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

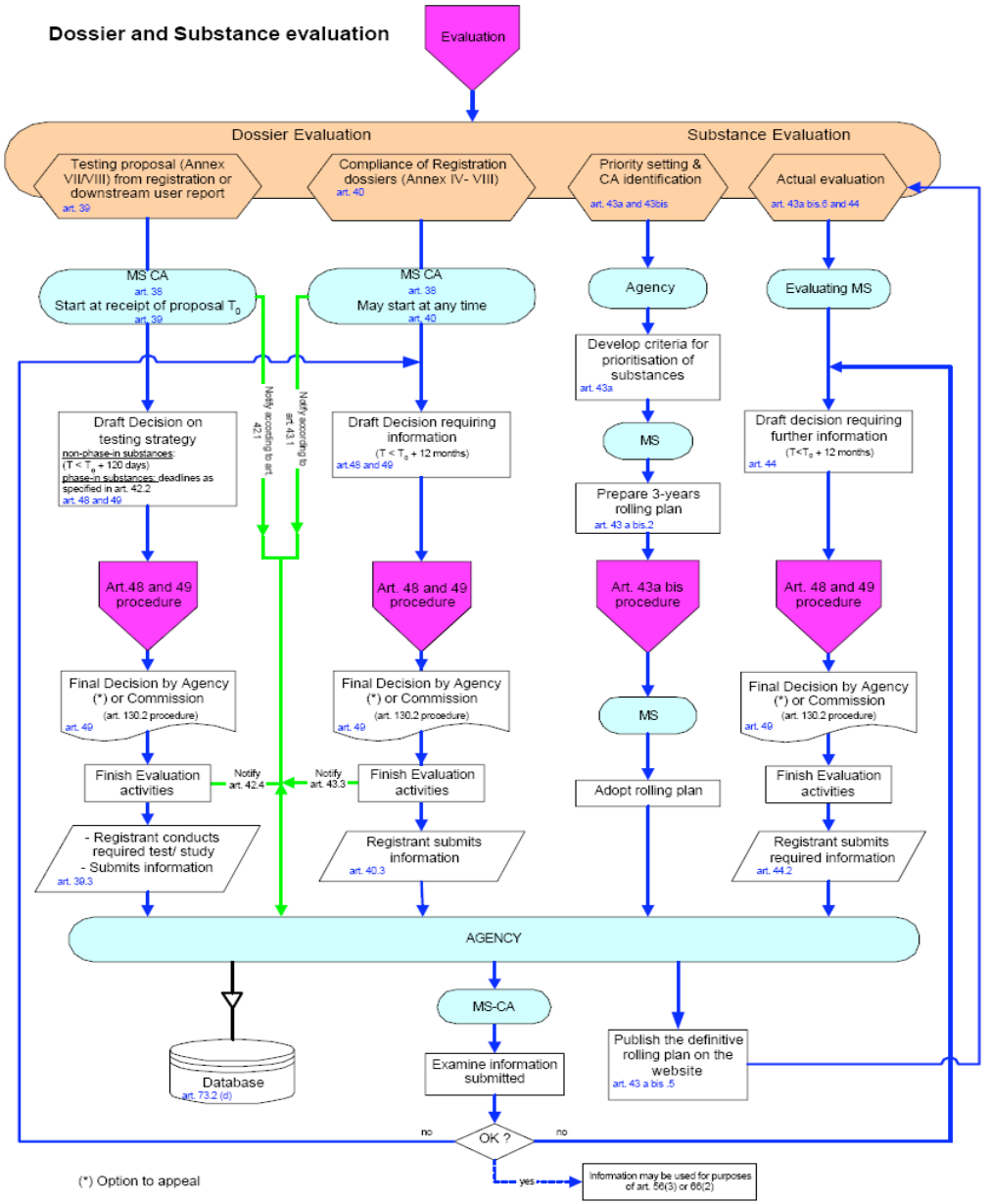
- US
  - Toxic Substances Control Act (TSCA)
  - Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- EU
  - Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
  - Regulation on Classification, Labelling and Packaging (CLP)
  - Pesticides Directives

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

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/regulatory 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

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.