Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation

Findings and Recommendations

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Overview

Introduction
1. Background on research project

Comparative Analysis of EU & US regulation
2. Chemicals
3. Food
4. Cosmetics

Policy recommendations
5. Towards transatlantic regulatory cooperation in nanomaterials regulation
1. Background on research project

- **US-EU Summit 2007:**
  - Remove barriers to transatlantic trade
  - Promote cooperation and convergence in regulation
- **European Commission request for proposals on “Transatlantic methods for handling global challenges”:**
  - Comparative analysis of regulatory approaches in EU and US
  - Congruent approaches to safety; regulatory convergence between EU and US
  - Safety and ethical concerns by citizens; implications of labelling requirements
- **Findings to feed into Commission workshop (November 2009) and US-EU Summit 2010**
Research design

Scope of research project:

• Environmental, health and safety risks
• Existing manufactured nanomaterials
• Key sectors: chemicals, food, cosmetics
• Transatlantic dimension; cooperation & convergence

Research design:

• Independent analysis
• Comparative approach
• Consultation with experts and stakeholders
• Peer review
2. Comparative analysis: chemicals

Principal laws and regulations

- **US**
  - Toxic Substances Control Act (TSCA)
  - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)

- **EU**
  - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
  - Regulation on Classification, Labelling and Packaging (CLP)
  - Pesticides Directives
Backdrop

Regulatory regimes are not insular

- Multinational companies
- EU importers/US suppliers
- Data
- Formal/informal consultation among regulators
A complex regime
TSCA

- Pre-manufacture notice/review of new chemicals and significant new uses
  - 50 pre-manufacture notices received for nanomaterials
  - Significant New Use Rules for nanomaterials
- Restrictions on existing chemicals
  - “Unreasonable risk” standard
  - Rarely used
  - Nanomaterials – the “new” versus “existing” determination
- Test rules
  - Multi-pronged showing by EPA required
  - EPA may issue such test rules for certain nanomaterials
- Reporting requirements
  - EPA may soon apply to certain nanomaterials
- Nanoscale Materials Stewardship Program
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REACH

- Registration requirements – no data/no market
  - Eliminates distinction between new versus existing chemicals
  - Phase-in and non-phase-in chemicals
  - Tonnage/toxicity determine information requirements
    - Application to nanomaterials
- Appropriate measures to control risk
  - Applies to nanomaterials registered under REACH
- Evaluation
  - Dossier (completeness)
  - Substance (clarify “suspicions of risks”)
- Authorization
  - Prioritizes substances of very high concern
  - Application process shifts burden to manufacturers/importers
- Restriction
  - Risk to human health/environment addressed on Community-wide basis
  - Not yet used
Key differences

• Pre-manufacture review/requirements
  – Registration versus pre-manufacture review
  – New versus existing chemicals distinction
  – Scope of information required

• Information and data collection
  – Scope and process
  – Confidential business information

• Regulatory controls
  – No TSCA equivalent to REACH authorization process
  – No TSCA equivalent to “appropriate measures to control risk” requirement
  – Premature to compare TSCA and REACH restriction processes and standards
Factors influencing convergence

• Regulatory interpretation
• Resources
• Implementation
• Statutory/regulated amendments
• Experience with nanomaterials
• Cooperation
3. Comparative analysis: food

1. Commonalities in EU & US regulatory systems
   • Structure
      • Product categories
      • Risk
   • Regulatory tools
      • Pre-market review & approval
      • Post-market monitoring, inspection, recall, & labelling

2. Differences in EU & US regulatory systems
   • Differing categories
   • General regulation of nanotechnologies/materials
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Food regulation: key elements

1. Pre-market review – general regulation
   - EU proposed amendment to novel foods regulation
     - New foods produced with new technologies, including nanoscience
       - Safety assessment
       - Mandatory labelling
     - US no comparable general regulation

2. Pre-market review – case-by-case approach
   - EU & US - new products/new uses of existing products
     - Molecular structure
     - May also consider particle size
Food regulation: key elements

3. Information collection
   • EU & US regulators recognize limitations
     • Affects risk assessment
     • Legal differences affect availability of information to regulators

4. Regulatory agencies may be able to share confidential information based on agreements to maintain confidentiality
4. Comparative analysis: cosmetics

1. Commonalities in EU & US regulatory systems
   - Structure
   - Regulatory tools

2. Differences in EU & US regulatory systems
   - Differing definitions (differentiation of drugs)
   - General regulation of nanotechnologies/materials
Cosmetics regulation: key elements

1. Pre-market review
   • EU Cosmetics Directive
     • Cosmetic product safety assessment
     • Mandatory reporting to Commission for new products
   • EU proposed Cosmetics Regulation
     • Specifically defines nanomaterials
     • Information reporting for nanomaterials
     • Labelling
   • No comparable US provisions
Cosmetics regulation: key elements

2. Case-by-case approach
   • EU & US both have authority to restrict specific nanomaterials in cosmetics
   • EU & US have similar post-market authorities
     • Recall
     • Inspection of records
     • Good manufacturing practices
     • Labelling
Cosmetics regulation: key elements

3. Information inadequacies
   • EU & US regulators recognize limitations in their information on nanomaterials in products
   • Information for risk assessment

4. Information sharing
   • Regulatory agencies may be able to share confidential information based on agreements to maintain confidentiality
   • US law prohibits disclosure of trade secrets
5. Policy recommendations – key issue areas

1. Scientific building blocks for risk assessment
   • definitions, characterisation, metrology, testing methodologies, etc.

2. Knowledge gaps
   • Potential EHS risks of nanomaterials
   • Commercial use of nanomaterials

3. Risk management
   • Consumer labelling

4. International governance
Creating scientific building blocks

- Critical importance for risk assessment
- Incomplete international standardisation and coordination
- Ongoing standardisation and coordination efforts (e.g. OECD, ISO & private initiatives); high degree of legitimacy

Recommendation:
1. Invest more political energy in the international process, esp. OECD
2. Enhance OECD’s transparency and participation by stakeholders
Closing knowledge gaps

• Need for transatlantic cooperation to reduce scientific uncertainty about potential risks of nanomaterials
• Lack of market transparency about use of nanomaterials in commercial products

Recommendation:
1. Significant increase in funding for EHS research; international coordination of research strategies;
2. Create mandatory reporting requirement for nanomaterials in commercial use;
Risk management/labelling

• Risk management more difficult area in which to achieve regulatory cooperation and convergence.
• Currently no technology-based labelling requirements; calls for comprehensive labelling of nanomaterials in consumer products (food, cosmetics), esp. in Europe.

Recommendation:
1. Stronger focus on coordination in area of risk management.
2. Consider implications of potentially diverging labelling regimes; promote development of common approaches.
Conclusion: Strengthening global nanomaterials governance

- US and EU are global leaders in nanosciences and in EHS regulation
- Opportunity exists now to strengthen transatlantic cooperation and convergence
- But globalization of nanotechnologies requires global policy responses, beyond transatlantic context.

Recommendation:
1. Create international governance capacity in other areas (e.g. UNEP, WHO)
2. Ensure that developing countries are more involved in international decision-making.