The Case for Regulating Nanotechnologies: International, European and National Perspectives

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Governments in leading industrialized countries are currently primarily relying on existing regulatory frameworks for environmental, health and safety regulation to cover nanotechnology risks. European and national regulators have generally concluded that any risks posed by nanomaterials can be addressed using existing frameworks, with minor adjustments to specific regulations. Identifying appropriate responses to uncertain risks is a difficult task for policy makers and regulatory agencies, as they are faced with a high degree of scientific uncertainty, the need to balance the costs and benefits of regulation, and the need to find a reasonable compromise between scientific freedom, technological innovation, consumer safety and environmental protection. As nanotechnologies are arguably only recently gaining public prominence, and their regulation is still in its infancy, this article examines some of the issues faced by regulators, offers insights into potential methods for regulation and critiques the current state of international, European and national law and policy. The article concludes that to address the current regulatory gaps and environmental and health safety concerns surrounding nanomaterials, nano-specific regulation establishing product-specification, notification, public disclosure and risk assessment requirements is necessary.

INTRODUCTION

The debate concerning the regulation of nanomaterials (NMs)[1] has focused on whether NMs could harm the environment and human health, much along the lines of the biotechnology debate of the 1990s and early 2000s.[2] Yet, concerted regulation in this area is still lacking. A key issue in the regulation of nanotechnologies is that the deliberate exploitation of properties at nanoscale is central to their application and may cause NMs to exhibit very different properties from their conventional bulk substances. Potential benefits of these technologies include vast product, industrial and

[1] In the absence of a generally accepted definition, the term 'nanomaterials' is used in this article to cover commonly used terminology such as manufactured (or engineered) nano-sized and nano-structured nanomaterials.

[2] See also L. Boisson de Chazournes and U.P. Thomas (eds.), WTO Law, Science and Risk Communication (Special Edition), 3 *EcoLomic Policy and Law* (2006), found at: <http://www.ecolomics-international.org/epal_2006_special_edition_wto_law_science_and_risk_communication.pdf>; and L. Boisson de Chazournes and M.M. Mbengue, 'GMOs and Trade: Issues at Stake in the EC Biotech Dispute', 13:3 *Review of European Community and International Environmental Law* (2005), 289.

technological applications, wealth generation, job creation, and other societal advances.[3] Conversely, risks associated with these technologies include potentially serious risks to human health and the environment,[4] as NMs may be discharged directly into rivers or the atmosphere by industry or escape when products are used or disposed of in the environment. However, at this stage, the effects of NMs and their toxicological impacts on human health and the environment are not yet fully understood.[5]

Rapid commercialization of NMs suggests that the potential for human and environmental exposure will increase dramatically.[6] However, the pace of regulatory progress lags behind the speed at which NMs are being introduced in the market.[7] Arguably, regulatory challenges are related to uncertainties regarding the development and commercial applications of NMs, hazards and exposure pathways, the speed of technological change and effectiveness of existing regulatory frameworks. The lack of scientific certainty about the behaviour of some types of nanomaterials in the environment or risks they pose for human health is a cause for concern. Indeed, some reviews on toxicity are beginning to indicate that NMs are more reactive and toxic than their unadulterated counterparts.[8]

Furthermore, the transboundary movement and trade of nanotechnologies across countries and sectors means that a number of existing international institutions and instruments will be relevant to the regulation of nanotechnology. A global approach to regulation is arguably necessary, in terms of the institutional frameworks, standards and policies addressing nano-regulation issues, as well as to address the potential transboundary environmental impacts.

The aim of this article is to assess the extent to which nano-specific regulation is necessary to address the recognized and perceived threats to health and the environment. The article first discusses the precautionary principle as the basis for nanotechnology regulation. It then reviews the approaches to the regulation of nanotechnologies at the international, European and national levels. The last part of the article assesses options for reform of the regulatory regimes currently in force.

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[3] For example, nanomaterials are used to create very fine membranes, which act as effective filters, and magnetic nanoparticles remove heavy metal contaminants from waste water. Nanotechnologies have also revolutionized manufacturing processes in the consumer sector, creating a new generation of NM products such as resistant glass, water repellents and anti-odour, crease-free fabrics. Nanotechnology is a multi-billion dollar industry expected to grow to US$ 1 trillion by 2015. See Q. Chaudhry, A. Boxall, R. Aitken and M. Hull, *A Scoping Study into the Manufacture and Use of Nanomaterials in the UK* (Central Science Laboratory, 2005).

[4] NMs covering relatively large surface areas are potentially more reactive and toxic compared to their conventional bulk substances. See K. Thomas *et al.*, 'Research Strategies for Safety Evaluation of Nanomaterials, Part VIII: International Efforts to Develop Risk-based Safety Evaluations for Nanomaterials', 92:1 *Toxicological Sciences* (2006), 23.

[5] See, e.g., Organisation for Economic Co-operation and Development (OECD), *Current Developments in Delegations on the Safety of Manufactured Nanomaterials – Tour de Table* (OECD, 2013); M. Kendall and S. Holgate, 'Health Impact and Toxicological Effects of Nanomaterials in the Lung' 17:5 *Respirology* (2012), 739.

[6] K. Floroni, S. Walsh, J.M. Balbus and R. Denson, 'Nanotechnology: Getting it Right the First Time', 6:3 *Sustainable Development Law and Policy* (2006), 46.

[7] Ibid.

[8] S.T. Holgate, 'Exposure, Uptake, Distribution and Toxicity of Nanomaterials in Humans', 6:1 *Journal of Biomedical Nanotechnology* (2010), 1; A.D. Maynard *et al.*, 'Safe Handling of Nanotechnology', 444:7117 *Nature* (2006), 267; Royal Commission on Environmental Pollution (RCEP), *Novel Materials in the Environment: The Case of Nanotechnology* (RCEP, 2008).

THE BASIS FOR NANOTECHNOLOGY REGULATION: THE PRECAUTIONARY PRINCIPLE

The regulation of the nanotechnology industry provides an opportunity for the application of the precautionary principle. The precautionary principle has been incorporated into international, regional and national environmental law and policy instruments.[9] It is a useful policy- and decision-making tool and has been discussed at length in its own right.[10] The implication of the adoption of the precautionary principle in the regulation of nanomaterials is that NMs would be placed in the highest hazard category, unless sufficient evidence or information is available to justify a lower level of hazard classification. Another implication of the precautionary principle is that the burden of proof of demonstrating risk would normally lie with the promoter of a potentially harmful activity, who must prove that there is no risk of harm. Hence, the precautionary principle would shift the burden of proof from the regulator to the producer.[11]

According to the precautionary principle, '[w]here 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'.[12] It thus gives policy makers leeway to move forward and tighten environmental regulatory controls despite a lack of scientific consensus regarding the nature and seriousness of the 'perceived' threat to the environment or human health. However, precautionary measures must be based on more than a mere hypothesis or purely theoretical assessments. There must be a 'reasonable ground for concern'.[13]

In the UK, a 2004 report by the Royal Society and the Royal Academy of Engineers[14] recommended that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous and seek to reduce or remove them from waste streams. It further suggested that industry should assess the risk of release of

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[9] See, e.g., Declaration on Environment and Development, found in Report of the UN Conference on Environment and Development (A/CONF.151/26/Rev.1 (Vol. I), 14 June 1992), Annex ('Rio Declaration'), Principle 15; United Nations Framework Convention on Climate Change (New York, 9 May 1992: in force 21 March 1994) ('UNFCCC'), Article 3.3; and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Cartagena, 29 January 2000; in force 11 September 2003) ('Cartagena Protocol'); Consolidated Version of the Treaty on the Functioning of the European Union, [2008] OJ C115/49 ('TFEU'), Article 191.2.

[10] See, e.g., N. de Sadeleer (ed.), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and USA* (Earthscan, 2007); E. Fisher, J. Jones and R. van Schomberg (eds.), *Implementing the Precautionary Principle: Perspectives and Prospects* (Edward Elgar, 2006); M. Fitzmaurice, *Contemporary Issues in International Environmental Law* (Edward Elgar, 2009); E. Hey, 'The Precautionary Concept in Environmental Policy and Law: Institutionalizing Caution', 4:2 *Georgetown International Environmental Law Review* (1992) 303.

[11] This is the approach taken, for example, under the EU chemical Regulations, discussed below. However, a different stance was adopted by the International Court of Justice in the *Pulp Mills* case (ICJ 20 April 2010, *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, Joint Dissenting Opinion, [2010] ICJ. Rep 14) ('Pulp Mills'), see in particular paragraph 164).

[12] Rio Declaration, n. 9 above; see also UNFCCC, n. 9 above, Article 3.3 (omitting the reference to cost-effectiveness).

[13] Commission of the European Community Communication of 2 February 2000 on the Precautionary Principle, COM (2000)1, at 2 and 8.

[14] Royal Society and Royal Academy of Engineering, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (Royal Society and Royal Academy of Engineering, 2004).

NMs from products or processes throughout their life cycle. The 'innovation' versus 'precaution' debate has evolved from the question of whether the benefits of nanotechnology are worth the risk taken and ventures into the realm of the debate over the (un)certainty of the risk. It is suggested that in the light of scientific uncertainty and considering the costs of (in)action, law and policy makers must apply the principle of precaution. Considering the magnitude of the risks, to 'err on the safe side' is a better policy option than to face the consequences.

This debate resembles that regarding the authorization of release of genetically modified organisms (GMOs), in which two major global markets players –the United States and the European Union – have taken opposing views on the legal implications of the precautionary 'principle' or 'approach'.[15] Despite these opposing views, the precautionary principle is gradually evolving into the corpus of customary international law, as has recently been opined by the International Tribunal on the Law of the Sea.[16]

INTERNATIONAL REGULATION OF NANOTECHNOLOGY: INSTITUTIONS, STANDARDS AND TRADE

The transboundary nature of nanotechnologies suggests that a number of international institutions and instruments are relevant to the regulation of nanotechnology. Therefore, a global approach to regulation may be necessary for regulating nanotechnologies and their environmental impacts. This suggestion is reinforced by the fact that economic globalization and the creation of international institutions have been powerful driving forces behind the growth of globally harmonized standards in areas including technical product specification and consumer, health and environmental protection.[17]

Presently, nanotechnology is not specifically subject to any single international regulatory instrument and many nanoproducts fall within pre-existing international and national regulations.[18] Yet the development of harmonized international standards is essential in facilitating trade across many jurisdictions and for regulating NMs. The absence of a consensus on definitions, common nomenclature and standards for

[15] The US insists on using the term precautionary 'approach' in the belief that it is less expansive than the term 'principle', hence giving it less legal weight. While the EU system of GMO authorization places more emphasis on the precautionary approach, the US places greater emphasis on sound science and risk assessment. On the transatlantic trade disputes applying and interpreting the precautionary principle, see in particular: WTO AB 16 January 1998, *European Communities – Measures Concerning Meat and Meat Products*, WT/DS26/AB/R (*EC-Hormones*); WTO DS 21 November 2006, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R.

[16] The Seabed Disputes Chamber of International Tribunal on the Law of the Sea (ITLOS) opined that the precautionary approach may have reached the status of customary law. See ITLOS 1 February 2011, *Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area (Request for Advisory Opinion submitted to the Seabed Disputes Chamber)*, found at: <http://www.itlos.org/fileadmin/itlos/documents/cases/case_no_17/adv_op_010211.pdf>, particularly paragraphs 131 and 135. This is the first time that there is a clear statement from an international tribunal regarding the legal status of the precautionary principle. Compare it with ICJ 20 December 1974, *Nuclear Tests Case (Australia v. France)*, [1974] ICJ Rep. 253; *EC-Hormones*, n. 15 above; and *EC-Biotech*, n. 15 above.

[17] D. Vogel, 'The Politics of Risk Regulation in Europe and the United States', 3 *Yearbook of European Environmental Law* (2003), 1.

[18] See D.M. Bowman and G.A. Hodge,'A Small Matter of Regulation – An International Review of Nanotechnology Regulation', 8 *The Columbia Science and Technology Law and Review* (2007), 1.

classification and testing of nanotechnology and NMs makes it very difficult to define or classify the objects or processes to be regulated.

A number of international soft law standards on NMs have been adopted, including codes of conduct and risk management standards.[19] They have been adopted by the International Organization for Standardization (ISO),[20] the Strategic Approach to International Chemicals Management (SAICM) (which considers nanotechnologies as an emerging issue),[21] and the ISO Technical Committee 229 in conjunction with International Electrotechnical Commission Technical Committee 113.[22] The work on standards represents an important first stage in national and international regulatory development processes.[23] Although they are non-binding, these initiatives are important in building a firm knowledge base to support policy decisions and may become an essential prerequisite to appropriate regulation.

One of the main fora through which States have sought to create common approaches on scientific building blocks for nanotechnology to date is the Organisation for Economic Co-operation and Development (OECD). The OECD's work on nanotechnology has been driven by the network of multidisciplinary experts within the Chemicals Committee, and has led to the establishment of a Working Party on Manufactured Nanomaterials[24] to promote international cooperation in health- and environmental safety-related aspects of manufactured NMs. Guidelines of the Committee are not binding on member countries but could form the basis for an emerging consensus on a global regulatory framework. The OECD's focus has been on information gathering and sharing with a view to addressing technical issues of scientific building blocks, including risk assessment and management, as well as broader political questions concerning the member countries.

Aside from these soft law instruments, international treaties play a significant role in regulating aspects of NMs. The main international treaties regulating the trade in chemicals are the 2001 Stockholm Convention on Persistent Organic Pollutants

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[19] Commission Recommendation of 7 February 2008 on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, C(2008) 424 final.

[20] The ISO established the 229 Nanotechnologies Technical Committee in 2005, with the aim to develop international standards for nanotechnologies. See <http://www.iso.org/iso/iso_technical_committee?commid=381983>. See also D.M. Bowman and G.A. Hodge, n. 18 above.

[21] The Strategic Approach to International Chemicals Management (SAICM) is a non-binding policy framework to promote chemical safety around the world. It was adopted by the International Conference on Chemicals Management in Dubai in February 2006. The SAICM has as its overall objective the achievement of the sound management of chemicals throughout their life cycle so that, by 2020, chemicals are produced and used in ways that minimize significant adverse impacts on human health and the environment. This '2020 goal' was adopted by the World Summit on Sustainable Development in 2002 as part of the Johannesburg Plan of Implementation. See <http://www.saicm.org>.

[22] This committee develops nanotechnology standards at the international level. Standard development in the committee took off quite rapidly in 2009-2010, particularly focusing on terminology, nomenclature, measurement, and characterization of NM. See <http://www.iso.org/iso/iso_technical_committee?commid=381983>.

[23] See D.M. Bowman and G.A. Hodge, n. 18 above.

[24] OECD, *Current Developments/Activities on the Safety of Manufactured Nanomaterials: Tour de Table at the 1st Meeting of the Working Party on Manufactured Nanomaterials* (OECD, 2006), The OECD Working Party on Manufactured Nanomaterials gathers data and information on characterization and safety of NMs in liaison with the ISO Technical Committee 229.

(POPs)[25] and the 1998 Rotterdam Convention on Prior Informed Consent (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade.[26] Despite the fact that nanotechnologies are not expressly mentioned in either treaty, or listed in their annexes, the conventions do not use particle size to define their scope or obligations. Hence, they do regulate the trade in NMs that meet the chemical composition and product characteristics regulated in those conventions.[27] Moreover, they could be used to address issues linked to the release of NMs into the environment.

The Stockholm Convention entered into force in May 2004, and at the time of writing has 179 ratifications.[28] Although the Convention has been successful in attracting a high number of ratifications, the United States – a major producer of nanotechnologies[29] – has not ratified it. The objective of the Stockholm Convention is to protect human health and the environment from POPs using a precautionary approach.[30] Like other international environmental agreements that restrict trade, the Convention works with a number of annexes. Trade in chemical substances listed in Annexes A, B and C are respectively prohibited, restricted or regulated, depending on their toxicity levels.[31] However, the Stockholm Convention lacks the mechanisms of advanced informed consent[32] and risk assessment procedures,[33] which are at the heart of the safeguards present in other trade-restrictive environmental treaties, such as the Cartagena Protocol on Biosafety, which regulates the trade in GMOs, or the Rotterdam Convention (discussed below). Moreover, unlike the Cartagena Protocol, no permanent compliance committee or international civil liability regime for environmental damage have been formally adopted by the parties.

The international legal framework for the trade in dangerous chemicals is

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[25] Stockholm Convention on Persistent Organic Pollutants (Stockholm, 22 May 2001; in force 17 May 2004) ('Stockholm Convention'). POPs are organic (carbon-based) chemical substances. They possess a particular combination of physical and chemical properties such that, once released into the environment, they remain intact for exceptionally long periods of time. On nanotechnology and POPs, see: O. Kharlamov, G. Kharlamova, N. Kirillova and V. Fomenko, 'Persistent Organic Pollutants (Pops) at Nanotechnology and Their Impact on People Health', in: E. Mehmetli and B. Koumanova (eds.), *The Fate of Organic Pollutants in the Environment* (Springer, 2008), 425.

[26] Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam, 10 September 1998; in force 24 February 2004) ('Rotterdam Convention'). For a more detailed analysis of the Rotterdam Convention, see, e.g., P. Barrios, 'The Rotterdam Convention of Hazardous Chemicals: A Meaningful Step toward Environmental Protection', 16:4 *Georgetown International Environmental Law Review* (2003), 679.

[27] A. Petitpierre-Sauvain (ed.), The Basel, Rotterdam and Stockholm Conventions on Chemicals and Wastes – Regulation, Sound Management and Governance (Special Edition), 5-7 *EcoLomic Policy and Law* (2008-2010). found at: <http://www.ecolomics-international.org/epal_2008_2010_special_edition_ruig_geneva_based_chemicals_and_wastes_conventions.pdf>.

[28] Status of ratifications, found at: <http://chm.pops.int/Countries/StatusofRatifications/tabid/252/Default.aspx>.

[29] At 49%, the United States currently has the largest share of the nanotechnology market, followed by the European Union (30%), and the rest of the world (21%). Within the European Union, the United Kingdom is said to account for close to one third of the European nanotechnology market share. See also Q. Chaudhry *et al.*, n. 3 above.

[30] Stockholm Convention, n. 25 above, Article 1.

[31] Parties must take measures to eliminate the production and use of the chemicals listed under Annex A, and must take measures to restrict the production and use of the chemicals listed under Annex B. Parties must also take measures to reduce the unintentional releases of chemicals listed under Annex C.

[32] Cartagena Protocol, n. 9 above, Articles 8-10 and 12.

[33] Ibid., Article 15.

complemented by the Rotterdam Convention. The aim of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm; and to contribute to the environmentally sound use of certain hazardous chemicals by facilitating information exchange about their characteristics and providing for a national decision making process on their import and export.[34] At the heart of the Rotterdam Convention is a voluntary advanced informed procedure that needs to precede the trade in dangerous chemical substances listed in Annex III.[35] Decisions by the Conference of the Parties may add further chemicals to Annex III; hence the regulatory regime may evolve in light of new scientific evidence. Once a chemical is included in Annex III, a 'decision guidance document', containing information concerning the chemical and the regulatory decisions to ban or severely restrict the chemical for health or environmental reasons, is circulated to all parties.[36] The Convention also contains further provisions on information exchange, requiring parties to prepare a response concerning the future import of a chemical within nine months.[37]

In addition to these environmental treaties, the General Agreement on Tariffs and Trade (GATT),[38] adopted under the auspices of the World Trade Organization (WTO), is the key international institution concerned with the liberalization of trade in goods. As such, it is of clear relevance in the governance of all nanotechnology products, in so far as domestic regulatory frameworks on NMs impact on trade. However, some scholars have questioned whether the WTO is the most appropriate venue for international coordination of nanotechnology regulation,[39] reflecting a similarly restrained role of the WTO regarding biotechnology products.

The WTO requires non-discrimination in matters of trade between countries, particularly, between imported and domestically produced 'like' products.[40] However, Article XX GATT permits exemptions for national measures that are necessary to protect human health, animals and plants or relate to conservation of exhaustible natural resources, provided they do not entail 'arbitrary and unjustifiable discrimination' between countries or constitute a disguised restriction on international trade.[41] Moreover, the State has to justify the measure as 'necessary', meaning that it would have to be the least trade restrictive measure reasonably available to achieve an environmental objective. The burden falls on the country imposing a trade measure to justify the exemptions. Some will argue that a product that contains NMs is 'like' the equivalent product without NMs and therefore should be subject to similar standards and should not be subject to trade-

[34] Rotterdam Convention, n. 26 above, Article 1.
[35] Ibid., Articles 10 and 11.
[36] Ibid., Articles 7-10.
[37] The Convention requires each party to notify the Secretariat when taking a domestic regulatory action to ban or severely restrict a chemical Ibid., Article 10.2.
[38] General Agreement on Tariffs and Trade (Marrakesh, 15 April 1994; in force 1 January 1995) ('GATT'). In addition, two key WTO agreements dealing with standards are relevant in the context of trade in NMs: the Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) (often cited in relation to biotechnology matters).Their implications on the development of regulations on nanotechnologies have been reviewed elsewhere. See D.M. Bowman and G.A. Hodge, n. 18 above.
[39] See E. Fisher, J. Jones and R. van Schomberg, n. 10 above.
[40] GATT, n. 38 above, Article III.4.
[41] Ibid., Article XX.

restrictive measures by the importing State. Others will claim that NMs could harm health or the environment and that NM products and normal products therefore are not 'like'.[42] NMs are often derived from common substances that are not new, and many industry stakeholders have taken the view that nanoparticles are no different from the bulk materials from which they are derived and therefore should be considered to be 'like' normal products.[43] However, NMs are of special interest precisely because they possess physical and chemical properties different from their parent compound. The fact that patents have been granted for numerous products containing NMs undermines the contention that engineered NMs should not be treated as new substances.[44]

Several arguments have been raised for further harmonization of international standards relating to nanotechnologies. First, some suggest that harmonization would facilitate international trade, avoiding the disputes and inefficiencies experienced as a result of, for example, the inconsistent US and EU interpretations of the precautionary principle.[45] Second, internationally consistent standards could avoid a 'race to the bottom' and could constrain national regulators from yielding to protectionist or alarmist demands with the view of shielding domestic producers from foreign competition.[46] Third, international regulatory coordination would act to regulate the release of engineered NMs into the environment in one country and control their cross-border movement, thereby addressing the potentially adverse effects that their release would have on other States or areas beyond national jurisdiction.[47]

Despite these potentially positive outcomes, the extent to which States may be willing to cooperate on the harmonization of nanotechnology standards and to improve the safety of trade in NM products should be balanced against the interests of advancing trade and technological innovation, development and dissemination. The following sections suggest that there are further disparities in national and regional regulatory regimes for nanotechnologies, which are likely to hinder any further attempts at international cooperation.

EUROPEAN AND NATIONAL REGULATORY STANDARDS

While the commercialization of nanotechnology is underway, the market entry of NMs has to date been relatively unconstrained due to a distinct absence of nano-specific regulatory frameworks. A significant regulatory loophole exists in the guise of chemicals regulations. Much of the recently adopted chemical regulatory frameworks in the EU, UK, Australia and the US are primarily focused on 'new chemicals'. However, at

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[42] For example, in the first *Tuna-Dolphin* case (1991), which involved the US ban on Mexican exports of tuna which were caught applying 'unsustainable' fishing techniques, the Panel established that the US could only rely on properties of the 'product' not on the 'process' of production. GATT Panel 3 September 1991, *United States – Restrictions on Imports of Tuna*, DS21/R - 39S/155. Beyond the question of discrimination between 'like products', the WTO dispute settlement bodies may assess the environmental grounds under Article XX to establish the validity of the measure.

[43] R. Weiss, 'For Science, Nanotech Poses Big Unknowns', *Washington Post* (1 February 2004).

[44] S. Vaidhyanathan, 'Nanotechnologies and the Law of Patents: A Collision Course', in: G. Hunt and M.D. Mehta (eds.), *Nanotechnology: Risk, Ethics and Law* (Earthscan, 2006), 225.

[45] M. Mansour and S. Key, 'From Farm to Fork: The Impact on Global Commerce of the New European Union Biotechnology Regulatory Scheme', 38:1 *The International Lawyer* (2004), 55.

[46] K.W. Abbott, D.S. Sylvester and G.E. Marchant, 'Transnational Regulation of Nanotechnology: Reality or Romanticism?',in: G.A. Hodge, D.M. Bowman and A.D. Maynard (eds.), *International Handbook on Regulating Nanotechnologies* (Edward Elgar, 2009), 525.

[47] Ibid.

present existing chemicals produced at nanoscale are not considered to be 'new'. For example, nanoscale versions of titanium dioxide, already in widespread use in sunscreen products, are treated the same way as the equivalent bulk material even if they have different properties.[48] The failure of each country to address this gap raises some concern because, while commercialization of products containing manufactured nanoparticles continues to escalate, work to understand the human and environmental impacts is lagging behind. Consequently, our review of national and EU regulatory efforts to develop a sound governance structure suggests that they remain fundamentally weak in all four jurisdictions. A cursory examination of these jurisdictions shows that none of them have enacted nano-specific regulations, although there have been recent proposals for reform.

EUROPEAN UNION

Within the EU, there are two main types of environmental legislation relating to chemicals: (i) environmental legislation concerning the protection of air, water and soil quality from pollution; and (ii) specific regulations concerning the manufacturing and commercialization of chemical substances. The latter can: prohibit or restrict the use of certain substances; limit the use of utilities (water, air and energy); impose controls over the production process by creating emission standards, efficiency goals or impose the adoption of the latest 'end of pipe' technology; or impose controls on the final product, that is, introduce notification requirements for the use and commercialization of new substances.

There are currently no specific regulations for nanotechnologies or NMs in the EU, but the manufacturers' use and disposal of NMs are at least in principle covered by a complex set of existing regulatory regimes. In addition to the 2006 Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH),[49] further discussed below, these include the Industrial Emissions Directive[50] and other consumer and environmental protection regimes. Particular product types are covered by a series of vertical legislation which include: product or sector-specific regulations for pharmaceuticals,[51] veterinary medicines,[52] pesticides[53] and biocides.[54] Specific legislation for toys,[55] cosmetics[56] and 'end of life' products, such as the Waste Electrical and Electronic Equipment Directive, are also of relevance.[57]

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[48] See RCEP, n. 8 above.

[49] Regulation 1907/2006 of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), [2006], OJ L396/267.

[50] Directive 2010/75/EU of 24 November 2010 on Industrial Emissions (Integrated Pollution Prevention and Control) (Recast), [2010] OJ, L334/17.

[51] See, e.g., Directive 2011/62/EU of 8 June 2011 Amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, as Regards the Prevention of the Entry into the Legal Supply Chain of Falsified Medicinal Products, [2011] OJ L174/74.

[52] Directive 2001/82/EC of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products [2001], OJ L311/1); Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC on the Community Code Relating to Medicinal Products for Veterinary Use, [2009], OJ L44/10.

[53] Regulation 1107/2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC, [2009] OJ L309/1.

[54] Regulation 528/2012 Concerning the Making Available on the Market and Use of Biocidal Products, [2012], OJ L167/1.

[55] Directive 2009/48/EC on the Safety of Toys, [2009] OJ L170/1.

[56] Regulation 1223/2009 of 30 November 2009 on Cosmetic Products (Recast), [2009] OJ L342/59.

[57] Directive 2002/96/EC of 27 January 2003 on Waste Electrical and Electronic Equipment (WEEE),

Until 1 June 2008, new chemicals in the EU were covered by regulations on the notification of new substances. This system has been superseded by the REACH Regulation. REACH constitutes the EU framework legislation for the management, control and use of chemicals, replacing several directives and simplifying the previous patchwork of over 40 separate pieces of legislation. REACH aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market and enhancing competitiveness and innovation.[58] REACH also created the European Chemicals Agency, which carries out several scientific, technical and administrative and management functions to implement REACH throughout the EU.

The effect of the REACH Regulation is to impose responsibility on those who manufacture and sell the products for the potential threats to human health and environment. It creates an obligation for these actors to minimize the risk of adverse effects.[59] However, given the speed of developments in the field of nanotechnology, there will likely be a gap between innovation and knowledge of possible 'new' hazards, making it difficult to resolve issues of safety of new materials using traditional risk-based regulatory frameworks.

REACH ended the different treatment of 'new' and 'existing' substances under EU law. However, the Regulation still distinguishes between non-phase-in (new) and phase-in (existing) substances for purposes of registration time frames and in some cases data requirements.[60] Eventually, all chemicals that fall within its scope will be subject to registration requirements and data sets will need to be prepared. This compilation of data will be useful in tracking and assessing the potential risks associated with nanotechnologies.[61] However, whether such data will be comprehensive enough remains to be seen. A 2009 Resolution by the European Parliament called for an inventory of nanomaterials on the market to address the fact that such information is not yet available otherwise.[62] According to a Communication by the European Commission, as of February 2012 seven substance registrations and 18 CLP notifications had selected 'nanomaterial' as the form of the substance, while a further assessment identified additional substances with nanoforms.[63]

REACH also transfers responsibility of carrying out risk assessments from the Member States to the producers and importers of a chemical substance.[64] This risk assessment will

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[2003] OJ L37/24.

[58] Regulation 1907/2006, n. 61 above, Article 1.1. The registration of substances and articles under REACH is being phased in over an 11-year period (2007-2018), with chemicals manufactured or imported in large volumes and certain 'substances of very high concern' (i.e., with particular hazardous properties) being registered first, followed by those manufactured or imported in smaller volumes.

[59] Ibid., Article 1.3.

[60] Ibid., preamble 20 and Article 60.2.

[61] Ibid., Annex II.

[62] European Parliament Resolution of 24 April 2009 on Regulatory Aspects of Nanomaterials (2008/2208(INI)), found at: <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P6-TA-2009-328>.

[63] Communication from the European Commission on the Second Regulatory Review on Nanomaterials, COM(2012) 572.

[64] The Food and Agriculture Organization of the United Nations (FAO) and the World Health

be 'use specific'. In other words, each downstream user is required to declare how it uses the chemical substance, and the manufacturer is required to produce a risk assessment document with specific instructions for each use situation.[65] The Regulation also requires information about risks associated with chemicals to be outlined for users in 'safety data sheets'.[66] Chemicals that pose a serious hazard may be banned or restricted (i.e. they may be used only following the grant of a specific 'authorisation').[67] REACH only applies to substances as well as substances in articles that are produced or imported in an amount of over one tonne per year.

The European Commission's action plan on nanosciences and nanotechnologies, published in June 2005,[68] recognizes the Commission's role in promoting investment and innovation in NMs, as well as in setting standards for improvement of public health and environmental safety and international cooperation between the EU Member States in the context of NMs. The Action Plan specified that all applications and use of nanosciences and nanotechnologies must comply with the high level of public health, safety, consumer and worker protection and environmental protection chosen by the Union. To this end, the Commission's Scientific Committee on Emerging and Newly Identified Health Risks issued an opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered NMs and products of nanotechnologies.[69] The European Commission subsequently published a Communication in 2008,[70] which concluded that current legislation to a large extent covers risks in relation to NMs, and that risks can be dealt with under the current legislative framework. However, the Commission also noted that 'current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation'.[71] The Commission's conclusions have been challenged by a non-binding resolution adopted in April 2009 by the European Parliament, following a detailed report on NMs presented by the European Parliament's Environment Committee.[72] The resolution asks for tighter controls on nanotechnologies, in particular with respect to legislation on chemicals, food, waste, air, water and workers' protection.

Organization (WHO) published a report in 2012 on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agricultural sector, highlighting the divergent methods applied to risk assessment in several jurisdictions. See FAO and WHO, *State of the Art on the Initiatives and Activities Relevant to Risk Assessment and Risk Management of Nanotechnologies in the Food and Agriculture Sectors* (Draft version for public review, 30 November 2012), found at: <http://www.who.int/foodsafety/biotech/FAO_WHO_Nano_Paper_Public_Review_20120608.pdf>.

[65] Regulation 1907/2006, n. 61 above, Article 70.

[66] Ibid., Article 31; Annex II.

[67] Substances of very high concern are not only subject to registration, but also authorization under REACH before they can be placed on the market. There is no limit on production volume for substances of very high concern, although all materials with these properties will require authorization. Ibid., preamble 22 and 69. REACH foresees the gradual substitution of substances of high concern. Ibid., Article 55.

[68] Communication from the European Commission on Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009, COM(2005) 243.

[69] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Modified Opinion (after Public Consultation) on The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies (10 March 2006), found at: <http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf>.

[70] Communication from the European Commission on Regulatory Aspects of Nanomaterials, COM(2008) 366.

[71] Ibid, at 3-4.

[72] European Parliament Resolution of 24 April 2009, n. 62 above.

In response, the Commission has been reviewing all relevant legislation with a view to proposing regulatory changes wherever necessary and to developing nano-specific instruments for the implementation of regulation. One example is the recent recast of the EU Cosmetic Regulation[73] which has taken the position of the Parliament into consideration, and already includes specific provisions for NMs (including a definition, requirements for notification, labelling provisions, specific guidelines for safety assessment and reporting of NMs).[74]

In October 2012 the Commission published its Second Regulatory Review on Nanomaterials.[75] The review highlighted the role of nanotechnology as a 'key enabling technology', providing the basis for innovation and growth and a key to solving major societal challenges. It recognizes the need to balance the protection of health and the environment with promoting competitiveness and capturing the benefits of nanotechnology, and stresses the need for international cooperation and responsible development. The review confirms that the REACH remains the best possible framework for the risk management of NMs and chemicals that are not the subject of more specific legislation, but that further detailed guidance is needed to clarify how NMs should be identified and addressed in the registration process. In particular, it is still unclear whether NMs should be registered as forms of, or distinct from, their corresponding bulk substance. The Commission has established a Working Group to explore the relevant technical and scientific issues and develop best practices.[76]

Similar findings were presented by the Commission in its 2012 REACH review, which concludes that the existing legal framework was sufficient to address nanotechnologies, but suggests that future reviews are likely to be forthcoming.[77] In particular, the Commission suggests that it will launch an impact assessment of relevant regulatory options, including possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. If appropriate, the Commission suggests that it will come forward with a draft implementing act by December 2013.[78]

The limitations of REACH in addressing nanomaterials are considerable. The classification of nanoscale materials as 'existing substances' – i.e., substances listed in the European Inventory of Existing Commercial Chemical Substances and placed on the market before September 1981 – is a recurrent regulatory gap.[79] This arises if it is considered that the chemical structure of the nanoscale form is no different from its bulk equivalent. The concern here is that the nanoscale substance may pass through its life cycle without additional scrutiny of its unique properties, possibly leading to a situation in which measures cannot be taken to reduce potential risks.

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[73] Regulation 1223/2009, n. 56 above.
[74] E. Mantovani, A. Porcari, D. Morrison and R.E. Geertsma, Developments in Nanotechnologies Regulation and Standards 2012 – Report of the Observatory Nano (April 2012), found at: <http://www.observatorynano.eu/project/filesystem/files/ObservatoryNano_NanotechnologiesRegulationAndStandards_2012.pdf>.
[75] COM(2012) 572, n. 75 above.
[76] See <http://echa.europa.eu/chemicals-in-our-life/nanomaterials>.
[77] European Commission, General Report on REACH, COM(2013) 49.
[78] Ibid.
[79] See Q. Chaudhry *et al.*, n. 3 above.

There are other areas of uncertainty regarding the scope of REACH in respect of NMs. Crucially, there are no specific provisions for NMs in REACH. The abovementioned annual production/importation thresholds, which potentially prevent the registration of NMs manufactured, used or imported in quantities of less than one tonne, is also an area of uncertainty. However, the European Commission has provided some clarification.[80] First, it has suggested that REACH requirements apply to NMs, even though there are no nano-specific provisions. Second, when an existing chemical substance is introduced on the market at the nanoscale, the registration dossier will have to be updated to include specific properties of the nanoform of the substance. Third, the additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. Although these guidelines have not amended REACH itself, they provide an important interpretative tool of the legislation and enhance clarity and certainty for the regulated industries.

UNITED KINGDOM

The UK is one of the EU Member States that has taken a leading role in generating the discussion on nano-regulation. In the majority of cases, UK law generally implements measures that have been agreed and harmonized at the EU level. Therefore, the UK and other Member States need to address any regulatory shortfalls through the European Commission. Although there is evidence [81] suggesting that present regulatory frameworks at the EU and UK level are sufficiently broad and flexible to govern nanotechnologies at the current stage of their development, some regulations may need to be modified on a precautionary basis.

Reviews of the UK regulatory framework have identified regulatory gaps due to: (i) legislative thresholds and definitions designed primarily to address risks associated with bulk chemicals; (ii) exemptions for products based on their size (i.e. on a tonnage basis); and (c) uncertainties over: current scientific knowledge and understanding of hazards and risks from exposure to NMs, including potential impacts of NMs on human and environmental health; agreed dose units that can be used in hazard and exposure assessments; and reliable and validated methods for measurement and characterization that can be used in monitoring potential exposure to NMs.[82]

To address these regulatory gaps, a report by the Royal Society and Royal Academy of Engineering recommended that all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and reduce the environmental hazards outlined in the report, and publish their review and details of how they will address any regulatory gaps.[83] The report also indicates that establishment of a regulation requires assessments of the hazards and the likelihood or duration of exposure, these factors combining to produce the risk to any exposed biological or human population. The overall aim is to determine the risk management measures

[80] COM(2008) 366, n. 70 above.

[81] See, e.g., S.T. Holgate, n. 8 above; A.D. Maynard, n. 8 above; RCEP, n. 8 above.

[82] Royal Society and Royal Academy of Engineering, n. 14 above; see also Q. Chaudhry *et al.*, n. 3 above.

[83] Royal Society and Royal Academy of Engineering, n. 14 above.

needed to eliminate the risks or (in practice) reduce them to acceptable levels. This process of evidence gathering needs to be informed by factual evidence, usually obtained from toxicological, environmental or epidemiological studies.

The UK government supported the recommendation by the Royal Society and Royal Academy of Engineering that nanomaterials be considered 'new chemicals' under existing UK and EU chemicals regulations.[84] Moreover, in their response, the UK government noted that 'in order to ensure that the products of nanotechnologies are properly regulated, the Government considers it likely that sector specific regulations, in addition to REACH, may be required'.[85] The UK government further contends that 'to reduce the threshold dramatically to take account of potential issues arising from nanotechnologies would result in a large number of chemicals (in addition to the products of nanotechnologies) that are not currently being produced on an industrial scale, being subject to regulations designed for industrial products'.[86] It thus plans to call for regulation of NMs at the European level whilst continuing to use REACH and keeping the regulatory situation under review as more evidence and information becomes available.

UNITED STATES

In the United States, regulators maintain that the unique size and properties of nanoscale materials do not warrant new regulation.[87] At present the 1976 Toxic Substances Control Act (TSCA)[88] is the principal statute that provides authority to regulate chemicals and, therefore, has been the primary vehicle used by the Environmental Protection Agency (EPA) to regulate nanomaterials. In contrast to other environmental laws in the United States, which govern only the release into the environment, the TSCA grants EPA the broad authority to regulate the entire life cycle of a chemical substance. The EPA has regulatory authority in three key areas: (i) regulating chemicals that present health or environmental risks; (ii) screening new chemicals and significant new uses of existing chemicals; and (iii) testing chemicals where risks are unknown. However, the legislation does not specifically address NMs.

It has been argued[89] that the TSCA and other legislation are inadequate for regulating nanoproducts, and that they have serious shortcomings related to their legal authority, a lack of resources, or both.[90] These shortcomings relate to the TSCA's low volume exemptions and the implicit assumption that no information on risk of a chemical means that there is no risk.

First, the TCSA contains volume exemptions for new chemicals or significant new

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[84] UK Government's Response to the joint Royal Society and Royal Academy of Engineering Report - Nanoscience and Nanotechnologies: Opportunities and Uncertainties (25 February 2005), found at: <http://webarchive.nationalarchives.gov.uk/+/http://www.berr.gov.uk/files/file14873.pdf>.
[85] Ibid, at 7.
[86] Ibid.
[87] A.C. Lin, 'Size Matters: Regulating Nanotechnology', 31:2 *Harvard Environmental Law Review* (2007), 350.
[88] 15 U.S.C. §2601ff. (1976).
[89] J. Davies, *Managing the Effects of Nanotechnology* (Woodrow Wilson International Centre for Scholars, 2006); J.M Davis. 'How to Assess the risks of Nanotechnology: Learning from Past Experience', 7:2 *Journal of Nanoscience and Nanotechnology* (2007), 402.
[90] See further A.C. Lin, n. 87 above; J. Davies, n. 89 above.

uses of chemicals produced in volumes of 10,000 kg or less per year, although this threshold does not apply if the EPA determines that a chemical may have serious environmental effects. This threshold would exclude most NMs.

Second, substances whose effects are uncertain are treated the same as substances that demonstrably pose no unreasonable risk. This presents a particularly difficult challenge to the regulation of nanotechnology given the vast uncertainty regarding its impact on health and safety. The EPA has to date not issued rules or guidance as to which nanoscale materials are 'new chemical substances' or 'significant new uses' such that they could be subject to TSCA notification requirements. It also has not yet changed the regulatory exemption for new chemicals produced in low volumes.[91] However, in 2012, the agency issued a series of actions to ensure the notification and registration of NMs. In particular, it adopted rules requiring companies to provide notifications of new use of existing chemicals on the basis of specific use and types of NMs (mainly carbon nanotubes, titanium- and silica-based compounds).[92] The EPA plans to adopt such procedures for any new NMs before they are put on the market.[93]

It can be noted that a basic difference between the US and the EU approach is that under the TSCA the burden of proof regarding the safety of a substance is on the regulatory authority (and not the manufacturer as under the REACH Regulation).

AUSTRALIA

Australia is also considering regulatory reforms. The Australian government has commissioned a review of its regulatory structure with respect to emerging risks related to nanotechnologies. The review found that Australia's regulatory frameworks are 'generally well suited to allowing adequate management and control of risk posed by engineered NM and products incorporating NM and their manufacture, use and handling'.[94] The review also outlined a few potential gaps, including whether NMs would be considered as new or existing substances and whether weight and volume thresholds are applicable. Australia has also developed a strategy for the regulation of NMs, supported by an in-depth stakeholder consultation, which concluded in 2010.[95] Since January 2011, Australia has implemented guidance for the notification of new NMs, making pre-market notification and the submission of safety information mandatory before new NMs can be placed on the market.

RECOMMENDATIONS FOR NANOTECHNOLOGY REGULATION

Generally, risk regulation ensures that scientific uncertainty does not hamper decision making and seeks to eliminate or reduce the possibility of harm. In the context of nanotechnology, the policy goal should be optimal precaution against risks, that is, the

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[91] C.L. Bell *et al.*, Regulation of Nanoscale Materials under the Toxic Substances Control Act 8-11 (American Bar Association, 2006), found at: <http://www.abanet.org/environ/nanotech/pdf/TSCA.pdf>;A.C. Lin, n. 87 above; J. Davies, n. 89 above.
[92] E. Mantovani *et al.*, n. 74 above, at 12.
[93] Ibid.
[94] K. Ludlow, D. Bowman and G. Hodge, *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (Monash University, 2007), at 92.
[95] Ibid.

point at which the marginal benefits of intervention are equal to its marginal costs.[96]For example, if the exposure to certain NMs in the workplace is known to cause serious harm to health and that harm could be eliminated at acceptable cost to society, protective measures ought to be put in place. However, costs alone should not determine the course of action. As discussed above, the precautionary principle comes into play when there is a lack of full scientific certainty about the threat of harm from a substance. On this basis, assumptions are made about the potential hazard, followed by as assessment of the risk of exposure, for example in the workplace or to the general public from use of products. For those substances that pose the most serious risk, regulatory measures are necessary to prevent harm to people or the environment. Identifying appropriate responses to uncertain risks is a difficult task for policy makers, as they are faced with a high degree of scientific uncertainty and the need to balance the costs and benefits of regulation as well as seeking a reasonable compromise between scientific freedom, technological innovation, consumer safety and environmental protection. Given that 'free' NMs present a more immediate risk of exposure compared to 'fixed' NMs embedded in composite materials, the proposed regulatory options should reflect this distinction by regulating products containing free NMs more closely. There are a number of possibilities for regulation, including: workplace controls; classification and labelling measures; control of emissions to air, water and land; waste disposal restrictions; marketing and use restrictions; and prohibition.

Though at present considerable uncertainties make it difficult to carry out a cost-benefit appraisal of the different regulatory interventions, this section discusses four key regulatory options to aid the future development of a governance framework for NMs: (i) maintain existing regulations; (ii) introduce a system of 'grandfathering' in which new regulations apply to new market entrants only; (iii) develop nano-specific and process-based regulations; and (iv) develop nano-specific and product-based regulations.

MAINTAINING EXISTING REGULATIONS

Maintaining existing regulations is synonymous with retaining the status quo. There are advantages of using existing regulations to manage the risks posed by nanotechnologies in that there are already systems in place to ensure enforcement and compliance. Another benefit is low operational costs due to the fact that frameworks are already established. Moreover, there are no costs associated with the introduction and administration of new regulations. This helps to explain why in the EU both industries and governments are in favour of using REACH and other existing regulations to govern NMs.[97]

Given the regulatory gaps identified above, using existing regimes could be particularly costly where a plausible risk of harm exists. For example, if we apply the distinction between free and fixed/embedded NMs, free NMs are more hazardous than fixed NMs. In cases where free NMs are used in workplaces (in aerosol form), there is cause for concern if they are inhaled or absorbed through the skin as in cosmetic products. It follows that the type of NMs and their application are key determinants of the potential harm.

[96] E. Stokes, 'Regulating Nanotechnologies: Sizing Up Options', 29:2 *Legal Studies* (2009), 281.
[97] Ibid.

Therefore, where there is direct exposure for current uses and applications of NMs – e.g. worker exposure or exposure through food applications – a precautionary approach should be invoked.

The costs of potential liabilities to industry and the costs of recovering environmental damage[98] are likely to outweigh the costs of improving safety under the existing regulations. Indeed, as nanotechnology enterprises grow, issues of civil liability (as well as criminal liability[99]) will become increasingly relevant. As the commercial applications of nanotechnology increase, so will the relevance of civil liability for defective products, and any damage caused by the release of nanoparticles into the environment.[100] Moreover, Hunt points out that legal claims arising out of nanotechnology may be generated by personal injury claims, whether arising directly out of, for example, nanomedical applications, or possibly caused by the toxicity of nanoproducts, for example, nanoparticles in the environment.[101] In this regard, parallels can be drawn to the experiences with asbestos-related claims in the United States.[102]

Governments in leading industrialized countries are currently relying on existing regulatory frameworks for environmental, health and safety regulation to cover nanotechnology risks and generally suggesting that any risks posed by NMs can be addressed using existing frameworks, although proposing minor adjustments to specific regulations. This is in line with the European Commission studies on

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[98] See Directive 2004/35 on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage, [2004] OJ L143/56.

[99] See also Directive 2008/99/EC of 19 November 2008 on the Protection of the Environment through Criminal Law, [2008] OJ L328/28. Although the offences under this Directive could cover instances of environmental damage caused by the release of NMs into the environment, REACH does not appear in the Directive's Appendix. For comments on the EU environmental crime Directive see, e.g., R. Pereira, 'The Legal Basis for Harmonisation of Environmental Criminal Law in the EU: Past and Future Challenges', in: M. Andenas and C. Baasch Andersen (eds.), *Theory and Practice of Harmonisation* (Edward Elgar, 2011), 403; R. Pereira, 'Environmental Criminal Law in the First Pillar: A Positive Development for Environmental Protection in the European Union?', 16:10 *European Energy and Environmental Law Review* (2007), 254.

[100] A. Hannah and G. Hunt, 'Nanotechnology and Civil Liability', in: G. Hunt and M.D. Mehta (eds.), n. 44 above, 237.

[101] G. Hunt, 'The Global Ethics of Nanotechnology', in: G. Hunt and M.D. Mehta (eds.), n. 44 above, 183.

[102] Although asbestos fibres and engineered nanoparticles, such as carbon nanotubes, fullerenes and metallic nanoparticles, are in many ways different from each other, there are similarities that point to adopting a precautionary approach. See A. Hannah and G. Hunt, n. 100 above. Future research can help identify the differences and similarities between asbestos and engineered nanoparticles in terms of their health implications. There is already ongoing work to address this issue. See, for instance, the section on human health impacts in: C.L. Tran *et al.*, *An Outline Scoping Study to Determine whether High Aspect Ratio Nanoparticles (HARN) Should Raise the Same Concerns as do Asbestos Fibres* (13 August 2008), found at: <http://nanotech.law.asu.edu/Documents/2009/07/Michael%20Vincent%20IOM%20(2008),%20An%20outline%20scoping%20study_182_2184.pdf>. The total corporate liability costs for asbestos-related diseases in the US has been estimated at US$ 30 billion, far more than the product ever earned its manufacturers. See Dunphy, A. Griffiths and S Benn, *Organizational Change for Corporate Sustainability: A Guide for Leaders and Change Agents of the Future* (Routledge, 2007). Moreover, asbestos litigation in the US is the longest running mass tort litigation in history. Asbestos has not only injured hundreds of people, but also caused an increased burden on public health systems, loss of jobs and company bankruptcy. See A. Hannah and G. Hunt, n. 100 above.

nanotechnologies,[103] discussed above, which concluded that current legislation to a large extent covers risks related to NMs.

Although the 'status quo' option appears to be the option preferred by regulators and industry alike, other stakeholders, such as non-governmental organizations, argue that the failure to address the current loopholes in nanotechnology regulation goes against the precautionary principle, and potentially heightens the risks to the environment and human health posed by certain types of nanotechnologies.[104]

A 'GRANDFATHERING' SYSTEM: NEW REGULATIONS FOR NEW MARKET ENTRANTS ONLY

Instead of revamping the current system in its entirety, there is a middle ground option of introducing a system of 'grandfathering', in which existing firms can continue to operate under existing laws, while new legal provisions only apply to new market entrants. A key drawback of this approach is that it may encourage firms to take advantage of their 'grandfathered' status by increasing the production and use of NMs, which they can do at a lower cost than new entrants who are subject to more stringent legal standards. This approach could act as a disincentive for new firms wishing to engage in nanotechnology; thus reducing the number of nanomanufacturers and suppliers and, consequently, consumer choice.[105] Decision makers need to consider these challenges in collaboration with industry. This collaboration between governments and industry is needed to reassure the public that the technology and its products are safe. A 'grandfathering' system, which segregates new and existing market participants and favours one over the other, is less likely to lead to collaborative outcomes.

NANO-SPECIFIC AND PROCESS-BASED REGULATION

A key feature of a process-based regime is the belief that the process of nanotechnology itself is a potential hazard, which presents unique risks that must be regulated. The underlying assumption is that the risk lies in the technique of nanotechnology, not its specific applications. This contrasts with a product-based approach, which addresses questions of regulation on a product-by-product basis. Measures adopted under such a regulatory framework seek to regulate the different uses of nanotechnologies in a uniform manner. This approach has been adopted in the regulation of GMOs in a number of jurisdictions, including the EU.[106] However, application of a process-based approach to nanotechnologies is complicated by the fact that nanotechnologies have a wide remit of application and encompass various stages of technological development.

Process-based regulation can be applied horizontally across different industrial and

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[103] See, e.g., COM(2008) 366, n. 70 above.
[104] A. Huw Arnall, Future Technologies, Today's Choices*: Nanotechnology, Artificial Intelligence and Robotics* (Greenpeace Environmental Trust, July 2003), found at: <http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf>.
[105] See E. Stokes, n. 96 above.
[106] See, e.g., N. Guehlstorf and L.K. Hallstrom, 'The Role of Culture in Risk Regulation: A Comparative Case Study of Genetically Modified Corn in the United States of America and European Union', 8:4 *Environmental Science and Policy* (2005), 327.

commercial sectors as well as vertically to products at different stages of their life cycle. The benefits of this approach are the significant reduction in risks and improved regulatory clarity; it thus arguably provides the best application of the precautionary principle. However, this approach has high administrative and compliance costs due to the introduction of new rules and requirements at the very early stages of nanotechnology development.[107] Another major drawback relates to the fast pace of development for nanotechnologies. Combined with a lack of common nomenclature, this means that an overarching regime would require frequent revisions of the regulations to deal with applications not envisaged at the time of drafting.[108]

NANO-SPECIFC AND PRODUCT-BASED REGULATION

A key feature of a nano-specific, product-based approach is that it recognizes that risks posed by NMs can vary and that these risks need to be addressed on a case-by-case basis. In contrast to process-based regulations that treat nanotechnology as a single entity, a product-based or substance-based approach to regulation addresses risks posed by particular uses of NMs in specific products, in specific sectors, and/or at specific stages in their life cycle. In other words, this approach allows regulatory measures to be introduced on an incremental basis targeting certain risks (and firms) when necessary. Some authors have called this approach 'differentiated' to denote it may be realized through the adoption of new legislation and the introduction of policy to supplement existing legislative measures.[109]

Proponents of this approach have highlighted that this is particularly relevant in the harmonized areas of EU law, such as food or chemicals regulation, where it is possible to adopt nano- and product-specific legislation.[110] Options for nano-specific regulation include product licensing, labelling schemes and notification requirements. These are discussed in turn below.

Product licensing

Command and control regulation tends to specify the required or prohibited conduct, and includes prohibitions or limitations on discharge of certain pollutants or waste, mandating the adoption of certain technologies or the setting of specific standards.[111] Command-and-control regulatory measures that can be employed in the context of nanotechnologies include interventionist measures such as restricting the market entry of nanoproducts through product-specific licensing.

A licensing regime could prohibit the manufacture or supply of certain products containing NMs unless minimum quality or safety conditions are met and authorization has been obtained. However, high costs are associated with the requirement for firms to acquire a licence prior to market entry as well as subsequent monitoring and

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[107] See E. Stokes, n. 96 above.
[108] Ibid.
[109] Ibid.
[110] Ibid.
[111] E. Blanco and J. Razzaque, *Globalisation and Natural Resources Law* (Edward Elgar, 2011); R. Pereira, 'Environmental Regulation, Business Competitiveness and Corporate Responsibility', in: K. Makuch and R. Pereira (eds.), *Environmental and Energy Law* (Wiley-Blackwell, 2012), 61.

enforcement.[112] The high costs to industry to comply with licensing conditions could also prevent smaller start-up companies from using nanotechnologies, thus inhibiting the placing of NMs on the market. The benefit of such an interventionist product-specific regulation is that high costs could be justified by increased public confidence in the safety of high-risk products due to *ex ante* scrutiny.[113]

Regulatory market-based incentives

Other authors[114] have proposed less interventionist, market-based measures for regulating NMs that are more palatable to the regulated community and therefore would be more easily justified. Market-based legal instruments aim to establish a price for environmental goods that reflects the true costs of pollution and natural resources use, and include tradable permits, taxation schemes and labelling schemes.[115]

A labelling requirement for NMs would enable consumers to decide whether to purchase conventional products whose risks are better known, or products containing NMs. The legislation requires that certain nanoproducts are labelled with warnings or instructions for use. In this vein, some authors have suggested that all products containing NMs should be subject to mandatory labelling requirements.[116] Examples in regulation already exist. the EU Food Information to Consumers Regulation,[117] for example, was approved by the Commission in July 2011 and will come into force in December 2014. It requires labelling of ingredients in the form of nanomaterials (material plus word 'nano' in brackets), and similar reforms were introduced in the context of the EU Biocides Regulation, which concerns the placing on the market and the use of biocidal products for non-agricultural uses.[118]

Mandating public disclosure of the presence of NMs in products would be in the long term interests of the nanotechnology industry, as it could help build the necessary public trust that the biotechnology industry never established when GMOs became available on the market. Eco-labelling and the provision of environmental information has been positively correlated with product and process innovations; more so than the introduction of environmental management systems.[119] Some commentators[120] have highlighted that product labelling systems that address health and environmental concerns are becoming a more widespread phenomenon in consumer societies worldwide, They argue that if European product-labelling legislation is to harness the considerable potential of consumer markets to advance environmental

[112] See E. Stokes, n. 96 above.
[113] Ibid.
[114] See A.C. Lin, n. 87 above.
[115] Economists tend to take the view that environmental protection is generally better achieved through market-based mechanisms than through command and control regulation. See, e.g., R. Pereira, n. 111 above.
[116] See A.C. Lin, n. 87 above.
[117] Regulation 1169/2011 of 25 October 2011 on the Provision of Food Information to Consumers, [2011] OJ L304/18.
[118] Regulation 528/2012, n. 54 above.
[119] M. Wagner, 'Empirical Influence of Environmental Management on Innovation: Evidence from Europe', 66:2-3 *Ecological Economics* (2008), 392.
[120] See, e.g., Z. Makuch, 'TBT or not TBT, that is the Question: The International Trade Law Implications of European Community GM Traceability and Labelling Legislation', 13:8-9 *European Environmental Law Review* (2004), 225.

policy, then there needs to be a balance between international trade law and consumer opinion, which drove the traceability and labelling requirements in the EU.[121]

However, this approach also has some drawbacks. Labelling requirements impose financial and regulatory burdens in terms of administrative costs, although these costs are generally lower than the mandatory controls typical of command and control regulations.[122] Concerns have been raised regarding the effectiveness of labelling; warnings may not be noticeable and may convey little information.[123] Furthermore, the environmental impact of labelling often depends on the scope and type of environmental information provided to consumers, and whether this environmental information will influence consumer or supplier behaviour. Most eco-labelling schemes have also received considerable industry opposition as there are costs associated with national broad-based schemes.[124] Finally, potential conflicts with WTO law may emerge as the labelling scheme may be used as a protectionist measure.[125]

Notification and monitoring requirements

Notification requirements are a common feature in international environmental agreements. Under the 'no-harm rule', States have a general duty under customary international law to notify and consult with other affected States before the start of an activity with transboundary implications,[126] particularly when activities within one State's territory can cause environmental damage in another State or in areas beyond national jurisdiction.[127]

Within the confines of national law, a nano-specific notification scheme serves a similar function as labelling or information disclosure. Under a notification scheme, manufacturers or suppliers of NMs are required to submit information relating to their toxicity to a regulatory authority prior to manufacture or supply. Submission of data by manufacturers is a key element of REACH because it shifts the burden of proof regarding the safety of a substance from the regulator to the manufacturers, importers and producers. However, in light of the limitations of REACH in dealing with risks posed by NM, a nano-specific notification procedure would be more appropriate.[128] Notification requirements are also at the heart of EU GMO legislation.[129]

These 'notification of new substances' requirements are also present in other countries, such as Japan, although the classification in this country is made before the substance

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[121] Ibid.
[122] W.F. Pedersen, *Regulating Nanotechnology by Information Disclosure* (Environmental Law Institute, 2005), found at: <http://www.eli.org/pdf/research/nanotech/presentations/pedersen.pdf>.
[123] See A.C. Lin, n. 87 above.
[124] N. Gunningham, P. Grabosky and D. Sinclair, *Smart Regulation: Designing Environmental Policy* (Oxford University Press, 2004); H. Wright and R. Pereira, 'A Legal Framework for Clean Technology Transfer and Finance', in: K. Makuch and R. Pereira, n. 111 above, 75.
[125] See, e.g., WTO AB 16 May 2012, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, WT/DS381/AB/R.
[126] See, e.g., *Pulp Mills*, n. 11 above.
[127] The no harm-rule is elaborated, for instance, in the Rio Declaration, n. 9 above, Principle 2.
[128] See E. Stokes, n. 96 above.
[129] See Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms, [2001] OJ L106/1, Article 13.1; Annex II.

can be manufactured. Mandatory base data sets are required under both EU and Japanese law, leading to some kind of classification. The US TSCA, by contrast, does not require such a data set and does not lead to a classification. The TSCA requires the EPA to keep an inventory of all substances regulated under the Act and requires new substances to be notified to EPA before manufacture or importation. However, since the Act does not specify a base data set, it leaves EPA with the responsibility of demonstrating that a chemical may pose an unreasonable risk.[130] Australia, as mentioned above, has implemented guidance for the notification of NMs, making pre-market notification and submission of safety information for new NMs mandatory.

The advantage of a notification scheme is that it imposes lower financial and regulatory burdens on manufacturers, because much of the information sought is generated in the development of new products. However, a notification system is not effective without a standard system of nomenclature and measurement. Given the current diversity and complexity of NMs, current nomenclature may not be adequate to characterize them. Both accurate labelling and notification systems therefore rely on standardized, globalized nomenclature.

In addition, existing regulatory provisions regarding chemicals and materials have started to include NMs in their listings and requirements to provide monitoring and control before and after their introduction to the market. There is a strong case that products containing free NMs should be subject to a screening process, as well as post-market monitoring and reporting requirements. In the UK government response[131] to the Royal Commission on Environmental Pollution (RCEP) report,[132] the government agreed with the RCEP recommendations on environmental monitoring and the development of a simple checklist as part of an early warning system to facilitate better collaboration between industry, government and the scientific community. The details of the simple checklist should include information on manufacturers and importers, information on quantities produced and how they are used in wider industry.[133]

Regulatory agencies in a number of countries are considering such specific notification requirements. For example, the US EPA has since 2009 been evaluating specific notification and registration procedures for NMs, in particular carbon nanotubes.[134] A debate in the US Senate on the Safe Chemical Act that took place in 2010-2011 included a proposal for reform of the TSCA that would introduce relevant changes to this statute and could lead to an approach similar to the one used under REACH regarding monitoring and notification requirements (with the burden of proof shifting to the producer), yet the bill is still to be adopted[135] The proposals in the United States

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[130] In December 2006, Berkeley City Council became the first US city to introduce legislation specifically regulating NMs on the premise that firms or individuals have a 'right to know' the hazardous properties of NMs they buy or use. Under its regulations, all those handling manufactured NMs would have to produce a separate written disclosure of the current toxicology of materials (to the extent known), and specify how the facility will safely handle, monitor, contain, dispose, track inventory, prevent releases and mitigate such materials. See E. Stokes, n. 96 above.

[131] UK Government Response to The Royal Commission on Environmental Pollution (RCEP) Report on Novel Materials in the Environment: A Case of Nanotechnologies Cm 7620 (The Stationery Office, 2009), found at: <http://www.official-documents.gov.uk/document/cm76/7620/7620.pdf>.

[132] See RCEP, n. 8 above.

[133] See UK Government Response, n. 131 above.

[134] See generally <http://www.epa.gov/nanoscience/>.

[135] S. 847 (112th): Safe Chemicals Act of 2011.

for NM monitoring following their market release are very much in line with EU GMO legislation, which requires that Member States take measures to ensure traceability at all stages of the placing on the market of GMOs.[136]

CONCLUSIONS

To date, nanotechnology is not regulated as a sector *per se*, as it represents an emerging family of heterogeneous technologies enabling manipulation of matter at the atomic level. Nanotechnology offers many potential benefits to society in areas as wide-ranging as consumer products, health care, chemicals, cosmetics and waste treatment. Still, as is the case with many new technologies, we currently have only a limited understanding of the potential risks of NMs, and some studies suggest certain NMs may have negative impacts on human health and the environment in case of exposure or release into the environment. However, information on toxicological impacts is still limited. It is precisely on account of this limitation of knowledge that the application of the precautionary principle makes sense. Furthermore, if policy makers and stakeholders recognize the full benefits of the technology's potential, the development of a governance system for nanoscience and nanotechnologies that is both effective and proportional to potential risks is of utmost importance.

There is an increasing recognition that nano-regulation is needed. In the past few years, the debate has focused on the first attempts to introduce adjustments for NMs to existing regulations, particularly in the EU. The most relevant example of this action is the recast of the Cosmetic Regulation in the EU.[137]

The progress made towards regulation of NMs is varied: some authorities focus on amending existing instruments and adopting mandatory reporting schemes while others prefer the use of voluntary measures or a combination of both. Yet a cursory examination of existing regulations indicates that there are still significant regulatory gaps, and extensive amendments are required to address the risks posed by NMs. In response, regulatory agencies in the EU and a number of other countries are starting to apply or considering the introduction of nano-specific legislation, including legislation pertaining to notification, monitoring, labelling and licensing schemes. It is encouraging that, at present, European and national regulatory regimes are under review and could be subject to reforms.

Due to the transboundary nature of NMs, international efforts to develop harmonized tools through bodies such as the OECD and WTO are critical. Successful efforts in international cooperation have sought to promote high levels of protection whilst enabling science and industries to operate freely in a global economic space. Difficulties have arisen due to differences in regulatory frameworks regulatory cultures and societal perceptions of risk, which have contributed to the divergence of regulatory responses across different jurisdictions.

Therefore, the development of nanotechnology regulation should consider and

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[136] See, generally, M. Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar, 2008). EU legislation also requires that following the placing on the market of a GMO, as or in a product, the notifier shall ensure that monitoring and reporting are carried out in according to the conditions specified in the consent. See Directive 2001/18/EC, n. 129 above, Article 20.

[137] Regulation 1223/2009, n. 56 above.

identify technological risks whilst promoting international cooperation at the early stage of policy processes, and acknowledge the challenges in ascertaining adequate information both to allow evaluation of the safety of NM and the presence of products containing NM.

In sum, different jurisdictions take different approaches to regulation. However, many factors will influence the extent to which these differences in approach result in disparate regulatory actions. These factors include resources for implementation, interpretations by regulatory authorities, subsequent reforms and, perhaps most importantly, the extent to which regulators coordinate and share information at this critical juncture in the regulation of NMs.

Social, political and economic factors influence views on nanotechnology. There are proponents and opponents of nanotechnologies. Any regulatory approach needs to account for these opposing views. For now, we recommend that lawmakers, regulators and standard-setting bodies find the appropriate balance between soft and hard law standards, command and control regulations and market-based incentives. The resulting regulatory mix should at least include nano-specific standards (particularly notification and monitoring requirements).[138] Furthermore, we suggest that risk assessment, sound scientific approaches and application of the precautionary principle ought to provide the basis for the regulation of NMs.

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[138] This type of nano-specific legislation should include amendments to existing legislation, such as REACH in the EU.

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