

Nanotechnology and Environmental Governance

The Problem(s) of Uncertainty

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The “Problem” of Nanotechnology – The AOL View

AOL NEWS SPECIAL REPORT

THE NANOTECH GAMBLE

BOLD SCIENCE. BIG MONEY. GROWING RISKS.



- *Nanoparticles can cause disease and death.* Regulators are doing little to respond.
- *Nanofoods coming to a store near you!* [Remember GMOs?]
- *NNI’s obsession with tech innovation and economic growth over safety*
- No U.S. agency leads on nanotech EHS – *companies can stonewall reform efforts.*
- Nanomaterials haven't yet sparked the backlash GMOs did -- *but that may change.*

WHAT'S BEING DONE

5%

FEDERAL NANOTECH FUNDING SKIMPS ON SAFETY

OF THE \$1.8 BILLION WASHINGTON HAS BUDGETED THIS YEAR FOR NANOTECHNOLOGY, **\$91.6 MILLION** WILL GO TO PROTECTING THE PUBLIC. SOME EXPERTS SAY THAT'S NOT ENOUGH. *More >*

Nanotechnology Interdisciplinary Research Team

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The “Problem” of Nanotechnology – NNI Response



Official NNCO Response – Clayton Teague

- No evidence of harm by engineered nanomaterials or products
- Series wrongly presumes that nanotechnology is inherently dangerous until proven safe
- The U.S. leads the way in nano EHS research: Federal nano EHS research has grown \$34.8 million in FY 2005 to \$74.5 million in FY 2009 and ~ \$91.6 million in FY 2010.
- *“Risk must be balanced against benefits, and the essentially theoretical risk that has so far been identified should be balanced against the benefits in terms of sophisticated products and economic growth and jobs created by this expanding industry.”* [emphases supplied]



On Uncertainty – “Framing Nano”

Andrew Maynard (2010) – nano as a "wicked" problem (Klijn 2008)

- The drivers of nanotechnology innovation \neq the drivers of oversight
- Inability of multiple stakeholders to agree on the nature of the problem

So what *is* the “problem” of nanotechnology?

- Fixation on how “new” is “new”
- How “revolutionary” is it?

Maybe we’re asking the wrong questions . . .



Outcomes of previous technological “revolutions”

- Largely Positive
 - Material comfort
 - Improved health
 - Longer lives
- Challenges Addressed (at least to some degree)
 - Worker exploitation
 - Consumer risks
 - Pollution and toxicity
 - Environmental degradation
 - Unequal access to benefits

Courtesy of Ron Sandler



The “Problem” of Nano Revisited

- Nanotechnology exacerbates even immediate and familiar challenges
- Nano as a “focusing” technology and as a challenge to governance
 - Uncertainties and lack of information about risk make it difficult to set priorities, design appropriate responses, and evaluate performance
 - It uncertainties may require granting flexibility to companies even as such discretion is not in political favor
 - Its promises *and* its uncertainties force promoters and critics off their accustomed stances – potential for a “grand bargain” on risk?
 - Even if not “revolutionary,” the broad range of nanomaterials to hit the marketplace will stress regulatory regimes and institutions



Contexts for Policy Discourse

- *New social context*
 - End of three decade dominance of free market / deregulation narrative?
 - Citizen demands for more vigilant government in general will shape responses to *all* materials and chemicals.
 - Salient concerns about cancer – BPA, President’s Cancer Panel Report
- *New political realities*
 - Government in office less reflexively opposed to regulation
 - Voluntary efforts have not panned out despite efforts by industry associations to bolster participation.
 - An era of more assertive government action



Contexts for Policy Discourse

- *Connected citizens* – Less trusting, more networked citizenry poses new types of challenges to the fundamental relationship between regulators and the regulated.
- *Constraints on industry discretion* – Even as conditions of uncertainty may require some discretion (e.g., limited self-regulation), demands for *accountability* will require greater transparency and stakeholder involvement.
 - Likelihood of greater demand for information transparency
 - No data / no market narrative taking hold
- Challenges posed by nano- and other emerging technologies (e.g., synthetic biology) is forcing a reexamination of regulatory approaches



At the federal level: a more assertive EPA

- *Perceived failure of Materials Stewardship Program* – Cancelled in 2010; EPA will consider how best to use Toxic Substances Control Act (TSCA) to gather more risk data.
- *Expanded use of TSCA* – CNTs, functionalized materials, coated metal products as “new” substances and subject to stricter scrutiny; focus on data development
- *Stricter applicability of FIFRA* – presence of a nanoscale material in a pesticide product will be reportable; applies to already registered as well new products; burden of proving the safety of the product will be placed on on the registrant
- *Narrower exemptions based on confidential business information*: May 2010 notice that EPA will review all CBI claims for chemical identity in health and safety studies; will deny a claim unless revealing the identity would *expressly reveal the process by which the chemical is made or the portion of a mixture the chemical comprises.*



At the federal level: Revising TSCA?

- First major congressional examination of TSCA in over 30 years
 - *Safe Chemicals Act* (S. 3209)
 - Resets TSCA inventory; ends grandfathering of “ceased” chemicals
 - Creates minimum data set for all chemicals – no data, no registration
 - All chemicals subject to safety assessment
 - Moves from “unreasonable risk” to broader “health based” standard
 - Switches burden of proof to industry
 - EPA to classify chemicals by level of aggregate concern about safety
 - Tighter rules on Confidential Business Information claims
 - Gives EPA expedited rule-making authority to require testing, other actions
 - EPA can decide when something with the same molecular identity as an existing substance should be treated as a new substance
- Prospects for passage improved by controversy over toxicity of dispersants used by BP



International: Impacts on U.S.?

- *European Commission* – extended REACH to address specific risks of carbon nanotubes
- *European Parliament* – proposed ban on use of nanosilver and long multi-walled carbon nanotubes in electrical and electronic products; labeling requirements on any nanoscale material used in such products (using 1-100 nm standard)
- *France* – August 2009 law requiring reporting on quantities and uses of nanomaterials and dissemination of such information to the public
- *Germany* – Federal Institute for Risk Assessment advising against nanoscale silver in consumer products
- *Canada* – Ongoing debate over a bill to include nanotechnology in the *Canadian Environmental Protection Act*; would include a public inventory of nanomaterials in Canada; mandate risk assessments before products can enter the marketplace.
- OECD – New nanomaterial testing guidance manual

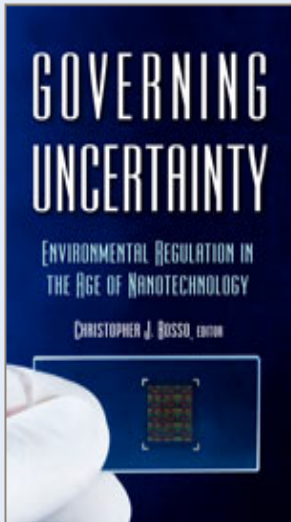


Going forward

- The era of deregulation is over. Swing back to more active governmental oversight will result in changes in laws and regulatory regimes generally
- Citizen demands for stronger governmental action in general will shape responses to emerging technologies (and existing materials/chemicals).
- Case by case assessment for foreseeable future, with potential for broader standards and rules as greater understanding of nanoparticle toxicity is obtained
- Challenge is to strike a better balance between the drivers of innovation and the drivers of oversight



New From RFF / Earthscan Press



Governing Uncertainty

Environmental Regulation in the Age of Nanotechnology

Edited By Christopher J. Bosso

This book makes a significant contribution to the issues it sets out to address, namely how government confronts conditions of acute uncertainty about environmental and health risks, and how, given such uncertainty, government structures its regulatory policy. Students and scholars of science and technology policy will find the work interesting and relevant, particularly in its treatment of the EPA and the federal scene.'

Albert H. Teich, Director, Science and Policy Programs, American Association for

the Advancement of Science

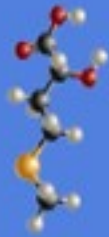
Foreword by J. Clarence Davies

1. Policy Consequences of the 'Next Industrial Revolution'
Christopher Bosso
2. A World of its Own? Nanotechnology's Promise -- and its Challenges
Sean T. O'Donnell and Jacqueline A. Isaacs
3. Institutional Evolution or Intelligent Design? Constructing a Regulatory Regime for Nanotechnology
Marc Allen Eisner
4. Engaging Business in the Regulation of Nanotechnology
Cary Coglianese
5. EPA and Nanotechnology: The Need for a Grand Bargain?
Marc Landy
6. Nanotechnology and the Evolving Role of State Governance
Barry G. Rabe
7. Nanotechnology and 21st Century Governance
Christopher Bosso and W. D. Kay

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