Regulating Nanotechnologies in the EU and US: Towards Effectiveness and Convergence

Project Consortium:

London School of Economics (LSE)
Chatham House
Environmental Law Institute (ELI)
Project on Emerging Nanotechnologies (PEN)

Project Coordination:

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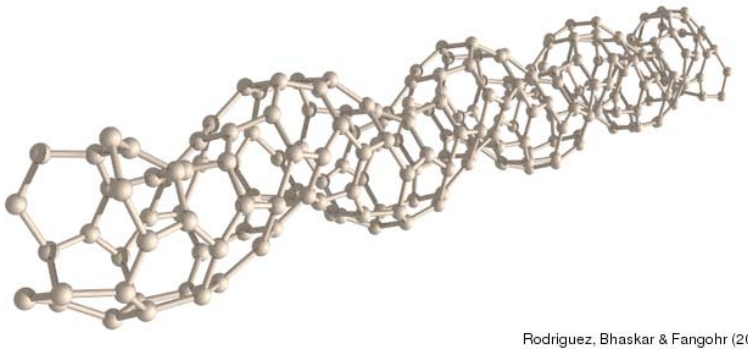
What is nanotechnology?

- Manipulation of matter at the nanoscale to create new and unique materials and products.
- 1 nanometer = 1 billionth of a meter (1/100,000 the width of a human hair)
- Commerical applications:
  - More lightweight and durable materials (carbon nanotubes);
  - more hygienic surfaces of medical appliances and food packaging (nano silver);
  - More effective sunscreens to protect human skin (titanium dioxide);
  - More efficient batteries (nano-titanate based).
- Ca. 1000 commerical nano-products
- Predictions of a future market:

  $1 to 3 trillion by 2015.



Rodriguez, Bhaskar & Fangohr (2007)

Why regulate nanotechnology?

- Concern that nanoparticles might be released into the air and inhaled, or end up in food, cosmetics or consumer products (intentionally or unintentionally) and lead to harm as a result.
- Regulatory challenges:
  - Uncertainty re potential harm and exposure;
  - Uncertainty of commercialization paths;
  - Rapid technological change;
  - Suitability of existing regulations;
  - Availability of sufficient regulatory and scientific resources.
  - International consistency

Call for Proposals

Three main objectives for this project:

1. Produce a comparative analysis of existing regulatory approaches in the EU and US
2. Consider the need for congruent approaches to safety; regulatory convergence between EU and US
3. Examine safety and ethical concerns by citizens; implications of labelling requirements

Research Design

- Political and legal analysis of existing regulatory frameworks for nanomaterials (in chemicals, food and cosmetics).
- Consultation with experts and stakeholders (regulators, policy-makers, industry, civil society, science)
  - Questionnaire
  - Semi-structured interviews
- Review process:
  - Project steering committee
  - Review workshops in London and Washington, DC
  - Written reviews by experts and stakeholders
- Independent analysis

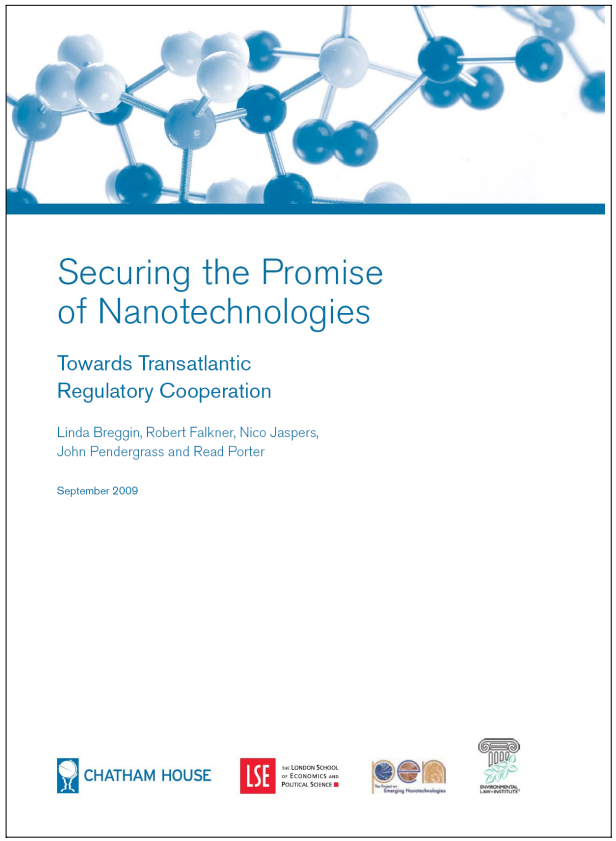
Research findings

- **Existing regulatory frameworks** in chemicals, food, cosmetics apply to nanomaterials; but uncertainty persists about how existing frameworks will be applied and whether they need to be adapted.
- **International coordination** in the field of scientific building blocks for risk assessment is likely to lead to a significant degree of convergence in regulatory praxis.
- **Important similarities but significant differences** between US and EU regulatory approaches; path dependence may create obstacles to deeper transatlantic convergence.
- **Growing divergence** in consumer labelling of nanomaterials (e.g. introduction of mandatory labelling in revised EU Novel Foods and Cosmetics law)

Policy recommendations

- Urgent need to create **scientific building blocks** for risk assessment. Make international coordination forums (OECD, ISO) more inclusive and transparent.
- **Close knowledge gaps** regarding
  - potential risks of nanomaterials (coordinated research strategy); and
  - the presence of nanomatericals in the market (mandatory reporting).
- Promote **international dialogue on risk management**; consider implications of diverging consumer labelling trends.
- Strengthen **international governance capacity**; better representation of developing countries in international decision-making.

Outputs



Project Report:

"Securing the Promise of Nanotechnologies: Towards Regulatory Cooperation"

(120 pages)

Contents:

-Introduction
-Nanotechnologies and Nanomaterials
-Regulatory Frameworks
-Chemicals
-Food
-Cosmetics
-Policy Recommendations

Outputs

Briefing Papers

"Regulating Nanomaterials: A Transatlantic Agenda"

(8 pages)

"Consumer Labelling of Nanomaterials in the EU and US: Convergence or Divergence?"

(12 pages)

Outputs

Analytical Papers:

"Oversight of Next Generation Nanotechnology"

(39 pages)

"New Life, Old Bottles: Regulating First-Generation Products of Synthetic Biology"

(50 pages)

International launch of report

International Conference at Chatham House, London (10-11 September 2009)

- Keynote:
  Steve Owens, Assistant Administrator, US Environmental Protection Agency
- 25 panellists
- Over 100 participants from EU and US

Outreach events

14 Sept 2009:	Brussels (KVAB)
15 Sept 2009:	Paris (Sciences Po)
23 Sept 2009:	Washington, DC (Woodrow Wilson Center)
28 Sept 2009:	Berlin (Nanotech Europe 2009)

Panel discussion in Washington, DC

Contact details

Project website:

www.lse.ac.uk/nanoregulation

Chatham House international conference (incl. presentations and recordings):

www.chathamhouse.org.uk/nanotechnology

Woodrow Wilson Center panel discussion (incl. presentations and recordings):

http://www.nanotechproject.org/events/archive/ec/