about risk?

- Risk Management Measures
  - What technologies and practices work?
  - Is a “performance-standard” approach feasible?
Risk Criteria

- What would make a nanomaterial risky?
  - Size affects exposure potential
  - But unique characteristics may dictate hazard

- Issue: What are the relevant analogies?
  - Without specific data, what is a comparable material?
  - Ex: crystalline silica vs. titanium dioxide?

- Issue: How to consider exposure?
  - During use, nanomaterial is usually in a mixture
  - But at disposal, it may take new form in environment
Information Needs

- Data needs likely to be greater for nano than for macroscale versions of same chemical
  - Need to account for migration in the body
  - Importance of unique structural properties

- Issue: When is new testing needed
  - Reliance on data from other chemicals?
  - Tradeoff between controls and additional data

- Issue: Who can commercialize nano?
  - Costs affect business models, product viability
Risk Management

- Nano oversight is seen as product oversight
  - Inherent limits to what can be achieved
  - Better at product design, manufacturing controls
  - Not as good at downstream use, disposal scenarios

- Issue: do performance standards work?
  - Depends on the ability to conduct monitoring that may never be feasible or cost-effective

- Issue: role of labeling?
  - What is the public message?
The Transparency Challenge

- As a broad principle, transparency can improve decisions and enhance public credibility.

- Yet many product-specific data are confidential:
  - Formula, process technology, production volume
  - Customers, distribution networks

- What information needs to be in the public domain, for policy and personal choices?
  - What decisions do people want to make?
  - What data are useful for that purpose?
  - How can data be assembled to inform those decisions, without revealing trade secrets?