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Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap

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Abstract

Nanosciences and nanotechnologies are set to transform the global industrial landscape, but the debate on how to regulate environmental, health and safety risks is lagging behind technological innovation. Current regulatory efforts are primarily

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focused on the national and regional level, while the international dimensions of nanotechnology governance are still poorly understood and rarely feature on the international agenda. With the ongoing globalization of nanosciences and the rapid expansion of international trade in nanomaterials, however, demand for international coordination and harmonization of regulatory approaches is set to increase. However, uncertainty about nanotechnology risk poses a profound dilemma for regulators and policy-makers. Uncertainty both creates demand for and stands in the way of greater international cooperation and harmonization of regulatory approaches. This paper reviews the emerging debate on nanotechnology risk and regulatory approaches, investigates the current state of international cooperation and outlines the critical contribution that a global governance approach can make to the safe development of nanotechnologies.

Introduction

Emerging technologies create a peculiar, often complex, and fundamentally political, problem for global governance. This problem exists not so much because technologies may produce environmental and health risks; systems of risk assessment and management are in place to deal with such risks. Rather, emerging technologies are problematic because of the persistent uncertainty that surrounds potential risks. This uncertainty—about whether, in what form and to what extent risks exist—makes it difficult, and often impossible, to apply routine decision-making procedures for risk assessment and management. It impedes the application of standard scientific approaches and pushes regulatory decision-making into a more political direction. As a result, differences in national priorities, societal values, domestic interest group dynamics and institutional contexts often stand in the way of deeper international cooperation and regulatory harmonization. Indeed, in cases such as agricultural biotechnology and others, national differences in risk regulation have not only prevented common international approaches but have also set off political and trade conflicts between industrialized countries.

Nanotechnology, which enables the manipulation of matter at the molecular level, is the latest technological innovation to surface in global debates on risk

regulation and international cooperation.¹ Over the last decade, nanosciences and nanotechnologies have emerged as a new transformative force in industrial society, with a rapidly increasing range of applications in chemicals, pharmaceuticals, electronics, energy, food and cosmetics, among others. Yet, as nanotechnology is beginning to reshape global markets, evidence has mounted that some applications create new and poorly understood risks. Regulatory systems face profound uncertainties about the adequacy of existing risk assessment and management frameworks, and about rapidly progressing scientific and commercial developments. These uncertainties are so fundamental that they go beyond the regulatory capacity of individual states and require extensive international cooperation as we go on to argue. At the same time, however, these uncertainties also increase the likelihood that national differences in risk regulation limit the scope for global governance approaches.

Nanotechnology risk is a relatively new, and hitherto largely neglected, concern in the study of global environmental politics. Most of the debate on its environmental and health risks has been confined to scientific and regulatory expert circles. Academic research on nanotechnology regulation has so far concentrated on the domestic legal, political and social dimensions, within the subfields of science and technology studies, applied ethics, regulation studies and law.² By contrast, the international dimensions of nanotechnology regulation have received relatively little attention and are only slowly coming into focus.³ This article seeks to help fill this gap and introduce existing debates on nanotechnology risk to the study of global environmental politics.

The purpose of this article is to examine the national and international regulatory challenges in the field of nanotechnology and to identify potential global

1. The singular “nanotechnology” is used in this paper to refer to the entire scientific and technological complex that comprises different nanotechnologies. “Nanotechnology regulation” refers to all regulatory policies that are focused on process-, material- and application-related aspects of nanotechnology. It should be noted, however, that most existing regulatory approaches are in the form of *nanomaterials* regulation (e.g. chemicals laws).

2. For an overview of recent scholarship in these fields, see Hodge, Bowman, et al. 2010.

3. Notable exceptions include Abbott et al. 2006, 2010; and Marchant and Sylvester 2006.

governance gaps and solutions.⁴ The article investigates the effect that uncertainty has had on emerging nanotechnology regulation. It argues that existing international approaches are insufficient to promote the effective coordination of regulatory policy and to avoid potential political and trade conflicts. It identifies three steps towards an enhanced global governance capacity: improving the cognitive environment for regulation, promoting convergence in risk assessment and risk management, and capacity building in and greater engagement of developing countries. The subsequent analysis is based on a two-year study of emerging regulatory trends in nanotechnology with a particular focus on the United States and European Union. Our research involved legal and political analysis as well as 68 semi-structured interviews with experts and representatives from regulatory authorities, parliaments, industry, civil society and science.⁵

In the first section, we set the scene by reviewing the literature on risk, uncertainty and precaution in global environmental politics. The second section outlines the rapid growth of nanotechnologies and their commercial applications and surveys the current debate on their potential environmental and health risks. In the third section, we review how governments in leading industrialized countries as well as emerging economies have responded to the challenges of scientific and regulatory uncertainty. The fourth section examines current efforts to promote information exchange and regulatory coordination at the international level. In the fifth section, we then turn to the question of the specific global governance deficits that need to be addressed if the international community is to develop an effective, inclusive and adaptive regulatory response to nanotechnology risks.

Risk, Uncertainty and Precaution in Global Environmental Governance

4. Our focus is limited to questions of environmental, health and safety (EHS) regulation, which is the focus of *Global Environmental Politics*. For discussions of broader global governance questions relating to intellectual property rights and technology transfer, or societal and ethical dimensions, see Hodge, Bowman et al. 2007; and Roco and Bainbridge 2007.

5. Further information on the research project is available at: www.lse.ac.uk/nanoregulation.

Scientific uncertainty in risk governance is one of the major challenges facing global environmental politics.⁶ Risk assessment, and to a lesser extent risk management, are often portrayed as being determined solely by scientific criteria and findings.⁷ In reality, however, both processes, which are about determining whether certain risks exist and deciding on how to deal with them, cannot be separated from political decision-making. Even though scientists play a central role in creating knowledge about potential harm to humans and the environment, their scientific judgments alone cannot suffice as the basis for risk assessment and management. This is most clearly the case with regard to risk management decisions, which involve decisions on the level of risk that is socially acceptable. It also concerns risk assessment itself, particularly with regard to the definition of harm, identification of causal links and establishment of thresholds as triggers for regulatory action.⁸

The distinction between uncertainty and risk is analytically important in that it demarcates the realm of calculable and controllable risk from the murkier field of uncertain knowledge about risk. In an ideal scenario, scientific research would provide regulators with sufficiently precise knowledge to remove the veil of uncertainty from decision-making. To a certain extent, this is the ideal that informs legal interpretations of risk assessment and management in the context of World Trade Organization (WTO) rules. In this view, regulatory decisions that interfere with international trade are to be based on reliable scientific evidence. Where such evidence is missing, further research is needed to seek to remove remaining uncertainties, even if full scientific certainty can never be achieved.⁹

As recent international trade disputes have shown, uncertainty is a pervasive phenomenon in environmental and health regulation. It may exist with regard to the selection of appropriate risk categories and models; it may arise from unreliable measurement and testing techniques; and it may afflict the underlying causal models used in risk assessment.¹⁰ Scientific uncertainty is particularly pronounced in

6. On uncertainty in risk governance, see: Van Asselt and Vos 2006; Walker 2003; and Winickoff et al. 2005.

7. Gaskell and Allum 2001.

8. Walker 2003.

9. Wirth 1994.

10. Walker 2003.

emerging technologies, such as biotechnologies, nanotechnologies or synthetic biology. Scientists and regulators often have to operate without a comprehensive understanding of what types of risk need addressing, what testing methodologies need to be applied or developed in order to assess those risks, and what exposure paths are to be taken into account during the life-cycle of particular products.¹¹

Regulators and policy-makers have responded to systemic uncertainty in different ways. At one end of the spectrum of responses, regulatory authorities have followed a “wait-and-see” approach and delayed regulatory action until sufficient knowledge about risks has become available. Their main focus tends to be on promoting scientific research to reduce uncertainty and facilitate science-based decision-making. At the other end, authorities have regulated new technologies and their products despite persistent uncertainty, particularly when potential harm is likely to be severe or irreversible. In this precautionary response, regulators typically seek to promote further research but simultaneously take regulatory action to limit or prevent potential harm from uncertain risks.¹²

Whether to adopt a “wait-and-see” or precautionary approach is an essentially political question, as it involves decision-making under uncertainty and the weighing up of sometimes competing values, such as technology promotion versus harm prevention. Scientific risk assessment criteria alone cannot guide regulators and policy-makers in such situations. Instead, a wider range of factors enter the calculations that inform regulatory action, from political ideology and societal risk attitudes to national or sectoral economic interests.¹³ Unsurprisingly, therefore, attempts to build global risk governance for emerging technologies tend to be politicized where scientific uncertainty is high.

The inherently political nature of technology risk is one important reason why leading industrialized countries have only partially succeeded in harmonizing international rules on risk regulation. Some limited progress has been made in the WTO, e.g. on animal and food safety standards and safety-related technical standards (Agreements on the Application of Sanitary and Phytosanitary Measures

11. Kuzma and Tanji 2010; and Renn and Roco 2006.

12. On different national approaches to precautionary risk regulation, see Sadeleer 2007.

13. Stirling 2007.

(SPS) and Technical Barriers to Trade (TBT)), but deeper international harmonization has proved elusive. In fact, national differences in risk regulation have repeatedly spilled over into commercial and political conflicts. The global conflict over trade in genetically modified organisms (GMOs), which led to acrimonious negotiations over the Cartagena Protocol on Biosafety and a WTO dispute over the EU's temporary ban on GMO imports, is but one high profile case in a long line of such disputes.¹⁴

The EU and the US have frequently been at the centre of such conflicts, reflecting a growing transatlantic divergence in regulatory approaches and conceptions of precaution.¹⁵ Even though the US and EU are not consistent in the use of precaution in domestic regulation,¹⁶ they have come to occupy opposing positions in international regulatory debates. While the US has repeatedly insisted that regulatory trade restrictions should be based on "sound science" in line with WTO law, the EU has pushed for the global expansion of precautionary standards and a re-balancing of the relationship between WTO rules and environmental policies in favor of the latter.¹⁷

Over the last thirty years, precaution has become an established, though not uncontroversial, concept in international environmental law. It first emerged in domestic environmental policy in industrialized countries during the 1970s and began to inform international environmental policy-making from the 1980s onwards. Today, the precautionary principle is reflected in well over 50 multilateral instruments.¹⁸ The 1992 Rio Declaration confirmed its growing importance in Article 15, and its definition of precaution ("Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation") has since become a widely cited reference point in international interpretations. Subsequent treaties, such as the 2000 Cartagena Protocol on Biosafety, have gone one

14. Falkner 2007.

15. On the growing transatlantic divide in environmental and regulatory politics, see Vig and Faure 2004; Schreurs, Selin, and VanDeveer 2009; and Kelemen and Vogel 2010.

16. Wiener and Rogers 2002.

17. Vogel 2004.

18. Wiener 2007.

step further and have included references to precaution not only in the preamble but also in the operational parts of the treaty.¹⁹

Despite its growing use in international environmental treaties, precaution should be seen as a contested norm. Countries remain divided about both its interpretation and application in specific cases. Some, such as the US, prefer to speak of a precautionary *approach* (as in the Rio Declaration) and reject the notion that precaution has assumed the quality of a full-fledged *principle* in international law. Others, mostly in the developing world, have long expressed concerns that precautionary regulation could give rise to trade protectionism in environmental disguise.²⁰ Countries will continue to use precaution selectively and on an ad hoc basis, but the danger exists that these divisions will lead to further international regulatory polarization and conflicts.²¹

Such profound differences in interpretation pose a serious challenge to the creation of comprehensive and effective global governance for emerging technology risk. They suggest that regulatory harmonization will prove difficult where scientific uncertainty prevails and the economic stakes involved are high. At a time when the need for global risk governance is constantly growing as technological innovation and economic globalization continue unabated, a gap is emerging between the demand for and supply of global policy solutions. This is increasingly the case for nanotechnologies, where uncertainties about risk simultaneously require and impede the establishment of a global governance structures.

Nanotechnologies: Opportunities, Risks and Regulatory Challenges

In this section, we provide some background on nanosciences and nanotechnologies before discussing their regulatory challenges. Nanoscience, often referred to as the science of the very small, operates at a scale measured in a billionth of a meter, or nanometer (nm). An atom of gold is approximately one third of a nanometer wide.

19. Graff 2002.

20. Najam and Robins 2001.

21. Wiener 2007, 611-612.

The period at the end of this sentence would provide enough space to fit 200 billion “buckyballs,” a common type of carbon nanoparticle.

Over the last decade, nanosciences have emerged from relative obscurity to occupy a central place in the scientific and, to some extent, public imagination. At the nanoscale, common materials often have different physico-chemical properties than in bulk-form: gold changes color, aluminum becomes explosive, silicon turns from being an insulator to being a conductor, silver becomes a highly effective antimicrobial, and carbon becomes extremely strong and stiff. These changing properties of substances can be commercially exploited in numerous ways. Notable recent developments include organically growing nano-enabled solar cells in the form of wall paper or as paint; silicon nanoparticles covered with a layer of gold and used in combination with infrared light to destroy cancerous tumors; silicon coated nanowires that form a highly efficient paper-like “sponge” to separate oil from water after, for instance, an oil spill; and nano-products that help to purify, desalinate and disinfect water, or store energy more efficiently.²²

These examples illustrate an important point: nanotechnologies are “enabling” or “platform” technologies, much like the personal computer or the internet, and have the potential to affect virtually every industrial sector. The future commercial value of nano-enabled products is difficult to predict, with some estimates as high as several trillion US dollars over the next five to ten years.²³ In 2007, the materials and manufacturing sector alone accounted for \$97 billion in nano-enabled products.²⁴ Investment in nanotechnology research and development has risen rapidly, with cumulative public spending reaching almost \$50 billion worldwide in 2009.²⁵

Several OECD countries have established themselves as leading developers of nanotechnologies, most notably the US, Japan, Germany, the United Kingdom, France and South Korea. They command a leading position worldwide, in terms of patent applications, expenditure on research and development, and success in

22. More information on commercial applications can be found at www.nanowerk.com and www.azonano.com

23. Lux Research 2008.

24. Lux Research 2008.

25. Cientifica 2009.

product development. But increasingly, emerging economies are conducting applied and basic research in nanotechnology. Among these countries, China has moved into a leadership position, followed by India, Russia, Mexico and Brazil. Indeed, a recent survey of nano-related patent applications puts China in second position world-wide, just after the US.²⁶ The globalization of nanotechnology is well underway.

The speed with which nanotechnologies have moved from research laboratories to markets has taken some observers and regulators by surprise. No reliable database exists that tracks commercial developments, but the Project on Emerging Nanotechnologies (PEN) has shone some light into the market by creating an internet-based inventory. According to its latest update in 2010, over 1000 nanoproducts are commercially available in sectors as wide-ranging as food, cosmetics, electronics, automotive, appliances and children's products.²⁷ Since the PEN inventory relies on the work of a small team conducting online research, it may well underestimate the true state of nanotechnology commercialization.

As more and more nano-products are being marketed, scientists and regulatory experts have voiced growing concerns about the safety of some nanomaterials. These concerns are focused on the miniscule size of nanomaterials and their unique physico-chemical characteristics. For example, some nanomaterials may enter the human body through mucous membranes or the skin and migrate via the bloodstream to vital organs including the brain. Some nanomaterials can also enter cells, interact with their molecular structure, and have cytotoxic or genotoxic effects.²⁸ Traditional protective equipment such as gloves or masks may not provide sufficient protection against accidental inhalation or absorption through the skin. Changes to the physico-chemical properties, especially when they lead to increased toxicity, may produce unexpected negative effects in the human body or the environment, particularly so as nanomaterials may change as a consequence of their interaction with living systems.²⁹

26. Dang et al. 2010.

27. Available at <http://www.nanotechproject.org/inventories/consumer/>, accessed 11 January 2011.

28. Monteiro-Riviere et al. 2005.

29. ICON 2008.

Considerable uncertainty exists with regard to the specific environmental and health threats that some nanomaterials pose along the path from production to use and disposal. Laboratory experiments have shown that the inhalation of certain insoluble ultrafine nanotubes may cause pulmonary inflammation, tissue damage and lung tumors. In particular, recent studies indicate that multiwalled carbon nanotubes (MWCNTs) of a certain shape can cause mesothelioma in the linings of the lungs if they are inhaled,³⁰ similar to the toxicological effects of asbestos. Nanosilver, which is used in textiles, washing machines, food supplements and surface coatings has also been the focus of recent studies and NGO campaigns, for example over concerns that if released into wastewater it could adversely affect aquatic organisms, including those that are needed in sewage treatment plants.³¹

No conclusive evidence exists of nanomaterials having caused actual health damage or deaths. However, reports in 2009 of an industrial accident in China received widespread attention in expert circles. According to a Chinese toxicologist, seven workers were exposed to unspecified nanoparticles over five to thirteen months, which is said to have caused two of these workers to die and the remaining workers to be severely disabled.³² The toxicologist's claims remain contested, however.³³

For regulators, the challenges are profound. Pervasive scientific uncertainty, rapid technological innovation and commercialization, global production, uncertain future technological pathways and ethical dilemmas all combine to create a regulatory and political minefield. Governments in industrialized countries have poured large sums of public money into nanosciences in the hope of nurturing the next industrial revolution. But balancing scientific freedom, technological innovation and an adequate level of environmental, health and safety protection can prove to be an elusive goal.

Many experts acknowledge that conventional risk management techniques, product categories, and weight- or volume-based categorizations of substances may

30. Takagi et al. 2008; and Poland et al. 2008.

31. International Center for Technology Assessment et al. 2008; and Kulinowski 2008.

32. Song et al 2009.

33. Maynard 2009.

be inadequate to address the novel risks posed by nanomaterials.³⁴ This calls into question the routine application of established risk assessment and risk management procedures. Furthermore, the rapid pace of commercialization and the prospect of more complex “future generations” of nanotechnologies, including active and self assembling materials,³⁵ underlines the limited capacity of existing regulatory frameworks to deal with emerging risks. Regulatory agencies increasingly need to *anticipate* future technological developments and establish regulatory frameworks that offer sufficient flexibility and adaptability to ensure long-term effectiveness.³⁶

Regulatory systems thus face challenges on a number of fronts. They must adapt to deal with novel and uncertain risks. They must expand scientific capacity against the background of a fiscally constrained environment and competition for scientific talent between public and private sectors. They must also anticipate rapidly changing scientific and technological systems, and develop globally oriented information-gathering systems to cope with the ongoing globalization of nanotechnology. These challenges are of such a fundamental nature that they go beyond the capacity of individual states and require international coordination and cooperation.

National and Regional Regulatory Approaches: Convergence or Divergence?

The nanotechnology safety debate has gathered momentum since the early 2000s and has come to focus more systematically on the appropriateness of existing regulatory policies. A series of scientific reports have highlighted persistent scientific uncertainties and knowledge gaps regarding environmental and health impacts, most notably the 2004 report on nanosciences and nanotechnologies by the UK’s Royal Society and Royal Academy of Engineering.³⁷ Other studies have also highlighted the scientific uncertainty and regulatory challenges surrounding

34. See, for example, Royal Society and Royal Academy of Engineering 2004; SCENIHR 2006; ICON 2008; and CDC and NIOSH 2009.

35. EPA 2007a.

36. Davies 2009.

37. Bowman and Hodge 2007, 7.

nanotechnology.³⁸ Regulatory authorities themselves have acknowledged some of the findings of the aforementioned reports but conclude that, by and large, existing frameworks provide appropriate regulatory coverage for nanotechnology risks. Indeed, a broad consensus has emerged among the major nanotechnology countries that no new nanotechnology-specific regulatory framework is needed. Mindful of the potentially damaging impact that over-zealous regulation could have on the future growth of nanotechnologies, governments have taken a step-by-step approach to assessing and adjusting regulatory frameworks and capacities.

United States

The incremental and de-centralized approach to nanotechnology oversight is clearly evident in the US.³⁹ Regulatory authority for nanomaterials and nanotechnology-based products is divided between several federal agencies. The Environmental Protection Agency (EPA) regulates any chemical substances or pesticides that are, or contain, nanomaterials. The Food and Drug Administration (FDA) considers the risks of nanomaterials used in drugs, medical devices, food, food additives and cosmetics. The Occupational Health and Safety Administration (OSHA) deals with workplace safety dimensions while the Consumer Product Safety Commission is concerned with protection against risks from consumer products. Finally, the Department of Agriculture deals with food and feed safety dimensions.

Despite relying on a de-centralized regulatory system, the US has sought to create a coordinated nanotechnology strategy through the National Nanotechnology Initiative (NNI). Launched in 2000 and situated within the White House, the NNI seeks to coordinate the nanotechnology-related research, development and policy activities of 25 different federal agencies. It has grown into the central program through which federal funding of nanotechnology is channeled. For Fiscal Year 2010,

38. Davies 2006; Hodge, Bowman, et al. 2007; and Marchant and Sylvester 2006.

39. For an overview of US nanotechnology regulation, see Breggin, Falkner, et al 2009.

Congress appropriated approximately \$1.8 billion for nanotechnology R&D, up from \$464 million in 2001.⁴⁰

Debate continues on whether the US regulatory framework for nanotechnology provides regulatory agencies with adequate authority and instruments.⁴¹ Proponents of the current approach can point to a number of recent decisions that suggest the regulatory system is sufficiently responsive to newly emerging risks. For example, in reaction to the marketing in 2006 of a washing machine that uses nanosilver as an antimicrobial, the EPA decided to regulate such equipment as a pesticide and to require registration accordingly.⁴² And in 2008, EPA decided that carbon nanotubes should be treated as new rather than existing chemicals under the Toxic Substances Control Act (TSCA), with the consequence that stricter regulatory requirements apply, including premanufacture notice.⁴³ EPA and FDA have also examined the regulatory challenges that nanotechnologies pose. FDA's nanotechnology taskforce, for example, concluded in 2007 that nanomaterials may present unique health risks and highlighted a number of uncertainties but rejected calls for the introduction of nano-specific labeling requirements, arguing that "the current science does not support finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials."⁴⁴

On the other hand, however, the specific instruments that regulatory agencies can apply—e.g. pre-market review and authorization, post-market monitoring and labeling, product recalls and adverse event reporting—vary considerably and depend on the unique characteristics and limitations of the legal authority that each agency possesses. For example, EPA's authority to regulate nanoscale substances rests on TSCA, a chemicals law that was introduced over 30 years ago and that provides more restricted regulatory powers than its European equivalent.⁴⁵ Furthermore, the unique characteristics of nanomaterials pose a challenge to existing

40. Sargent 2010.

41. Davies 2009; Denison 2007; and GAO 2010.

42. EPA 2007b.

43. EPA 2008a.

44. FDA 2007, 35.

45. Breggin, Falkner, et al. 2009, chapter 4.

regulatory systems. Nanomaterials with the same molecular structure as the bulk form may end up being treated as existing chemicals, which could weaken regulatory oversight of such materials.⁴⁶ EPA acknowledged in late 2009 that the uncertain status of nanomaterials under TSCA's provisions may need to be clarified, and that the distinction between new and existing chemicals with regard to nanomaterials would need to be reconsidered.

US regulatory agencies have also acknowledged knowledge gaps and scientific uncertainty with regard to nanomaterials risk. EPA, for example, has identified research needs on the toxicology and ecotoxicology of nanomaterials and recommends greater collaboration with other agencies and stakeholders.⁴⁷ To close potential knowledge gaps, EPA introduced a voluntary reporting initiative, the Nanoscale Materials Stewardship Program (NMSP), which invited producers of nanomaterials to report to the agency safety-relevant information. The interim review of the program in 2009 suggested, however, that companies were reluctant to participate in the scheme, leading the EPA to conclude that, "a number of the environmental health and safety data gaps the Agency hoped to fill through the NMSP still exist."⁴⁸ As a consequence, the agency is now considering whether to move towards a mandatory reporting system.⁴⁹

Europe

European governments face similar knowledge gaps and scientific uncertainties as the US. They also rely on existing laws and regulations, mostly at EU level, in the fields of chemicals, food, cosmetics, drugs, etc. The EU has also opted for a sector- and product-specific regulatory approach, in contrast to its technology-focused regulatory system for agricultural biotechnology. Although specific regulatory provisions and authorities vary across the different areas of EU law, it is fair to say that most nanotechnology regulation originates at the EU level, and that EU institutions play a central role in carrying out risk assessment and management for

46. See EPA 2008b.

47. EPA 2007a.

48. EPA 2009a.

49. EPA 2009b.

the majority of nanomaterials, with Member States continuing to play a role in implementing EU law and regulatory decisions.

Mindful of the political controversies that have erupted around emerging technologies in the past, especially genetically modified food, the EU has been proactive in developing a European nanotechnology strategy and encouraging stakeholder engagement. From the publication of its first strategy paper in 2004 until today, the European Commission has consistently stressed the need for “appropriate and timely regulation in the area of public health, consumer protection and the environment [...] to ensure confidence from consumers, workers and investors.”⁵⁰ It has sought to promote voluntary safety initiatives by researchers and companies through its Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, which calls for adherence to the precautionary principle and stresses the importance of “anticipating potential environmental, health and safety impacts.”⁵¹

Because most nanomaterials enter the market as chemical substances, the EU’s new chemicals law REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), which entered into force in 2007, has become the cornerstone of nanotechnology oversight in Europe. Once fully implemented, REACH will create one of the most advanced and comprehensive chemicals laws in the world. Its provisions contain extensive obligations for manufacturers to produce and assess data on chemicals and their safe use; and to provide regulators with this information through reporting requirements. At the same time, regulators have a range of tools at their disposal to require additional information and testing, restrict the use of chemicals that are deemed to be of very high concern or even ban their use. Unlike its US equivalent TSCA, REACH will no longer distinguish between existing and new chemicals once certain transitional provisions have expired.⁵²

As in the US, European regulators have taken the first regulatory decisions on specific nanomaterials. These underscore the principle of case-by-case risk assessment and support the gradualist approach to regulatory adjustment that characterizes approaches on both sides of the Atlantic. For example, the EU decided

50. European Commission 2004, 18.

51. European Commission 2008a, 6.

52. Breggin, Falkner et al. 2009, chapter 4.

in 2008 not to exempt carbon and graphite from registration under REACH due to safety concerns about certain carbon nanotubes.⁵³ And in the food safety area, the European Food Safety Authority (EFSA) has produced scientific assessments of the safety of nanosilver for use in food supplements and of nanostructured silicon dioxide and titanium nitride in food contact materials. In both cases, EFSA pointed to persistent knowledge gaps, which prevented it from determining the safety of nanosilver in food products.⁵⁴

Faced with uncertainty about EHS risks and regulatory coverage of nanomaterials, the European Commission produced a systematic review of existing laws and regulations. Published in 2008, the review concluded that “current legislation covers to a large extent risks in relation to nanomaterials” despite knowledge gaps but conceded that “current legislation may have to be modified in the light of new information becoming available.”⁵⁵ Similar to the position adopted by EPA and FDA, the European Commission rejected calls for entirely new and technology-based regulations.

Unlike its US counterparts, however, the European Commission has since considered a number of changes to the regulatory framework. Driven largely by political demands from the European Parliament (EP), recent reforms to European cosmetics law⁵⁶ and proposed reforms to food laws⁵⁷ have included nanotechnology-specific provisions that go well beyond the state of play in the US, particularly with regard to mandatory labeling and pre-market safety assessment requirements. The Commission has also bowed to EP pressure and committed to carrying out a further review of nanotechnology-related regulations by 2011. As yet, European and US approaches share many common characteristics. But with the adoption of nanotechnology-specific rules, more extensive labeling requirements in food and cosmetics and the implementation of the more comprehensive REACH legislation,

53. European Commission 2008c.

54. EFSA 2007, 2008a, 2008b.

55. European Commission 2008b, 3.

56. European Parliament and Council 2009.

57. European Parliament Committee on the Environment, Public Health and Food Safety 2010.

European nanotechnology oversight is set on a path that may end up diverging from US law and regulatory practice in important areas.

Other Industrialized and Emerging Economies

Other industrialized countries have also investigated the potential risks of nanomaterials and are applying existing EHS regulations. Australia and Canada have introduced their own voluntary reporting schemes, with the latter currently considering whether to make this scheme mandatory. Some have conducted their own reviews of existing regulations (e.g. Australia, Canada, Korea and New Zealand) and have developed guidelines on the safe handling of nanomaterials (e.g. Japan). None have adopted nanotechnology-specific rules and regulations beyond existing safety frameworks.⁵⁸

Emerging economies, and to some extent developing countries, occupy a special place in the regulatory debate. On the one hand, countries such as China, India, Russia, Brazil and South Africa are investing increasing sums of public funding in basic and applied research in nanosciences.⁵⁹ They are keen to close the nanotechnology gap with leading industrialized countries and are also beginning to produce nanomaterials and nano-enabled products in commercial quantities. On the other hand, however, the regulatory capacity of emerging economies to deal with nanotechnology risks remains constrained. Some (e.g. China) have initiated research programs into potential EHS hazards and are developing regulatory frameworks, while others (e.g. India) have barely begun to identify regulatory challenges. In any case, such efforts tend to lag behind those of industrialized countries. As in other areas of technology risk, emerging and developing countries are keen to promote technological uptake as part of wider developmental efforts but face considerable limitations in their regulatory capacity. It remains to be seen whether economic and political globalization will promote a strengthening of regulatory systems in the

58. The OECD publishes an annual update of regulatory developments: http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html, accessed 11 January 2011.

59. Michelson 2008.

developing world, through processes of international norm diffusion or trading up.⁶⁰ It also remains unclear whether EU or US approaches will serve as the dominant model for developing regulatory systems in other countries, or whether a trend towards regulatory polarization or diversity is likely to emerge.⁶¹

International Regulatory Coordination and the Global Governance Gap

In contrast to the rapid pace with which the commercialization of nanotechnologies has proceeded, international governance initiatives have so far been slow off the mark and limited in scope. Profound scientific and regulatory uncertainties have held back efforts to advance global governance approaches for this emerging technology. Regulators remain focused on developing and implementing national regulations. As the global dimensions of nanotechnology are becoming apparent, however, international standardization, coordination and harmonization have slowly emerged on the international agenda.

The EU and the US have taken a lead in international coordination efforts, working primarily through the Organization for Economic Cooperation and Development (OECD) and the International Organization for Standardization (ISO) as well as through bilateral links. Other international organizations are only beginning to develop nanotechnology-specific work programs. Furthermore, a small number of private initiatives have sprung up to promote information gathering, standardization and international debate about regulatory challenges. However, most of these are still at an early stage and involve only low levels of international coordination. As yet, no comprehensive global governance structure for nanotechnologies has come into existence.

Scientific debates have been one of the driving forces in the internationalization of the regulatory agenda. The publication in June 2004 of the Royal Society and Royal Academy of Engineering report was one of the landmark

60. On norm diffusion and trading up, see Vogel and Kagan 2002.

61. On regulatory polarization versus diversity in biotechnology regulation, see Bernauer 2003; and Falkner and Gupta 2009.

events that helped to focus attention on scientific knowledge gaps.⁶² The report was widely noted in international circles and underlined the importance of addressing safety concerns in a proactive and anticipatory manner. Later that year, similar issues were debated for the first time at the international level. A joint meeting of the OECD's Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology took place in September 2004, at which representatives from major industrialized countries considered the emerging safety issues of nanotechnologies.⁶³ And in early 2005, the International Risk Governance Council, an independent body that develops policies and guidelines for risk governance, identified long-term nanotechnology risks as an area of growing concern.⁶⁴

The international institutionalization of research and regulatory coordination began in 2005. Although an early proposal by the European Commission to establish an international "code of good conduct" in research as a "global agreement on base principles for the responsible development of nanotechnology"⁶⁵ was met with skepticism, notably from the US, both Europe and America have repeatedly expressed their commitment to work together in other international forums. The OECD held two international workshops on safety aspects of nanomaterials in 2005 and established a Working Party on Manufactured Nanomaterials (WPMN) within its Environment Directorate in 2006 to "help member countries efficiently and effectively address the safety challenges of nanomaterials."⁶⁶ The Working Party, which consists of 30 OECD member countries, five non-member countries, other international organizations, environmental NGOs and industry and trade union organizations, has since become the most important international forum in this area.

Shortly thereafter in 2007, the OECD established a second working group, the Working Party on Nanotechnology (WPN),⁶⁷ under the Directorate for Science, Technology and Industry. The WPN's remit was defined more broadly in terms of advising "on emerging policy-relevant issues in science, technology and innovation

62. Royal Society and the Royal Academy of Engineering 2004.

63. OECD 2004.

64. Ibid. See also <http://www.irgc.org/-Nanotechnology-.html>, accessed 11 January 2011.

65. European Commission 2004, 23.

66. OECD 2010.

67. See http://www.oecd.org/document/30/0,3343,en_2649_34269_40047134_1_1_1_1,00.html, accessed 11 January 2011.

related to the responsible development of nanotechnology.”⁶⁸ The WPN focuses mostly on surveying international developments in research and development, and on outreach and public dialogue.

However, the OECD’s role as a potential institutional host for more comprehensive global governance suffers from several shortcomings. First, the remit of the two Working Parties is limited mainly to coordinating the creation of scientific building blocks of risk assessment, and not risk assessment and risk management approaches as such. In line with the nature of the OECD as a forum for international collaboration without central regulatory powers, both the WPMN and WPN serve primarily as advisory bodies and forums for information exchange. Second, the OECD’s exclusive membership basis makes it unlikely that it could gain the broader legitimacy it would need to become a global forum for governing nanotechnology risks. Even though a select group of emerging economies (China, Brazil, Russia and Thailand) has been participating in the OECD Working Party processes, the lack of representation and participation by other developing countries will become more problematic as nanotechnology production and use further spreads through the global economy.

Aside from the OECD, ISO has taken a lead in developing internationally harmonized terminology and standards. Its technical committee on nanotechnologies (TC 229), which was created in 2005, has published 11 international standards to date and continues to work on various issues relating to the standardization of terminology, definitions, toxicity testing and environmental studies protocols, measurement techniques, calibration procedures, and reference materials.⁶⁹ The growing push to internationalize the safety and regulatory debate is also evident from the number of public-private and private initiatives that provide forums of debate and informal coordination mechanisms such as the International

68. http://www.oecd.org/document/35/0,3343,en_21571361_41212117_42378531_1_1_1_1,00.html, accessed 11 January 2011.

69. As of January 2011; See also ISO TC229 website, at http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&published=on&development=on, accessed 11 January 2011.

Council on Nanotechnology (ICON),⁷⁰ the International Alliance for NanoEHS Harmonization and the aforementioned International Risk Governance Council.

Genuine multilateral nanotechnology governance initiatives that are based on UN processes are few and far between. The United Nations Industrial Development Organization's International Centre for Science and High Technology (ICS UNIDO), for instance, has hosted dialogues that seek to promote regional networking between scientists, industrialists and policy-makers. And the WHO's Intergovernmental Forum on Chemical Safety (IFCS) has only recently begun to work on nanotechnology-related safety issues. The WHO's Dakar Statement on Nanotechnology and Manufactured Nanomaterials⁷¹ was adopted in 2008 and calls for more international cooperation in information sharing and risk assessment. Among other recommendations, it calls on governments to apply "the precautionary principle as one of the general principles of risk management throughout the life cycle of manufactured nanomaterials" (Recommendation 1). Developing countries and NGOs also wanted to include a call for a global code of conduct, but following objections from industrialized countries, led by the UK, the Dakar Statement merely refers to the objective of evaluating "the feasibility of developing global codes of conduct in a timely manner" (Recommendation 15).⁷²

Of perhaps greater significance for future nanotechnology governance is the adoption of the Strategic Approach to International Chemicals Management (SAICM) in 2006 by UNEP's International Conference on Chemicals Management (ICCM).⁷³ SAICM emerged out of the collaboration of various international organizations and stakeholders, including the WHO's IFCS, and supports the goal adopted at the 2002 World Summit on Sustainable Development of ensuring the safe production and use of chemicals by 2020. It is a global process involving over 160 countries and a diverse range of stakeholder groups. At ICCM-2 in May 2009, nanotechnology was identified for the first time as an emerging issue for SAICM. The resolution that was adopted includes recommendations on enhanced exchange of scientific information, research into safety aspects, and promotion of dialogue

70. See <http://icon.rice.edu/index.cfm>, accessed 11 January 2011.

71. IFCS 2008.

72. For a summary of the negotiations on the Dakar Statement, see IISD 2008

73. See <http://www.chem.unep.ch/ICCM/ICCM.htm>, accessed 11 January 2011.

between stakeholders and governments, among others.⁷⁴ It is a first step in the direction of addressing nanotechnology-related matters in a truly multilateral setting, involving a wide range of developing countries, but falls short of any aspiration to go beyond mere information exchange and international coordination.

In sum, as this brief survey of international initiatives has shown, the internationalization of the regulatory debate in nanotechnologies is now well underway, but remains limited in its scope and degree of international participation. International governance of nanotechnology risk as it exists today is mostly limited to scientific and technical standardization and coordination efforts by the leading nanotechnology countries in the OECD, with a few other international forums having emerged to consider broader policy challenges. No deeper structures for global governance of nanotechnology have been created despite the rapid globalization of nanotechnologies.

As argued earlier, uncertainty about the nature and scope of nanotechnology-related risk is one of the factors that stands in the way of a broader political consensus on how to create global governance structures. At the same time, however, leading nanotechnology countries have engaged in some forms of international collaboration on regulatory policy. In the next section, we turn to the question of how global governance approaches can help enhance international cooperation and fill governance gaps.

What Role for Global Governance?

As our analysis shows, a global governance gap has emerged that is likely to grow in the coming years unless governments and other stakeholders step up current coordination and cooperation efforts. While recent regulatory and policy reviews have highlighted the need for greater international cooperation,⁷⁵ proposals for filling the global governance gap vary considerably, ranging from the use of soft law

74. Resolution II/4 on Emerging policy issues, at <http://www.saicm.org/index.php?menuid=9&pageid=392&submenuheader>, accessed 11 January 2011.

75. Royal Society and Royal Academy of Engineering 2004; IRGC 2007; and Breggin, Falkner, et al. 2009.

approaches and building sector-specific governance capacity to the creation of an international framework convention.⁷⁶ At this point, the shape of any future global governance architecture is uncertain.

Governments face a dilemma with regard to the global governance of nanotechnology. For the profound uncertainty that characterizes risk regulation cuts both ways, at the same time requiring *and* impeding closer international cooperation. On the one hand, reducing underlying uncertainty, in terms of the scientific understanding of risks, regulatory coverage and institutional capacity, is of utmost importance, and global governance approaches can make a significant contribution in this respect as we argue below. On the other hand, the very uncertainty that pervades risk assessment and management militates against the early creation of appropriate global governance structures. Faced with an uncertain cognitive environment, governments will want to develop national regulatory approaches first before committing to international efforts. They are likely to be hesitant to undertake potentially costly steps towards a global regulatory regime for what are as yet uncertain risks. In other words, while early international cooperation may be desirable and mutually beneficial, the associated transaction costs are likely to be prohibitive.

Where the coordination problem and the interests and capacities of key players are uncertain, international cooperation is bound to be more tentative and exploratory in nature (Abbott, Sylvester and Marchant 2010). It is thus more realistic to expect global governance functions to be built in a flexible, step-by-step, approach. In our view, three areas of international cooperation provide opportunities for developing the first building blocks of a global governance architecture for nanotechnology. They are concerned with improving the cognitive environment of risk assessment, encouraging greater coordination of risk management approaches, and supporting capacity building in developing countries to strengthen their regulatory systems and promote their involvement in international processes.

Improving the Cognitive Environment

76. Abbott, Marchant, et al. 2006, 2010.

One of the most urgent tasks for global governance approaches is to build a sound and reliable cognitive basis for identifying and assessing environmental and health risks throughout the life-cycle of nanomaterials. This relates, in first instance, to technical and scientific standardization for risk assessment. It also includes the internationally coordinated promotion of research into environmental and health risks and the creation of more reliable knowledge on the presence of nanomaterials in international markets.

Technical and scientific standardization is progressing already, albeit slowly. Despite the work done by ISO and the OECD, substantial uncertainties persist in a number of key areas, as discussed above. Regulatory authorities themselves have stressed on several occasions that such uncertainties may limit the effectiveness of regulatory frameworks.⁷⁷ Given the inherently global nature of nanosciences and nanotechnologies, and the similarity of the challenges that regulators in different countries face, a global approach to standardization would ensure that different national standards do not stand in the way of greater cooperation between national regulatory authorities.

Furthermore, international cooperation in research funding on environmental and health risks would help create a more reliable knowledge base for risk assessment and management. National research institutions will of course remain at the forefront of developing the required scientific knowledge, but internationally coordinated approaches could ensure a more efficient use of research funds and promote information sharing. The OECD has recently created an internet-based database of current safety research on nanotechnologies, and is also hosting a series of research projects on the potential hazards of selected nanomaterials.⁷⁸ What is missing, however, is a more concerted effort at defining an internationally coordinated research strategy, which would pull together the different strands of the current research landscape and promote coherence and strategic vision.

77. European Commission 2008b; EPA 2007a; and FDA 2007.

78. Available at http://www.oecd.org/document/26/0,3343,en_2649_37015404_42464730_1_1_1_1,00.html, accessed 11 January 2011.

A further area of uncertainty that plagues current regulatory approaches and that requires international cooperation concerns the state of commercialization of nanomaterials. While a vast number of commercial applications of nanotechnologies have emerged in recent years, regulators are still uncertain about the extent to which nanomaterials have penetrated international trade. Discussions about creating a market register for nanomaterials are currently underway in various national settings.⁷⁹ But given the rapid globalization of nanotechnologies, international cooperation on developing a register would provide regulators with a reliable basis for determining pathways of nanomaterials and their potential risk to humans and the environment.

Promoting Convergence of Risk Assessment and Risk Management

A further, and arguably more demanding, step towards global nanotechnology governance would be the creation of internationally agreed principles and rules for risk assessment and management. The international community has sought to create such internationally harmonized rules in a number of areas of environmental and health risk, though with varying degrees of success. For example, among the more successful and widely accepted agreements is the WTO's SPS Agreement on food safety and animal and plant health, while the Cartagena Protocol on Biosafety remains contested by most GMO-exporting countries. No such international regime exists for nanotechnologies, however. Bilateral talks between regulatory agencies and multilateral discussions at the OECD eschew the bigger question of international harmonization. They are aimed at dialogue and information exchange in risk assessment and tend to exclude the more politically charged dimensions of risk management.

Yet, given the global nature of nanotechnologies, demand for international coordination, and eventually harmonization, is likely to grow soon. As leading nanotechnology countries apply existing regulatory frameworks and begin to take regulatory decisions, differences in national laws and regulatory culture may create an uneven regulatory field for the increasingly global market in nanotechnology

79. OECD 2010.

applications.⁸⁰ In the transatlantic context, for example, newly created requirements in the EU for labeling nanomaterials in food and cosmetics products go well beyond similar provisions in US law, creating in fact the first nanotechnology-specific labeling system.⁸¹ Just as in other regulatory policy areas, such differences often end up souring international trade relations and may become a source of international commercial and political conflict. An early and proactive approach to promoting convergence in regulatory approaches to nanotechnologies would go some way towards preventing such conflicts.

Capacity-Building in and Engagement of Developing Countries

As in previous technological revolutions, leading industrialized countries are at the forefront of developing regulatory policies for nanotechnology. They are also leading international standardization and coordination efforts, centered mainly on the ISO and OECD. By contrast, the vast majority of developing countries have been absent from international nanotechnology debates. A few emerging economies that engage in nanotechnology research and production (e.g. China, Thailand) have been involved in the OECD working parties in an ad hoc fashion. Overall, however, participation by developing countries in the global regulatory debate ranges from weak to nonexistent.

The current North-South divide in global nanotechnology governance poses a number of challenges. Already, a number of emerging economies are investing heavily in nanotechnology R&D, and some of them are emerging as major sites of nanomaterials production (e.g. China). Even those developing countries that are not engaged in research and commercialization will become importers of nanomaterials and nano-enabled products in what is already a global business. Developing countries and emerging economies will soon be faced with similar regulatory challenges that industrialized countries are addressing today, yet few of them are actively engaged in international processes.

80. Jaspers 2010.

81. Falkner, Breggin, et al. 2009.

As in other areas of technology governance, one of the primary tasks in global governance will be to promote capacity building in developing countries. In order effectively to engage in global regulatory debates and carry out risk assessment and management at home, developing countries will need to build up scientific and regulatory capacity, by training toxicologists and regulatory experts, establishing testing facilities, creating international scientific networks and promoting information exchange, and developing safety guidelines and implementation guidelines for regulatory frameworks. The specific needs will vary according to the level of economic development and state of investment in nanosciences and nanotechnologies, but international support will be of critical importance to fill the capacity gaps that are fast emerging in many countries.

Finally, a global governance approach also promises a higher degree of legitimacy for emerging norms and rules for nanotechnology regulation. In the past, global governance initiatives have suffered from legitimacy deficits due to the weak involvement of developing countries. Developing countries have on numerous occasions been marginalized in international rule-making and only weakly represented in private standardization process.⁸² Given that global nanotechnology debates are only just starting up, the international community still stands a chance of creating a more inclusive approach to developing global governance in this area.

Conclusions

Nanotechnologies are set to transform the global industrial landscape. The speed with which this change is occurring is breathtaking. Only a few decades ago, the manipulation of matter at the molecular level belonged to the realm of scientific speculation. It has now become a commercial reality. Nanotechnologies also introduce profound uncertainties that require international responses while at the same time impeding the creation of global nanotechnology governance. As in other emerging technologies, global regulatory debates and governance initiatives are lagging behind nanotechnology innovation.

82. Clapp 1998; and Raines 2003.

The international dimensions of nanotechnology regulation are still poorly understood and rarely feature on the international agenda. Leading nanotechnology countries in the OECD have started to promote international coordination, and UNEP and the WHO have begun to debate nanotechnology as an emerging concern. Yet, the global debate on how to address nanotechnology and its associated risks has barely begun. As more and more nanomaterials and nanotechnology-enabled products enter international trade, a global governance gap is emerging with regard to environmental, health and safety regulation.

A review of existing regulatory approaches in leading industrialized countries shows how governments in North America and Europe are working with existing frameworks for EHS regulation—in chemicals, food, cosmetics, medicines, etc.—to provide coverage of potential nanotechnology risk. In order to balance technology promotion with EHS regulation, most governments have opted for an incremental, case-by-case, approach to risk assessment and management. But persistent scientific uncertainty and information gaps about EHS risks and the state of nanotechnology commercialization raise doubts about the effectiveness of existing regulatory frameworks in dealing with potential risks.

In the last five years, the first international coordination mechanisms have been created, primarily through the OECD and ISO. The scope of their efforts is limited, however, as is their authority to develop a more broadly-based global governance framework. Several analysts and regulatory reviews have called for increased international cooperation, standard-setting and capacity-building. Some point to the growing internationalization of nanotechnology, and the burgeoning international trade in nanomaterials and products made with nanotechnology, which are likely to create a greater need for international harmonization of regulations. Yet few governments have come out in support of a more comprehensive global governance framework that could provide a forum for debating and developing international regulatory approaches.

Developing nanotechnologies in a responsible manner will require governments to work together to reduce uncertainties and promote coordination and cooperation at an early stage. But as we argue in this paper, persistent uncertainty both creates demand for and stands in the way of greater international

cooperation and harmonization of regulatory approaches. Against the background of this profound dilemma of international risk regulation under conditions of uncertainty, global nanotechnology governance is likely to emerge only slowly and in incremental fashion. This paper has identified three areas in which international approaches could and should be taken forward, as building blocks for an emerging global governance architecture. These are first, improvements in the cognitive environment for regulatory approaches, second, the promotion of convergence in the principles and rules for risk assessment and management, and third, capacity-building and greater involvement of developing countries in international processes. By developing global governance in an incremental way, governments can respond to emerging nanotechnology risks in a more coordinated and informed yet flexible manner.

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