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# *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)

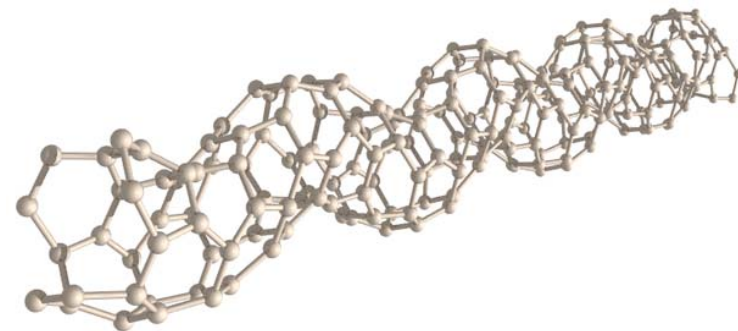
## **Project Coordination:**

Robert Falkner (LSE)

# What is nanotechnology?

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- 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)
- Commercial 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 commercial nano-products
- Predictions of a future market:  
\$1 to 3 trillion by 2015.



Rodriguez, Bhaskar & Fangohr (2007)

# Why regulate nanotechnology?

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- 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

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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

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- 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

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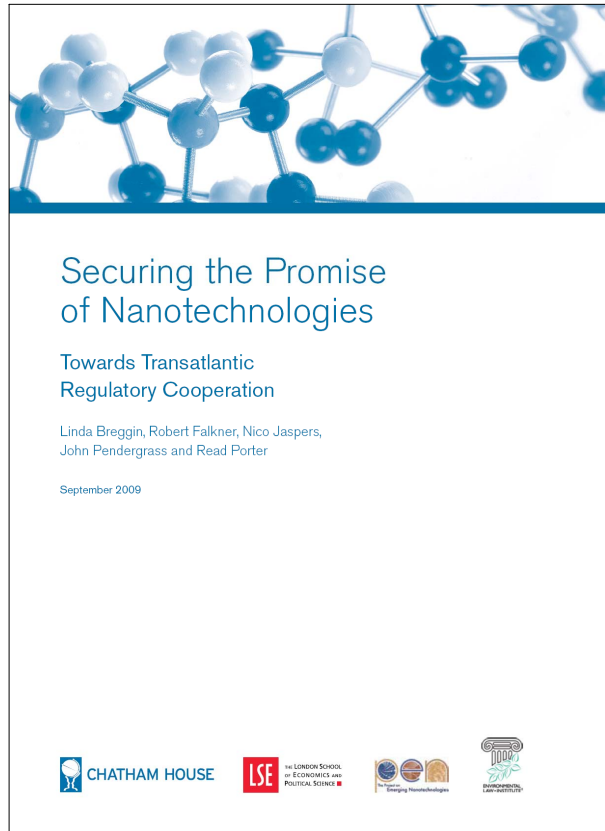
- **Existing regulatory frameworks** in chemicals, food, cosmetics apply to nanomaterials; but uncertainty persists about how existing frameworks will be applied and whether they need to be adapted.
- **International coordination** in the field of scientific building blocks for risk assessment is likely 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

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- 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 nanomaterials 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



## Regulating Nanomaterials: A Transatlantic Agenda

Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter  
Energy, Environment and Resource Governance | September 2009 | EERG BP 2009/02

### Summary points

- The US and EU need to strengthen international regulatory cooperation if the promises of nanotechnologies are to be fulfilled.
- Persistent scientific uncertainty could limit the effectiveness of existing frameworks and risk assessment approaches. International efforts to build blocks for risk assessment of nanomaterials should be expanded.
- The EU and US need to provide significantly increased funding for research on environmental, health and safety risks of nanomaterials and promote greater such funding at an international level.
- Governments should strengthen existing mandatory reporting requirements for nanomaterials in commercial use and, where necessary, create new ones.
- US and EU authorities should explore the implications of potentially divergent labelling requirements for nanomaterials, given international trade obligations towards common approaches on standards for labelling.
- In view of the ongoing and accelerating globalization of nanotechnology, the US should complement existing international initiatives with the development of international governance capacity in other areas (UNEP, WHO), not least in developing countries where more involvement in international decision-making is needed.



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

Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter  
Energy, Environment and Resource Governance | October 2009 | EERG BP 2009/03

### Summary points

- Consumer labelling of nanomaterials is set to become an important and potentially controversial issue on the transatlantic regulatory agenda.
- With an estimated 1,000 nano-enabled products already on the market, calls are rising for mandatory consumer labelling of nanomaterials.
- The US and EU currently do not have a general labelling requirement for nanomaterials, but certain product-specific labelling rules in the food and cosmetics area may apply to nanomaterials.
- While US authorities have to date failed to respond to calls for comprehensive nanomaterials labelling, draft versions of the EU's revised novel foods and cosmetics laws already contain such requirements.
- In the light of the potential divergence between US and EU approaches to consumer labelling of nanomaterials, governments should consider the implications of such a development for international trade and potential means of promoting the development of common approaches.

[www.chathamhouse.org.uk](http://www.chathamhouse.org.uk)

## 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

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## 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

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- 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

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Project website:

[www.lse.ac.uk/nanoregulation](http://www.lse.ac.uk/nanoregulation)

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

[www.chathamhouse.org.uk/nanotechnology](http://www.chathamhouse.org.uk/nanotechnology)

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

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