Considerations for Government Oversight of Nanotechnology

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Agenda

- Who is the "industry"?
- Public perceptions
- Challenges facing product oversight programs
- Challenges facing waste management programs
- Potential collaboration?

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Nature of the "Industry"

- Nanotechnology is not really a single industry
  - It is a technology applicable in multiple contexts
  - It is sweeping across many industries
  - 10-15 years: it will not be distinct from "technology"
- Yet it may be treated as an "industry" for policy and political purposes, at least initially
  - Separate interest groups, policies, programs
  - Over time this may not make sense
  - Beware efforts to separate it from ongoing risk assessment and management activities

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Nature of "Industry" (con.)

- Defining it as a separate industry is confounded by the "nanotechnology" definition
- National Nanotechnology Initiative definition
  - Technology manipulating materials that have at least one dimension below 100 nanometers
  - Creating structures with novel properties and functions
- What constitutes a "novel property"?
  - What is "novel" can vary with commercial context
  - This could occur in many industries
  - Uncertainty of definition leads to unclear scope

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Public Perceptions

- Initial surveys of public perceptions
- Low general awareness of what nano is
- When explained, mostly positive reaction
  - Medical applications draw greatest interest
  - Then better consumer products
  - Little support for a ban pending more information
- Concerns about the unknowns
  - Affected by perception of past failures in policy
  - Need for adequate testing
  - Will it go where it should not (e.g., food)?

Public Perceptions (con.)

- Confused about existing structure of oversight
  - Roles of EPA, FDA, OSHA, CPSC
- Perceptions of government actors
  - Highest trust in CDC, EPA, CPSC, OSHA, FDA
  - Lower for White House; lowest for Congress
- Government oversight perceived as needed
  - Voluntary not enough; but many undecided
- Key actions to build public trust
  - Increased safety testing
  - Good public information to inform choices

Product Oversight Challenges

- Key agencies in product oversight
  - EPA: TSCA (program has begun); FIFRA (developing); CAA (first fuel additive under review)
  - FDA (sunscreen petition, October public meeting)
  - OSHA/NIOSH (testing of protective clothing, HEPA filters)
- Difficult jurisdictional issues
  - TSCA: Are nanomaterials "new" chemicals?
    - Chemical formula vs. unique physical structures
  - FDA: When is a product a "new" drug?

Product Oversight (con.)

- Defining the potential hazards
  - Is "nano size" inherently dangerous?
    - Probably not; but it affects exposure (e.g., migration to brain)
  - How to assess effect of "novel" properties on hazard
    - What is the novel property? Is it a sliding scale?
    - Ex: electrical charge vs. surface area?
    - Understanding cellular chemistry and mechanism of action
  - How to factor in what is known about macro-molecule
  - Form in use and in the environment
    - Ex: coatings; mixtures with other materials
  - Agglomeration potential can affect likely hazard

Product Oversight (con.)

- Considerations for exposure potential
  - Uncertainty of fate, transport in environment
    - What happens to a small particle with an "active" surface
  - Context: other nanoparticles in environment
    - Engineered nanomaterials vs. environmental nanoparticles
    - Ex: wood smoke, auto exhaust
    - How to define unique risk of engineered nanomaterial?
  - Challenges of monitoring
    - Not possible for specific engineered nanomaterials
    - Product oversight will rely on models, surrogates, mass balance calculations; very limited exposure data

Product Oversight (con.)

- What are the data needs?
  - Probably more extensive than for regular chemicals
    - Translocation of nanomaterials in body
    - Need to understand physical structure and attributes
  - Ultimately it is impractical to test every material for every potential concern; what are priorities?
  - May trade off data requirements for risk management measures
  - Will be guided by analogies drawn from existing data to answer questions and guide data requests

Product Oversight (con.)

- What forms of risk management make sense?
  - Protecting workers
    - Testing of gloves, masks now under way
  - Product design to reduce exposure
    - Focus on use only? What about disposal scenarios?
  - Performance of measures to control particles
    - Can high performance filters work at nanoscale?
    - Conflicting claims in marketplace
  - Effectiveness of treatment, destruction technologies
  - Labeling: notice, warnings, instructions?

Waste Management Challenges

- Do waste management agencies need a "nano program"?
  - Some actions (e.g., spill) will trigger responsibility
  - Logical program to respond to public concerns
  - Less a "program"; more a "capability"
- Key questions
  - Am I ready for likely public questions?
  - Can I take effective remedial action if needed?
  - Can I estimate nanomaterials in the environment?
  - Can I identify effective control strategies?

Waste Management (con.)

- Answering public questions
  - Basics of nanotechnology
  - Government responsibilities for oversight
  - Hazard potential: what concerns have arisen?
    - Ex: specific chemistry matters
  - Exposure potential: what is the likelihood that I could be exposed to dangerous levels?
    - Potential loadings from particular sources
    - Comparisons to other things (e.g., other nanoparticles)
  - What actions can the government take?
  - What actions can I take to reduce concerns?

Waste Programs (con.)

- Effective remedial action
  - Spill control measures
  - Management of uncontrolled particles
    - Ex: asbestos abatement measures?
  - Opportunity to use nanomaterials in treatment and remediation: What are the contingency plans?
- Estimation of nanomaterials in the environment
  - Know the primary sources in your jurisdiction
  - Determine estimation techniques
    - Surrogate monitoring vs. mass balance estimation

Waste Programs (con.)

- Identification of effective control strategies
  - Effectiveness of particle control measures
    - Ex: what air filters control nanoscale particles?
    - Ex: application of ultra-filtration process equipment to wastes
  - Protective measures for individual
    - Analogies to occupational exposure
  - Disposal, treatment measures
    - Ex: destruction capabilities of typical waste treatment
- Public engagement is key to risk communication
  - It is a process, not a one-way message

Potential Collaboration

- What you can expect from product programs
  - Chemical, material characterizations
    - Available physical-chemical, toxicity data
    - Analogs to help identify, narrow potential hazards
  - Production processes, product formulations
    - Ex: pesticide Confidential Statements of Formula
  - Occupational risk measures
    - Potential analogies to consumers using particular products
  - Exposure models
    - May be question about relevance to nanoscale material

Potential Collaboration (con.)

- What <u>not</u> to expect from product programs
    - Monitoring data
        - They probably did not need it to do their job
    - Risk management measures for waste
        - Likely to be borrowing from waste programs, if at all
    - Fate, transport testing data
        - Accepted methods probably not tailored to nanomaterials
        - More likely that models were used
- Great program variation based on product use
    - Ex: FDA drug, EPA pesticide vs. FDA cosmetic

Conclusion

- Nanotechnology presents a unique challenge for the design of government programs
    - Technology offers great social, economic benefit
    - It will spread broadly throughout society before health and environmental implications are fully understood
    - Potential "Wow to Yuck" response by public
    - Some hazards are present, but difficult to define
    - Hard to calibrate government oversight to real concerns
    - Life cycle effects mean that all programs are relevant
- Important for OSWER to define its role