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briefing paper

Regulating Nanomaterials: A Transatlantic Agenda

Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter

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Summary points

- The US and EU need to strengthen international regulatory cooperation if the commercial promises of nanotechnologies are to be fulfilled.
- Persistent scientific uncertainty could limit the effectiveness of existing regulatory frameworks and risk assessment approaches. International efforts to create scientific building blocks for risk assessment of nanomaterials should be expanded.
- The EU and US need to provide significantly increased funding for research into the environmental, health and safety risks of nanomaterials and promote greater coordination of 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 diverging consumer labelling requirements for nanomaterials, given international trade obligations, and work towards common approaches on standards for labelling.
- In view of the ongoing and accelerating globalization of nanotechnologies, the EU and the US should complement existing international initiatives with the development of international governance capacity in other areas (UNEP, WHO), not least to ensure that developing countries are more involved in international decision-making.

Introduction

Nanotechnologies are set to transform industrial society. They promise benefits in a wide range of applications, from health care to food, cosmetics, chemicals, information technology and energy storage. The manipulation of matter or creation of structures down to the molecular level (typically at a scale of approximately 100 nanometres or less, a nanometre being one-billionth of a metre) has led to the creation of novel materials, so-called engineered nanomaterials, which are already being used in numerous consumer products. Additional commercial applications can be expected in coming years.

Our understanding of how nanomaterials interact with the environment and the human body has not kept pace with the development of nanotechnologies. Early results of research suggest that the safety of all nanomaterials cannot be taken for granted.[1] The ongoing expansion of nanotechnologies may produce novel nanostructures that cause currently unknown forms of hazard. Developing nanomaterials governance that is both effective and proportional to potential risks is critical to the future success of existing and emerging nanotechnologies.

The European Union and the United States are worldwide leaders in the scientific and commercial development of nanotechnologies. Their regulatory responses to potential risks will send an important signal worldwide. In the past, they have cooperated in international efforts to harmonize their respective risk regulation, through the Organization for Economic Cooperation and Development (OECD) and the World Trade Organization (WTO). Where successful, such efforts have promoted high levels of protection while enabling scientists and industries to operate freely in the transatlantic economic space.

In some cases, however, transatlantic coordination and cooperation have proved difficult. Differences in legislative frameworks, regulatory cultures and societal risk perceptions can contribute to a divergence of regulatory responses. This was the case, for example, with high-profile transatlantic disputes over hormone-treated beef and genetically modified food, which have had a negative impact on transatlantic relations and trade. These experiences have shown the importance of identifying technological risks and promoting international cooperation at an early stage in the policy process.

This briefing paper identifies key issues and challenges in nanomaterials regulation and aims to stimulate the debate on how to promote coordinated and convergent approaches in the EU and US. It provides a concise summary of key findings of a project that was carried out by a consortium of research institutions from both sides of the Atlantic: the London School of Economics and Political Science (LSE) and Chatham House (the Royal Institute of International Affairs) in the UK, and the Environmental Law Institute (ELI) and the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars in the United States.

The project was funded by a research grant from the European Commission, and involved extensive consultation with experts and stakeholders in nanomaterials regulation on both sides of the Atlantic. This briefing paper is based on a larger report, *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation*, which is also published in September 2009.

The growing market for nanomaterials

It is difficult to predict precisely how nanotechnologies will develop owing to the diversity of potential commercial pathways and the complexity of the nanotechnology value chain. However, the commercial promise of nanotechnologies is beyond doubt, as is reflected in the increasing number of nanotechnology patent filings and expanding investment in research by both private companies and national governments.

An inventory of consumer products containing nanomaterials, maintained by the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center of Scholars, lists over 1,000 nano-enabled prod-

1 See, for example, recent reviews of scientific uncertainties in the Royal Society and the Royal Academy of Engineering (2004). *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*. London; and Royal Commission on Environmental Pollution (RCEP) (2008). *Novel Materials in the Environment: The Case of Nanotechnology*. London.

ucts that are currently on the market in 24 different countries.[2] The vast majority of these products appear in the cosmetics, clothing, personal care, sporting goods, sunscreens and filtration sectors, and are available primarily on the US market, with East Asia and Europe following in second and third place. The materials most frequently mentioned as being contained in products are nanoscale silver, carbon, titanium, silicon, zinc and gold. While the PEN inventory relies on self-identified products and may thus potentially overstate (but also understate) the true degree of commercialization of 'nanoproducts', it is indicative of the wide range of commercial applications of nanotechnologies in consumer products.

Nanosciences and nanotechnologies are driving the development of a broad array of products and industries in various sectors ranging from manufacturing and materials to electronics and IT, and healthcare and life sciences. For instance, between 2004 and 2006 the value of manufactured goods and materials incorporating nanomaterials expanded from $13 billion to $50 billion, and in 2006, $1.5 billion worth of nano-enabled drugs were sold. Current projections for the future growth of commercial applications of nanotechnology range from $1 trillion to over $3 trillion by 2015. But because nanotechnologies are enabling technologies, such estimates do not always distinguish clearly enough between the more limited value-added of nanotechnologies and the larger face value of products that 'contain' nanotechnology products. Nonetheless, market research estimates suggest that by 2014 as much as 4% of total manufacturing and materials sector output may incorporate nanotechnologies, and 50% of manufactured output in electronics and IT and 16% of manufactured goods in healthcare and life sciences may be nano-enabled.[3]

Regulatory challenges of nanomaterials

Governments in leading industrialized countries are currently relying on existing frameworks for environmental, health and safety (EHS) regulation to deal with nanotechnology risks, making minor adjustments to specific regulations and their implementation in order to close any potential gaps or eliminate uncertainties.[4] Regulators face a number of challenges in dealing with the potential risks of nanomaterials. These challenges are related to a series of uncertainties, with regard to the development and commercial application of nanomaterials, hazards and exposure pathways, the direction and speed of technological change, and the suitability and effectiveness of existing regulatory frameworks.

Rapid technological change. While the current regulatory focus is on passive nanomaterials, future developments will include active nanomaterials and are likely to converge with other technologies such as information, bio- and cognitive technologies. These future-generation nanomaterials will develop in ways that are difficult to foresee. Regulators will need to constantly expand their knowledge base covering multiple areas of scientific and engineering inquiry and to develop flexible responses to a constantly changing technological environment.

Uncertainty of commercialization paths. While the number of existing commercial products using nanomaterials keeps growing, uncertainty exists regarding future commercialization paths. As the range of commercial applications expands, governments will have to address potential risks of nanomaterials in diverse regulatory contexts covering different industries and commercial applications, potentially adding to existing uncertainty about the regulatory coverage of nanomaterials risks.

2 Available at http://www.nanotechproject.org/inventories/consumer/.

3 Lux Research (2008). *Overhyped Technology Starts to Reach Potential.* See http://www.luxresearchinc.com/press/RELEASE_Nano-SMR_7_22_08.pdf.

4 EU and US regulatory authorities have concluded that that the existing regulatory framework, consisting of a range of laws and regulations, is broadly sufficient to deal with potential risks associated with nanomaterials, and that only small adjustments or amendments to regulations and implementation guidelines may be needed in order to close any potential gaps. See US Food and Drug Administration (FDA) (2007). *Nanotechnology: A Report of the U.S. Food and Drug Administration Nanotechnology Task Force.* At http://www.fda.gov/nanotechnology/taskforce/report2007.pdf, and European Commission (2008). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Regulatory Aspects of Nanomaterials, COM(2008) 366 final. At http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF.

Uncertainty regarding nanomaterials risks. A lack of data on the hazards and exposure pathways of certain nanomaterials, combined with uncertainty about the applicability of some existing testing methods, are widely recognized impediments to the effective implementation of regulations. It is therefore too early to establish whether existing regulatory frameworks can and will be effective in the face of potential risks.

Uncertainty regarding the suitability of regulatory frameworks. Whether current laws provide adequate oversight for certain applications of nanotechnologies or whether new legislative instruments are needed depends very much on how existing statutes and regulations are implemented. Adequate guidance for implementation and the provision of the necessary resources for regulatory oversight thus become critical factors in developing effective regulatory responses.

Uncertainty regarding regulatory and scientific resources. The challenges presented by novel technologies such as nanotechnologies require significant investment in human resources. Statutes are a necessary but insufficient condition for success if the regulators lack enforcement capacity, scientific expertise and foresight. The public sector will increasingly have to compete with industry for talent in these emerging technology areas.

Towards regulatory effectiveness and convergence in the EU and US: policy recommendations

What should the EU and US do to promote more effective and convergent regulation of nanomaterials? Below we present key policy-relevant findings of this project, based on our own research and consultations with experts and stakeholders. We focus on three clusters of issues that we identified as the most important areas:

- the creation of the scientific building blocks that are necessary for risk assessment;
- the closure of existing knowledge gaps with regard to the commercialization of nanomaterials and potential EHS risks; and
- questions of societal and ethical perspectives and how they are addressed in risk management, especially through labelling.

The focus of our research has been on the transatlantic dimensions of nanomaterials regulation, and the broader objective of promoting cooperation and convergence between the EU and US. We understand regulatory convergence to be a process rather than a specific outcome. It involves the gradual adjustment of regulatory frameworks, institutions and practices, but can occur through a variety of processes and mechanisms. These range from informal policy diffusion to international coordination and cooperation, whether formal or informal, and to treaty-based international harmonization efforts. When speaking of the promotion of greater regulatory convergence in the field of nanotechnologies, we therefore have in mind the full range of convergence processes that can be observed in other international policy areas, from environmental to financial regulation, and from trade policy to investment rules.

While we have focused on ways to promote regulatory convergence, we recognize its limits, in terms of both feasibility and desirability. In the area of EHS regulation, full harmonization of national rules and practices is rarely, if ever, achieved. As discussed in our main report, there are some distinctive benefits, but also costs, that result from regulatory convergence, and policy-makers ultimately need to decide how to balance these. The subsequent discussion reflects this reality and seeks to enlighten the political and regulatory debate by identifying opportunities for, but also barriers to, a movement towards greater transatlantic consistency and convergence.

Creation of scientific building blocks

Recent analyses and scientific reviews have revealed a number of areas in which scientific uncertainty is limiting the effectiveness of existing regulatory

frameworks and risk assessment approaches.[5] In their reviews of regulatory frameworks for nanomaterials, both EU and US agencies have acknowledged that, while nanomaterials are broadly covered by existing frameworks, scientific uncertainties remain to be resolved in order to strengthen the implementation of regulatory oversight mechanisms. Creating a reliable science base is thus an essential first step towards an effective risk assessment process for nanomaterials.

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Nearly all experts whom we consulted agreed on the need to establish a firm scientific basis for risk assessment. Many of the scientific building blocks, with regard to definition and characterization of nanomaterials, metrology and testing methods, are as yet missing or have not been internationally standardized. Developing common practices in these areas is a critical step towards more effective regulation; they are key building blocks of risk assessment.

Regulators and experts in the US, Europe and elsewhere are currently seeking to fill existing gaps in this area by working together in various international forums, such as the OECD and the International Organization for Standardization (ISO). Our research suggests that ongoing work on creating scientific building blocks for risk assessment needs to be stepped up and expanded if it is to produce results in a timely fashion. The rapid pace at which nanomaterials are becoming commercialized demands a greater sense of urgency in this area.

The OECD, which has set up two nanotechnology working parties – the Working Party on Manufactured Nanomaterials (WPMN) in 2006 and the Working Party on Nanotechnology (WPN) in 2007 – is currently the predominant international forum for coordination efforts by regulators and industry experts from the US, the EU and a select group of other countries. It enjoys broad legitimacy in promoting coordination on the building blocks for risk assessment, and is a central institution in the context of transatlantic regulatory convergence. At the same time, more political energy and resources need to be invested in the OECD process, and greater transparency and inclusiveness should be achieved in its work. While it is desirable for the nanotechnology working parties' inclusiveness and transparency to be enhanced, it will be a serious challenge to accomplish this within the existing intergovernmental structures and processes of the OECD.

Closing knowledge gaps

Regulators face two important knowledge gaps, one on potential EHS risks associated with the production and use of nanomaterials, and one on the presence of nanomaterials in commercial products. These two dimensions of uncertainty are closely linked and complicate the search for effective regulatory approaches. Knowing as soon as possible what types of nano-enabled products are on the market, what types of nanomaterials are used and how they move through possible product life-cycles provides some grounding for establishing research needs in the field of EHS risks. Uncertainty in both these areas afflicts US and EU regulatory systems in equal measure. Transatlantic cooperation on reducing uncertainty with respect to the commercial use of nanomaterials and on EHS risks would help both sides in addressing certain regulatory challenges.

Accordingly, as a matter of priority, governments on both sides of the Atlantic need to provide significantly increased funding for research into EHS risks of nanomaterials. They should also promote greater

5 International Council on Nanotechnology (ICON) (2008). Towards Predicting Nano-Biointeractions: An International Assessment of Nanotechnology Environment, Health and Safety Research Needs. *ICON Report* 4; Scientific Committee on Consumer Products (SCCP) (2007). 'Opinion on Safety of Nanomaterials in Cosmetic Products.' At http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf. See also references in footnote 1.

coordination of research funding at a transatlantic and global level. International research coordination has its limits and can be difficult to achieve, but the benefits of improved transatlantic coordination of EHS research outweigh the costs. Against the background of strained public finances and urgent research needs, enhanced transatlantic cooperation would give a greater sense of strategic direction to existing research efforts and strengthen the basis for sustained research funding streams into the future.

Regulators would also benefit from better access to information available to their counterparts abroad, particularly in the area of potential EHS risks. The sharing of commercially sensitive data poses a problem, however, given regulatory approaches to the protection of confidential business information. We encourage regulators and policy-makers to explore all options available to them, whether through domestic reform or international agreement, to promote better sharing of information on EHS risk-related data for nanomaterials while ensuring that commercially sensitive data remain protected.

A second knowledge gap concerns the state of the commercialization of nanomaterials. As mentioned above, uncertainty exists not only about EHS risks of nanomaterials but also with regard to their commercial use and, specifically, the type of nanomaterials contained in intermediate or consumer products. Many companies themselves are uncertain about the use of such materials within their own industry, and regulators on both sides of the Atlantic have acknowledged that they currently do not have comprehensive knowledge about their presence in commercially traded goods. Recently introduced voluntary substances reporting programmes are unlikely to close such knowledge gaps.

Existing attempts to establish comprehensive market registers, such as PEN's product inventory, are laudable but need to be taken further. In view of the persistence of these knowledge gaps, governments on both sides of the Atlantic should strengthen existing mandatory reporting requirements and, where necessary, create new ones, with a view to gaining a comprehensive overview of the commercial use of nanomaterials. Given the high degree of economic interdependence between the US and the EU, any effort to enhance market transparency through improved reporting schemes would benefit from a coordinated effort by both sides.

Risk management and consumer labelling

Efforts to promote international coordination and cooperation are currently focused on establishing the scientific building blocks needed for risk assessment. In comparison, transatlantic efforts to coordinate risk management are likely to be less productive, may be premature and would face greater obstacles. At the same time, the internationalization of nanosciences and nanotechnologies will inevitably bring any differences in risk management approaches into sharper focus in transatlantic relations. As more and more nanomaterials are adopted commercially and enter global supply chains, differences in national or regional risk management approaches may end up complicating the free flow of goods across national boundaries. For this reason, coordination in the area of risk management will need to be given greater prominence on the international agenda in the coming years.

One important but controversial element of risk management is consumer labelling. So far, neither the US nor the EU has introduced legally binding consumer labelling requirements that specifically target nanomaterials, but moves are under way to do so, particularly in the EU. Our research has shown strongly divergent views among experts on the need to go beyond this state of affairs by creating more comprehensive labelling requirements, and on whether more convergent approaches could and should be developed in this area.

In view of the contentious nature of labelling, in terms of its general necessity and specific form of implementation, we conclude there is currently no overwhelming case for arguing that the US and EU should prioritize international efforts to create new, mandatory, labelling requirements or harmonize existing ones. But both sides should still consider the implications of different labelling requirements,

whether already established or newly created, for the proper functioning of international trade in a transatlantic context.

Furthermore, if the US and EU were to explore the possibility of developing common approaches or standards for nanomaterials labelling, such an undertaking should involve a multi-stakeholder forum to engage relevant groups from industry and civil society in order to give full weight to the different commercial and ethical concerns. Current transatlantic dialogues, such as those within the Transatlantic Consumers Dialogue (TACD) and the Transatlantic Business Dialogue (TABD), could provide useful forums for taking this debate forward. Such an effort would be less urgent than the creation of common building blocks for risk assessment, but is nevertheless important in its own right.

Addressing global dimensions

Current efforts to promote greater convergence between US and EU regulatory approaches for nanomaterials have been focused on informal processes of communication and policy learning between regulators, as well as formal and informal processes of coordination through international bodies. Authorities dealing with chemicals, food and cosmetics regulation have engaged in regular but informal transatlantic links, in order to promote the exchange of information and experiences with the implementation of existing nanomaterials regulations. Moreover, regulators, scientists, industry representatives and other stakeholders from civil society have established formal coordination processes through the OECD's two working parties on manufactured nanomaterials and nanotechnology policy. Finally, parallel processes of international standardization, such as those conducted under the auspices of the ISO, are aimed at creating technical and scientific standards that are central to effective risk assessment processes.

No efforts have been undertaken as yet to create a formal, treaty-based, international framework for nanomaterials regulation. Our research suggests little, if any, interest in pursuing this more ambitious objective. The political energies required for such a project would be better spent on strengthening existing forums for international coordination and adjusting domestic regulatory frameworks where needed. Given the globalized nature of nanotechnology developments and commercialization, however, one cannot rule out the possibility that an international framework treaty might be needed in the future, particularly as new players from the developing world are emerging in the global nanotechnology business.

In view of the ongoing and accelerating globalization of nanotechnologies, the EU and the US should perceive the global governance challenges arising from nanomaterials in broader terms. The OECD serves an important function as a forum for coordination among leading industrialized countries, but its work should be complemented by the development of international governance capacity in other areas, not least to ensure that developing countries are more involved in international decision-making. Other international organizations, such as the United Nations Environment Programme (UNEP) and the World Health Organization (WHO), play important roles in their respective areas of global environmental protection and health promotion, but are only just beginning to identify the potential EHS risks of nanomaterials as emerging areas of concern. The current imbalance in the development of international governance capacity should thus be redressed, and developing countries should be better represented in global regulatory cooperation.

As global leaders in developing regulatory oversight for nanomaterials, the EU and US should extend their leadership to other areas and institutions of international governance. This would ensure that the twin goals of securing the future of nanotechnologies while safeguarding against potential environmental and health risks of nanomaterials are firmly established at the international level.

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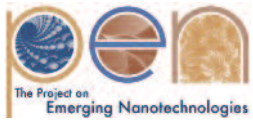
- Robert Falkner is Senior Lecturer in International Relations at the London School of Economics and Political Science and Associate Fellow of the Energy, Environment and Development Programme at Chatham House.
- Linda Breggin is a Senior Attorney and Director of the Environmental Law Institute's Nanotechnology Initiative.
- Nico Jaspers is a researcher and PhD candidate in the International Relations Department at the London School of Economics and Political Science.
- John Pendergrass is a Senior Attorney and Co-Director of International Programs at the Environmental Law Institute.
- Read Porter is an attorney at the Environmental Law Institute.

This paper summarizes the key policy recommendations of the report *Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation* (September 2009). The full report can be downloaded at www.chathamhouse.org.uk/nanotechnology.



Chatham House
10 St James's Square
London SW1Y 4LE
www.chathamhouse.org.uk

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