Risk Management of Nanotechnology

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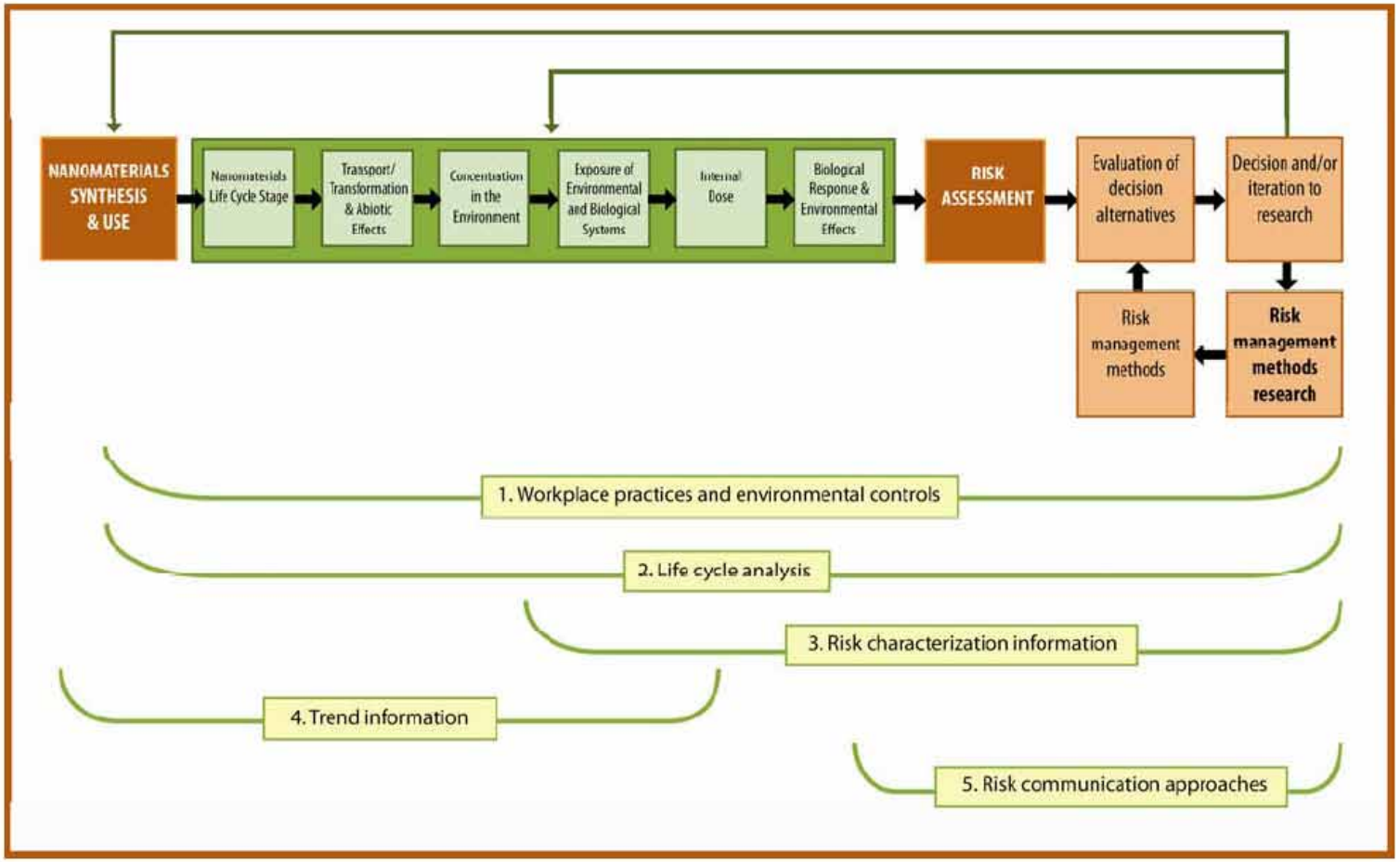
Nanotechnology Risk Management: Session Overview

- Gary Marchant, Arizona State
  - Risk management of nanotechnology from a top-down perspective
    - i.e., role of government and governance in implementing risk management
- Greg Lowry, Carnegie Melon
  - Risk management of nanotechnology from a bottom-up perspective
    - i.e., building science-based techniques for risk assessment/risk management under uncertainty

STRATEGY FOR NANOTECHNOLOGY-RELATED ENVIRONMENTAL, HEALTH, AND SAFETY RESEARCH

Figure 12. Framework for EHS research supporting Risk Management Methods*



Risk Management: Potential Levels of Organization

- Government regulatory agencies
- Non-regulatory public bodies
  - e.g., NAS/NRC
- Public-private partnerships
  - e.g., ICON
- NGOs/Think Tanks
  - e.g., Project on Emerging Nanotechnologies
- Business coalitions
  - e.g., Responsible Care
- Individual companies
- Individual scientists/engineers/risk managers

Growing Pressure for More Nanotechnology Oversight

- Many voices in U.S. calling for more regulatory oversight of nanotechnology:
  - Environmental & citizen groups
  - Media
  - Members of Congress
  - Insurers
  - Investors/Venture Capitalists
  - Local and state governments
  - Scientists/Public health representatives
  - Academics

But ...

Problem 1: Definition

- Most definitions use, at least in part, size (e.g., 1-100 nm)
- What does this mean from a regulatory perspective:
  - All dimensions must be 1 to 100 nm, or 1 or 2 dimensions?
  - What if some particles <100nm but also some >100nm?
    - Does it matter if 50%? 10%? 1%?
  - Almost all materials include some nano-sized particles
- Bottom line: Hard to define enforceable bright-line between nano and non-nano materials

Problem 2: Uncertainties/Data Gaps

- Very large number of nanotechnology processes, application, materials, products and facilities with different risk profiles
- Only very preliminary hazard data available
- Nanotoxicity appears to be affected by large number of variables
  - prevents using structure to extrapolate risks
- Kristen Kulinowski, ICON:
  - “We are in this awkward middle territory where we have just enough information to think there is an issue, but not enough information to really inform policymakers about what to do about it.”

Problem 3:
Rapid Technological Change

- Nanotechnology applications and systems are developing rapidly
  - "If you think that any existing regulatory framework can keep pace with this rate of change, think again." David Rajeski, Wilson Center
- Highly legalistic, politically polarized, and slow acting U.S. regulatory system may not fit rapidly emerging new technologies
  - "Governance Gap" – innovation rates in nanotech exceed our capacity to assess human and environmental consequences

    - Renn and Roco, J. Nanoparticle Res. (2006)

Problem 4:
Benefits and Risks

- Large uncertainty about risks might argue for precaution
- But many critical environmental and health benefits also possible from nanotechnology
  - Clean energy technologies
  - Hazardous waste remediation
  - Cancer treatment
- Not clear which way precaution cuts

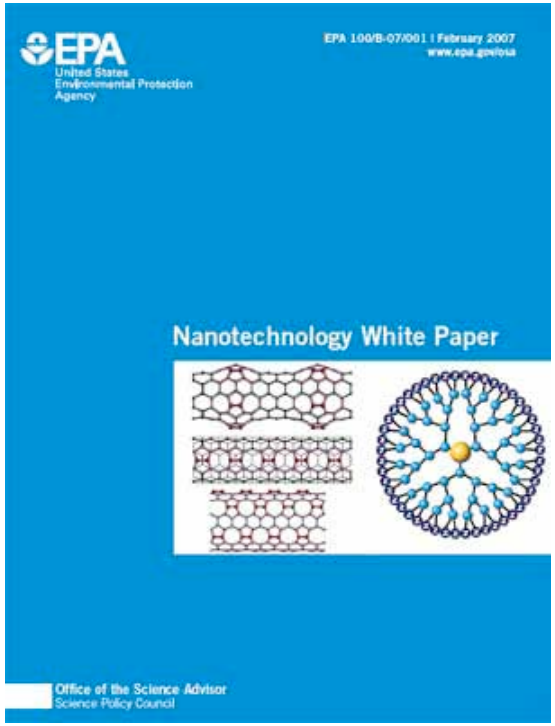
Problem 5:
Level Playing Field

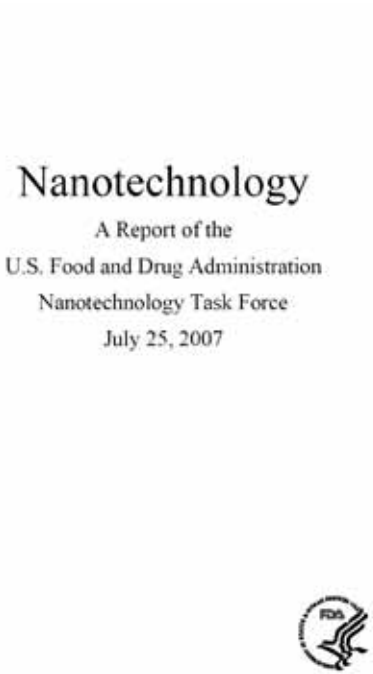
- Do we want to systematically treat all nano products more stringently than non-nano products?
  - i.e., tilt scales against nanotechnology products?
- Many historical products have contained nano-size range materials
  - have not triggered special regulatory consideration
- Magic Nano incident in Germany
  - example of double standard?

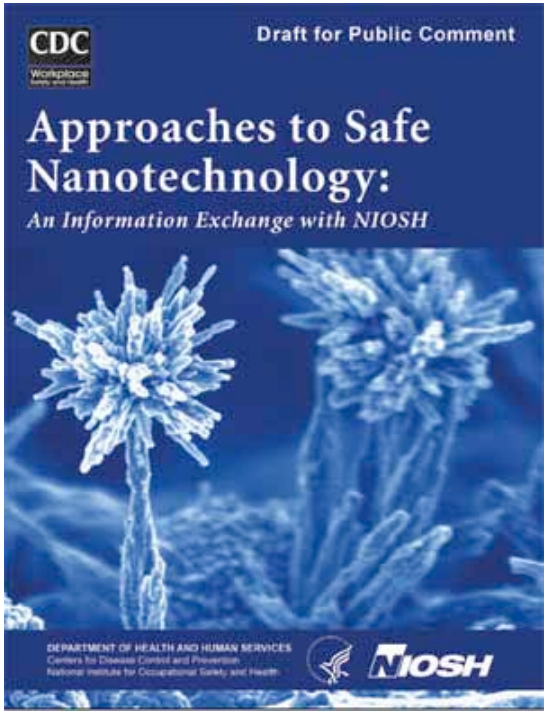
Additional Problems

- Obsolete or inapplicable statutory criteria, requirements, or triggers
- International competitiveness concerns
- Limited agency resources

Federal Agencies Are Making Some Progress







OSTP/CEQ Principles for Nanotech EHS Oversight (2007)

- “existing statutory authorities are adequate to address oversight of nanotechnology and its applications”
- “The Federal government should use standard oversight approaches to assess risks and benefits, and manage risks…”
- “Regulation should focus where need exists and where scientific information supports action (e.g. targeted to specific groups and classes of materials instead of a ‘one-size-fits-all’ approach)”

Traditional Regulatory Risk Management Approaches Unavailable or Insufficient At This Time

- Health based standards
  - insufficient data for risk assessment
- Cost-benefit weighing
  - too much uncertainty to calculate risks or benefits
- Feasibility or Best Available Technology
  - key information lacking
  - potential for over- or under- regulation

Marchant et al., Risk Management Principles for Nanotechnology, *NanoEthics*

Other Existing Regulatory Tools

- Reporting requirements
  - Definitional issues?
- Testing requirements
  - Legal authority?
  - What types of tests?
- Labeling?
  - Definitional problems
  - Almost every product would eventually need nano label?
  - Stigmatization?
- Liability
  - Difficult to prove causation?

Robust, Science-Based Regulatory Approach Not Presently Possible?

- “At present, it is not possible to implement a robust and reliable ‘science-based’ regulatory approach to nanoproducts. In this situation it is important to ensure that the appropriate precautionary measures guide the scientific assessment of risk and the selection of standards of safety”
  - Council of Canadian Academies, *Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale: Report of the Expert Panel on Nanotechnology* 21 (July 2008).

Precaution/Precautionary Principle?

- Nanotechnology would seem to be a textbook case for application of precaution/precautionary principle
- But problem: precautionary principle under-specified and does not provide clear guidance for how to address nanotechnology
  - e.g., Cass Sunstein: “Precautions, in other words, themselves create risks - and hence the principle bans what it simultaneously requires.”
- Nanotechnology may be good opportunity to develop/explore/experiment/learn tools for the prudent implementation of precaution

New Approaches Needed

- "Traditional governance mechanisms such as statutory enactments and/or … notice and comment rulemakings are thought by some to be challenging and possibly ill-suited tools for addressing potential EHS risks posed by the fast pace of evolving nanotechnologies. Even if these tools are believed suitable, most government agencies are of the view that they now lack sufficient data and information to make informed judgments on the potential hazards and risks of nanoscale materials, and it may take years not months, to obtain needed data."
  - Lynn Bergeson, The New Business of Nanotechnology: Exploring Commercial Opportunities and Risks (2008)

Lack of Oversight Not Acceptable

- "How to apply adequate oversight when the state of scientific knowledge is not adequate is one of the basic dilemmas in developing and applying 21st-century oversight mechanisms. In most cases, the science related to risk will be primitive and uncertain, but the potential risks will be serious enough so that *lack of oversight will not be an acceptable option*."
  - Terry Davies, *Oversight of Next Generation Nanotechnology* (2009) (emphasis added)

Interim Conclusion: More Is Needed

- Traditional regulatory responses unlikely to provide satisfactory oversight of nanotechnology in near- to mid-term
  - prevention of risk/harm
  - public confidence
- New approaches based on:
  - “Soft Law” approaches
  - “Governance” models

“Soft Law”

- Substantive obligations and requirements created by instruments that are not directly legally enforceable
- “in the absence of detailed research into the risks associated with many nanomaterials, we believe that voluntary approaches need to be developed and implemented to complement existing regulations and to provide guidance on prudent measures to control risk”

  - Vladimir Murashov & John Howard, *Nature Nano* (2009)
- “[I]t appears on balance that the current state of the science supports non-regulatory ad hoc approaches that are responsive to specific circumstances”.

  - Andrew D. Maynard, *J. Law Med Ethics* (2009)

“Governance”

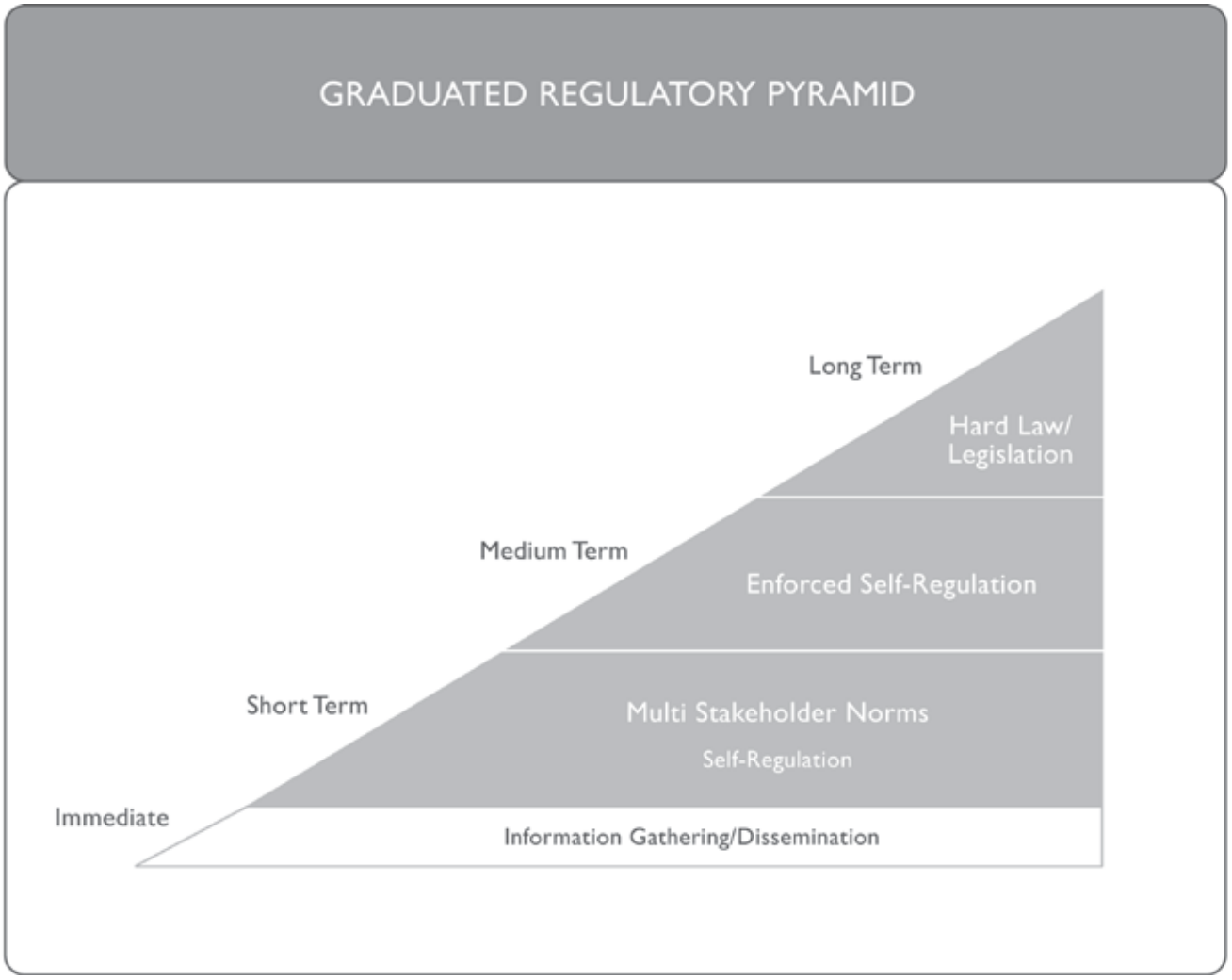
- Broadening oversight from top-down government requirements to include a much broader range of decision-makers – e.g., companies, NGOs, public-private partnerships, third parties
- “Risk governance includes the totality of actions, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analyzed and communicated and management decisions are taken.”

  - Renn & Roco, *J. Nanoparticle Res.* (2006)

Advantages of Soft Law/Governance Approaches

- Voluntary; cooperative
- Reflexive
- Can be adopted or revised relatively quickly
- Many different approaches can be tried simultaneously
- Can be gradually “hardened” into more formal regulatory oversight

Incremental, Cooperative, Reflexive Oversight



Marchant et al., Risk Management Principles for Nanotechnology, *NanoEthics* (2008)

Example of Existing “Soft Law” Programs

- Dupont/EDF Nano Risk Framework
- Standards bodies – e.g., ISO
- Responsible NanoCode
- EU Code of Conduct for Responsible Nanotechnology Research
- CENARIOS® risk management certification
- Responsible Care program
- GoodNanoGuide (ICON)
- Other company & industry standards

Some Potential Limitations of Soft Law/Governance Approaches

- Accountability
- Credibility
- Participation
- Transparency

Other Proposals: Certification Program

- Government would provide "Tested NT" certification for products that underwent specified battery of safety tests
  - all data would be publicly available

Marchant et al, *UCLA Environmental L.J.* (forthcoming, 2010)

Other Proposals: Decision Analysis Methods

- e.g., multi-criteria decision analysis (MCDA)

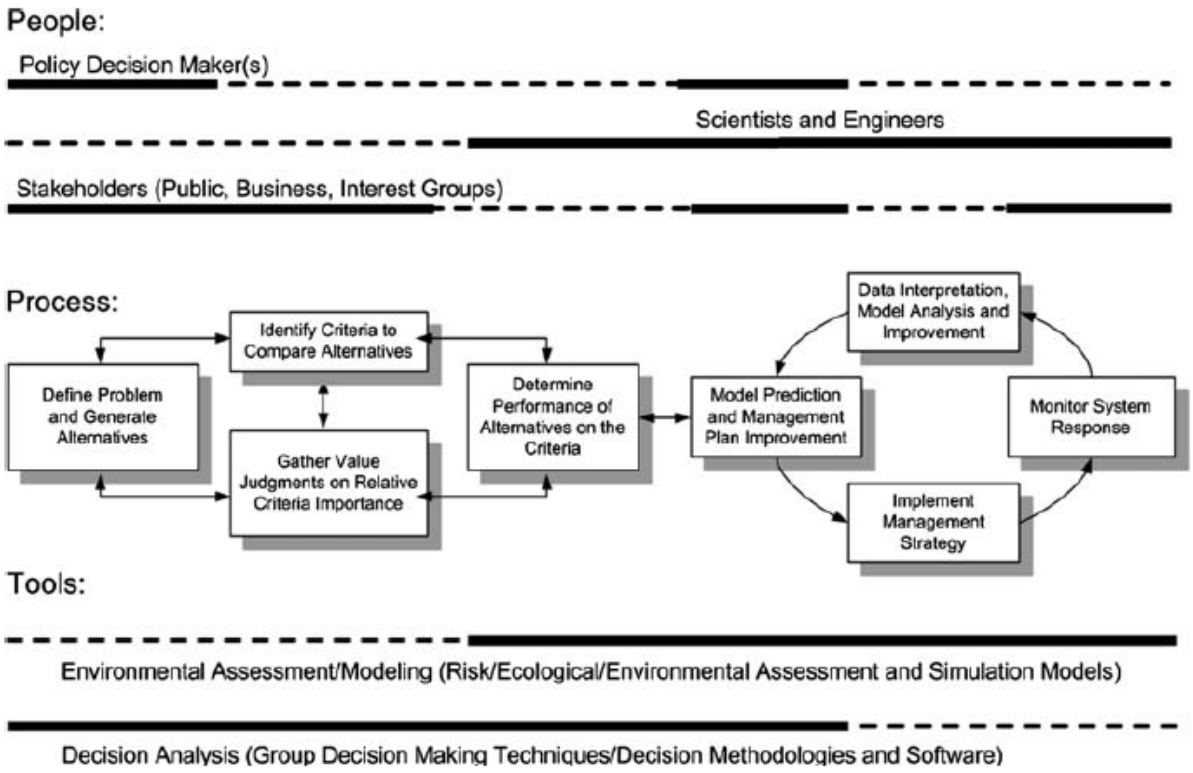


Figure 2. General MCDA framework. Solid lines symbolize direct group involvement; dashed lines symbolize less direct involvement.

Conclusion:
How Not To Do Risk Management

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