Regulation of Nanotechnologies in the United States

Linda K. Breggin
Senior Attorney and Director, Nanotechnology Program
Environmental Law Institute

Global Governance of Nanotechnologies
Northeastern University School of Law
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Overview of Presentation

• Outline of U.S. Laws that Could Be Used to Regulate Nanomaterials

• Overview of Toxic Substances Control Act

• Comparison of TSCA and Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)/Regulation on Classification, Labelling and Packaging (CLP)
Environmental Law Institute’s Nanotechnology Program

Web Site:  http://www.eli.org/Program_Areas/nanotech.cfm

The Environmental Law Institute’s Nanotechnology Program seeks to respond to the urgent need to develop an effective environmental, health, and safety governance structure for nanotechnologies. The nano-revolution is upon us, yet our current environmental, health, and safety programs do not adequately address the risks nanotechnologies may pose to public health and the environment. Nanotechnology, the manufacture and manipulation of materials that are, approximately 1 to 100 nanometers, has many applications that have yet to become commercially available. However, over 1,000 products that use nanomaterials are already on the market, including fabrics, sporting goods, and cosmetics. Nanomaterials are being emitted into the air, discharged into the water, and disposed of on land with limited federal or state review or understanding of the possible effects on human health and the environment. Substantial work is needed to develop an effective governance structure. Core areas of research needed to establish a foundation for a governance structure include:

- A comprehensive analysis of existing legal authorities and development of a regulatory and oversight blueprint.
- An assessment of alternative governance approaches.
- Development of public information and engagement tools and mechanisms, and
- An examination of management and implementation issues and strategies.

Recent Projects

ELI recently completed an international research project on regulating nanotechnologies in the European Union and the United States ($50,000 awarded by the European Commission on Nanosciences, Metrology, Information and Communication Technologies, and Photonic and Quantum Technologies) and the Woodrow Wilson Project on Emerging Nanotechnologies. Click here to read the press release and the report, Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation.

Publications and Convenings

Since 2005, the Nanotechnology Program at the Environmental Law Institute has been producing timely publications and convening key stakeholders to foster the development of an effective environmental, health, and safety governance structure for nanotechnologies. ELI’s publications and convenings examine principles that should direct the development of an environmental, health, and safety governance structure, application of U.S. environmental laws to nanomaterials, and harmonization of international approaches to regulating nanotechnologies.

Most recently, ELI convened experts to discuss its recent publication, Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation, in London at Chatham House and in Washington, DC, at the Woodrow Wilson International Center for Scholars.
ELI Sample Publications/Convenings

- Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation (2009)
- Application of the Toxics Release Inventory to Nanomaterials (2008)

☐ The ELI Nanotechnology Deskbook (ELI Press 2007)
U.S. Laws that Could Be Used to Regulate Nanomaterials

• Chemicals Laws
  – Toxic Substances Control Act (TSCA)
  – Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

• Federal Food, Drug and Cosmetic Act

• Media-Specific Environmental Laws

• Pollution Prevention Laws
Key Impediments to Using Environmental Laws

• Quantitative Thresholds/Exemptions

• Information and Data Gaps
  – Definition and characterization
  – Metrology
  – Testing methods
  – EHS studies

• Monitoring and Detection
TSCA Background

• History and Views of Statute
• Potential for Legislative Reform
  – Principles for reform (Obama Administration, stakeholder and States)
  – Congressional hearings
  – Senate bill introduce (April 15, 2010)
  – House Energy and Commerce Committee Discussion Draft
TSCA

• Pre-Manufacture Notice (PMN) and Review of New Chemicals
  – Scope of notice and review
  – 100 PMNs received for nanomaterials

• Significant New Use Rules (SNURs)
  – Similar to PMN notice requirements
  – SNURs for nanomaterials
  – New proposed SNUR in 2010?
TSCA (continued)

Key Exemptions

• Low volume
• Low release/low exposure
• Research and development
TSCA (continued)

• Restrictions on Existing Chemicals
  – “Unreasonable risk” standard
  – Rarely used

• Test Rules (Section 4)
  – Multi-pronged showing by EPA required
  – Proposed rule for nanomaterials in 2010?

• Reporting Authorities (Section 8)
  – Limited in scope
  – Proposed rule for nanomaterials in 2010?
Comparative Analysis

Regulatory Regimes Overlap

- Multinational companies
- EU importers/US suppliers
- Data
- Formal/informal consultation among regulators
REACH: a complex regime
Key Differences

- Information and Data Collection
  - Process
  - Scope
  - Substantive requirements
- Regulatory Controls
  - No TSCA equivalent to “appropriate measures to control risk” requirement
  - No TSCA equivalent to REACH authorisation process
  - Premature to compare TSCA and REACH restriction processes and standards
Thank You!

Linda Breggin
Environmental Law Institute
breggin@eli.org