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ARTICLE

Governance by Disclosure: Transnational Convergence in the Field of Nanotechnology†

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Abstract
'Nanotechnology', the manipulation of matter on an atomic and molecular scale, is projected to profoundly alter manufacturing systems globally. However, along with the promise that these new technologies hold, there are concerns about the possibility of unknown latent risks to human health or the environment. Under current scientific uncertainties, regulators explore new strategies for overseeing the development and safe use of nanotechnologies. Information disclosure plays a prominent role among these strategies. Thus far, however, the informational strategies actually employed by governments have focused on means by which to collect information from industry, and the types of information requested do not allow for an adequate health risk assessment. Moreover, little effort has been made to make the information collected publicly available. The article addresses the question of what information is disclosed (or not disclosed) and why, highlighting the socio-political context within which these decisions are made, and their democratic implications. It argues that the current 'light-touch' disclosure-based approach may lie in technical, evidence-based, 'risk' conception, which is common to both the United States and the European Union. It further argues for a more democratic 'governance-by-disclosure' approach, which allows society to prioritize risks that it is willing to take to enjoy the benefit of technological progress.

Keywords: Nanotechnology Regulation, Scientific Uncertainty, Risk Management Approach, Information Disclosure, Risk Conception, Technological Innovation

1. INTRODUCTION

'Nanotechnology' is an emerging field which attracts the interest of many because of its potential benefits and concerns regarding its potential environmental, health and

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safety impacts.[1] The latter concerns are often raised as a result of the ability of nanotechnology to modify the molecular aspect of nano-objects,[2] including their physical and chemical properties.[3] Nano-objects can be used alone, or with other materials to manufacture engineered nanomaterials. These characteristics give engineered nanomaterials novel electrical, catalytic, magnetic, mechanical, thermal or imaging properties that are useful for applications in the commercial, medical, military and environmental sectors.[4] Because of the same properties, each nano-object can elicit its own unique biological or ecological response.[5] Furthermore, these properties have the potential to elicit toxicity (or, if modified, reduced toxicity).

Early in their development, immediately after the first products containing engineered nanomaterials entered the market, pleas emerged for some control of the technologies and related products.[6] Today, with over 1,317 nano-enabled consumer products or product lines already in the market (including textiles, food packaging, cosmetics, luggage, children's toys, floor cleaners and wound dressings),[7] exposure to nano-objects has become a regulatory issue. As a result, regulators focus on defining the optimal regulatory or governance approach to oversee the development and safe use of nanotechnologies under conditions of scientific uncertainty.

For more than two decades, information disclosure mechanisms – such as product labelling and certification schemes, and emissions reporting – have been advocated by legal scholars as part of the new 'reflexive law' approach for controlling environmental

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1 The term 'nanotechnology' is difficult to define. Institutes around the world define 'nanotechnology' and other related terms such as 'nanomaterials', 'nano-objects' and 'nanostructures' in different ways. There are no binding definitions in the regulatory context. The various definitions for 'nanoscale' and 'nanomaterial' proposed so far have sought mainly to identify an inclusive size range of 1–100 nanometers that help to understand the terminology that uses the prefix 'nano'. The European Commission (EC) was the first to publish its recommended definition on nanomaterials for regulatory purposes in Oct. 2011: see EC Recommendation 2011/696/EU on the Definition of Nanomaterial [2011] OJ L 275/38.

2 This is a material with one, two or three external dimensions in the nanoscale: see ISO/TS 80004-1:2010, Nanotechnologies – Vocabulary – Part 1: Core Terms, available at: http://www.iso.org/iso/catalogue_detail.htm?csnumber=51240.

3 A. Dowling et al., *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (Royal Society & Royal Academy of Engineering (UK), 2004), available at: http://www.nanotec.org.uk/finalReport.htm.

4 US Environmental Protection Agency (EPA) Science Policy Council, *Nanotechnology White Paper*, EPA 100/B-07/001, Feb. 2007, available at: http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

5 A. Nel et al., 'Toxic Potential of Materials at the Nanolevel' (2006) 311(5761) *Science*, pp. 622–7, at 624.

6 C. Lucas, 'We Must Not Be Blinded by Science: Nanotechnology Will Revolutionise Our Lives – It Should Be Regulated', *The Guardian*, 12 June 2003, available at: http://www.guardian.co.uk/politics/2003/jun/12/nanotechnology.science; ETC Group, 'No Small Matter II: The Case for a Global Moratorium – Size Matters!' (2003) 7(7) *Occasional Paper Series*, available at: http://www.etcgroup.org/upload/publication/165/01/occ.paper_nanosafety.pdf; Dowling et al., n. 3 above; EPA Science Policy Council, n. 4 above.

7 Project on Emerging Nanotechnologies (PEN), 'A Nanotechnologies Consumers Products Inventory' (2011), available at: http://www.nanotechproject.org/inventories/consumer/analysis_draft.

risks in lieu of command-and-control or market-based regulatory approaches.[8] Whether information disclosure is required to encourage responsible behaviour by businesses, support regulatory decisions, or empower citizens and consumers, it is generally believed that the flow of information will improve environmental outcomes and enhance informed decision-making and democracy. However, more recently some have criticized information disclosure mechanisms as being ineffective.[9] These scholars focus mainly on the questions of how, by whom, and to whom disclosure is made, highlighting the competing normative rationales within which information disclosure is being embraced and institutionalized.

This article adds to the debate by focusing on the question of *what* information is disclosed (or not disclosed) and why, highlighting the social-political context within which these decisions are made. It shows that under the hegemonic evidence-based approach, current 'governance by disclosure' schemes are unlikely to be effective regardless of the goal they aim to achieve – whether normative ('right to know'), procedural ('informed decision') or substantive ('environmental improvement').[10] None of these presents a viable framework for governance of emerging technologies.

It is argued that justifying disclosure regulation based solely on scientific evidence of risk, rather than considering other societal aspects of nanotechnological development, assumes a private right to innovate that limits the power of governments and citizens to oversee innovation. Governments wishing to prevent potential negative consequences of this type of technology enter into a vicious circle of scientific data collection to lift the veil of uncertainty. However, as this article shows, information-gathering initiatives have not achieved their objectives to date. Even systematic mandatory programmes have limited ability to collect the whole range of risk data that is necessary for quantitative risk assessments. Any attempt to effectively oversee the development of nanotechnologies using an evidence-based approach is unlikely to succeed, because of the major scientific uncertainties in this field. An approach going beyond evidence alone is all the more necessary when the importance of the societal dimensions of impact is taken into account.

This article begins by echoing the demand for more disclosure in the field of nanotechnology. It then analyzes governments' rationalities (the rhetoric) for justifying specific

[8] See, e.g., D.W. Case, 'Corporate Environmental Reporting as Informational Regulation: A Law and Economics Perspective' (2005) 76 *Universtiy of Colorado Law Review*, pp. 379–442; D.C. Esty, 'Environmental Protection in the Information Age' (2004) 79 *New York University Law Review*, pp. 115–211; E.W. Orts, 'Reflexive Environmental Law' (1995) 89 *Northwestern University Law Review*, pp. 1227–340; C.R. Sunstein, 'Informing America: Risk, Disclosure, and the First Amendment' (1992) 20 *Florida State University Law Review*, pp. 653–77; I. Rosenthal et al., 'Regulation of Existing Chemicals under TSCA: Information Disclosure as the Route to Reducing Risk and Increasing Available Data' (1992) 1(2) *Quality Assurance*, pp. 89–97; R.B. Stewart, 'A New Generation of Environmental Regulation?' (2001) 29 *Capital University Law Review*, pp. 21–182; M. Graham, 'Information as Risk Regulation: Lessons from Experience' (2001), available at: http://www.transparencypolicy.net/assets/information.

[9] See, e.g., A. Gupta, 'Transparency in Global Environmental Governance: A Coming of Age?' (2010) 10(3) *Global Environmental Politics*, pp. 1–9.

[10] For an elaboration on this 'governance by disclosure' typology, see A. Gupta, 'Transparency to What End? Governing by Disclosure through the Biosafety Clearing House' (2010) 28(1) *Environment and Planning C: Government & Policy*, pp. 128–44, at 131.

modes of regulation based on their risk conception in this field. The article further analyzes the regulatory mechanisms that governments adopt to foster their rationalities and the implications of these rationalities on governance by disclosure (the practice). Finally, it discusses the democratic implications of the current 'governance by disclosure' approach, pointing to its limited functionality under conditions of scientific uncertainty. The article concludes by suggesting a more democratic conceptualization of 'governance by disclosure'.

2. THE DEMAND FOR GOVERNANCE BY DISCLOSURE IN THE FIELD OF NANOTECHNOLOGY

Information disclosure has been advocated as a regulatory approach for nanotechnology, based on the reasoning that 'in the immediate future, the greatest need for "regulation" is to increase the accumulation and dissemination of knowledge about the current state of nanotechnology research, development and applications, and about the risk and benefits of specific products and processes'.[11]

At the 5th International NanoRegulation Conference held in Switzerland in 2009, participants discussed the crucial need for nano-information and nano-communication along the value chain. They recommended a 'Nano-Information Pyramid' to provide user-specific data within the value chain.[12] This pyramid contains four levels (see Figure 1):

- at the bottom, regulators collect safety data from industry to generate a database for registration and further regulation;
- on the second level, producers provide processors and recyclers with user-specific information on nano-specific properties of the substances, as well as recommendations for their safe use and handling;
- on the third level, industry provides retailers, consumers and recyclers with user-specific information on the properties of the materials and product (including its benefits, risks and recommendations concerning waste treatment), and it addresses questions from users; and
- at the top, product labelling is applied to indicate, in a concentrated manner, certain quality features or environmental, health and safety properties of a product containing engineered nanomaterials. Such product labelling may also certify the safe production of a product, indicating responsible risk management behind the product.[13]

This approach received extensive stakeholder support in Europe. The results of a public online consultation held by the European Commission (EC) on its *Strategic*

11 G.E. Marchant, D.J. Sylvester & K.W. Abbott, 'Risk Management Principles for Nanotechnology' (2008) 2(1) *NanoEthics*, pp. 43–60, at 53.

12 S. Knébel & C. Meili, '"No Data, No Market?" Challenges to Nano-Information and Nano-Communication along the Value Chain', Conference Report, Rapperswil (Switzerland), 25–26 Nov. 2009, at pp. 3–5, available at: http://www.innovationsgesellschaft.ch/media/archive2/publikationen/NanoRegulation_5_Report_2009.pdf.

13 Ibid.

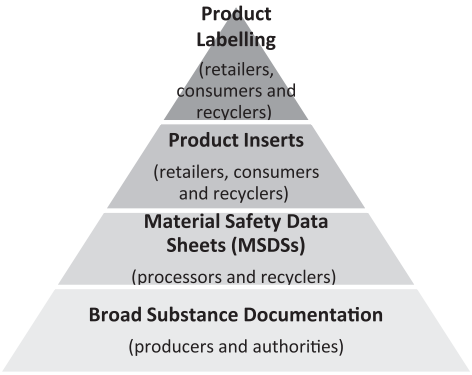

Figure 1: Nano-information pyramid

Nanotechnology Action Plan 2010–2015, show that Europeans want active communication and dissemination of information. Europeans further support the establishment of an inventory of types and uses of nanomaterials, including safety aspects, as well as the requirement for adequate information on consumer products (for example, claims verification and labelling of the nano-content of consumer products).[14] Furthermore, most consumer organizations and environmental non-governmental organizations (NGOs) worldwide are forcefully demanding more transparency about products containing nanomaterials.[15]

Despite calls for urgent action, the response by regulatory bodies has been insignificant. An online review I conducted of worldwide nano-specific regulatory initiatives, released between the years 2004 and 2012, identified 105 government agency initiatives (see Figure 2).[16] Of those, nine adopted disclosure and labelling mechanisms (equivalent

14 G. Kirmizidis, 'Report on the European Commission's Public Online Consultation: Towards a Strategic Nanotechnology Action Plan', 2010, at pp. 16–7, available at: http://ec.europa.eu/research/consultations/snap/report_en.pdf.

15 See, e.g., US Environmental Working Group, 'EWG Comments to FDA on Nano-Scale Ingredients in Cosmetics', Oct. 2006, available at: http://www.ewg.org/node/21738; US Consumers Unions, 'Re: Food and Drug Administration-Regulated Products Containing Nanotechnology Materials', Docket No. 2006N-0107, 6 Oct. 2006, available at: http://www.consumersunion.org/pub/core_product_safety/004667.html (urging the US Food and Drug Administration (FDA) to require warning labels on products which cannot be substantiated for safety). Still, some NGOs show concerns regarding governance by disclosure in this field: see, e.g., M. Singer, 'Safety Fear Over $150 Face Cream Ingredient', *The Sydney Morning Herald*, 6 Sept. 2010, available at: http://www.smh.com.au/national/safety-fear-over-150-face-cream-ingredient-20100905-14w4h.html (citing Friends of the Earth Australia which was concerned that labelling was being used in place of a comprehensive assessment approach).

16 The database is based on an analysis of documents and electronic material available in English on publicly accessible websites conducted during the period Oct. 2009 to Dec. 2012. Data was collected mainly from Europe, the US, Canada and Australia, and only sporadically from Asian countries. It was verified using information reported in official OECD reports (available at: http://www.oecd.org/env/ehs/nanosafety), External Liaison Report to ISO/TC 229 'Nanotechnologies' (on file with author), and other independent reviews such as ObservatoryNANO (available at: http://www.observatorynano.eu/project/catalogue/5). The first public regulatory initiative was introduced in 2004. All data, together with comprehensive analysis and review results, is on file with author and will be published in the future.

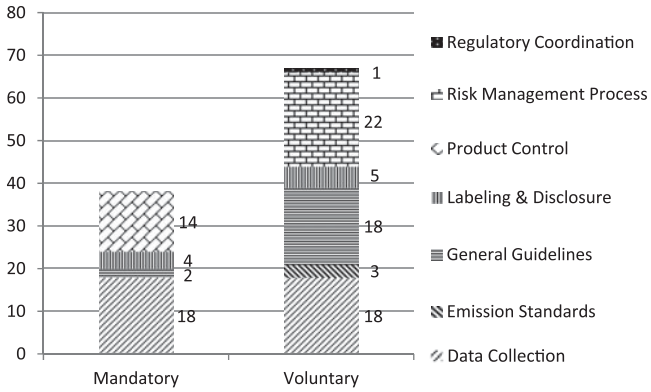

Figure 2: Worldwide government nano-specific regulatory initiatives 2004–2012

to pyramid levels 2, 3 and 4),[17] and five of those were based on voluntary compliance. By comparison, 51 initiatives (~48%) were data collection related, with 36 initiatives collecting data for regulatory purposes (level 1 of the pyramid);[18] six initiatives were classified as product control,[19] focusing mainly on additional testing requirements as a pre-condition for manufacturing and importing permits, and nine classified as general guidelines[20] to provide companies with guidance on how to develop the necessary data. The question is, therefore, why governments focus their efforts on data collection, and are reluctant to require information disclosure along the value chain.

To understand 'modes' of governments, Rose and Miller suggest analyzing governments' political rationalities, and governmental technologies which deploy their rationalities.[21] Following this method of analysis, the following sections discuss government rationalities (based on their risk conception) to justify regulation of nanotechnologies, and the regulatory mechanisms they deploy to foster these rationalities. In this analysis, the article explains how governments approach regulation by disclosure in the field of nanotechnology and how they implement disclosure mechanisms.

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17 This includes requirements or recommendations for third party information disclosure regarding nanomaterials such as preparation of Material Safety Data Sheets (MSDSs), as well as requirements, recommendations or certification systems for labelling products containing ingredients obtained through nanotechnology. It does not include initiatives to collect data for regulatory purposes.

18 This includes requirements (obligatory) or requests (voluntary) by government authorities for information on production, handling, use, risk assessment, control measure methods and surveillance practices regarding nanomaterials. Initiatives can collect either data already existing by the information provider, or require/request the development of new data.

19 This includes requirements or recommendations to restrict, condition or ban the distribution and use of nano-enabled product or substances in the markets. This includes conditional registration, quantity limitations of production and selling, product bans, etc.

20 This includes documents providing general policy principles for risk assessment, risk management and risk communication of nanomaterials, or for health surveillance. Such documents may include corporate codes of conduct, regulatory advices, best practices, etc.

21 N. Rose & P. Miller, 'Political Power Beyond the State: Problematics of Government' (1992) 43(2) *British Journal of Sociology*, pp. 173–205. According to Rose & Miller, the concept of 'political rationalities' refers to the morals, epistemology and language which support the rationalities (at pp. 178–9). By 'governmental technologies', they refer to the strategies, techniques and procedures which deploy government rationalities and programmes (at p. 183).

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3. GOVERNMENT RATIONALITIES FOR NANOTECHNOLOGY REGULATION

The rhetoric used by most governments to describe their vision of nanotechnology governance reflects mainly two risk management approaches: the risk-based approach, which is commonly supported by the United States (US) federal government, and the precautionary approach, which is commonly advocated by the European Union (EU). Literature on risk management approaches tends to describe these two approaches as rivals, leading scholars to argue for transnational divergence in risk management policies.[22] This article questions this premise by arguing that these two approaches only appear contradictory in theory, while having practical similarities. Both approaches are evidence-based and define the regulatory risk object of nanotechnology in the same way, which in turn implies similar risk governance. The result is an overall transnational policy convergence in the field of nanotechnology.[23]

A preliminary step towards the adoption of any regulatory programme is the justification for government intervention in the market. The rationalities for intervention may vary between fields, countries and individuals, depending on the conceptual risk that constructs the 'risk object'[24] that requires control. Renn identifies several approaches to the conception and assessment of risk, which vary in their conceptualization of uncertainty, the scope of negative effects, and the degree to which human knowledge reflects reality. The various conceptions can be divided into four groups – technical, economic, psychological, and social-cultural.[25] Each conception elicits different risk objects which require different risk analysis approaches.[26]

The international debate over the regulation of genetically modified organism (GMO)-based agro-food products can illustrate how competing risk conceptions eventually define different risk objects and thus different risk analysis approaches. The literature on GMOs illustrates that the objections to biotechnology are based not only on the health risks

[22] See, e.g., R. Falkner & N. Jaspers, 'Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap' (2012) 12(1) *Global Environmental Politics*, pp. 30–55 (arguing that recent EU nanotechnology-specific legislation on notification and labelling of cosmetics and novel foods set it on a path that may end up diverging from US regulatory practice); see also D. Vogel, *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* (Princeton University Press, 2012) (arguing that European policy-makers are more willing to regulate risks on precautionary grounds, whereas American policy-makers call for higher levels of scientific certainty before imposing additional regulatory controls on business).

[23] Studying the regulation regimes for food and for pharmaceuticals, Demortain concludes that they share a similar outcome in the emergence of the logic of risk evaluation. The regulatory 'scientization' and 'rationalization' which demands scientific justification for the benefits or risks of a product creates, in fact, a convergence between domains and markets: D. Demortain, *Scientists and the Regulation of Risk: Standardising Control* (Edward Elgar, 2011), at p. 212.

[24] A 'risk object' is a socially constructed definition that frames the 'scope of what constitutes a risk for regulatory purposes. The existence of a risk object justifies regulatory intervention to control its impact on society, and the way it was defined determines how it should be managed: S. Hilgartner, 'The Social Construction of Risk Objects: Or, How to Pry Open Networks of Risk', in F.J. Short & C. Lee (eds), *Organizations, Uncertainties, and Risk* (Westview Press 1992), pp. 39–53.

[25] O. Renn, 'Concepts of Risk: A Classification', in S. Krimsky & D. Golding (eds.), *Social Theories of Risk* (Praeger, 1992), pp. 53–79, at 59.

[26] A. Klinke & O. Renn, 'A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies' (2002) 22(6) *Risk Analysis*, pp. 1071–94.

(physical harm) that this technology might cause, but also on cultural, ethical, religious, ideological, or competitive grounds.[27] In the absence of sufficient scientific indications of a *realistic and serious risk* posed by these products to human health or the environment (an *a priori* requirement to invoke the precautionary principle), other grounds eventually led the EU legislators to impose a de facto moratorium on GMO food. It was not a precautionary principle decision *per se,* rather a multi-faceted decision not to support the development of such technology. Similarly, nanotechnology-enabled applications also raise societal, legal and ethical concerns, including issues of privacy, human enhancement, intellectual property and international power relationships.[28] Yet, as demonstrated in this article, so far none of these concerns have influenced the current hegemonic risk conception, which focuses solely on the physical harm of nanotechnologies.

3.1. *The Risk-Based Approach*

The risk-based approach is traditionally associated with the US. Indeed, the Policy Principles for the US Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials state that 'regulation should be based on risk, not merely hazard, and in all cases the identification of hazard, risk or harm must be evidence-based'.[29] It further states that the regulatory approach should be *flexible, adaptive,* and *science-based.*[30]

This regulatory approach relies on the liberal rationale of freedom of innovation. It places innovation beyond political control (subject to some boundary conditions for the use of new technology) based on the assumption that society is better off dealing with the consequences than suppressing innovation in the first place.[31] It further

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27 See further, B. Wynne, 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10(4) *Science as Culture*, pp. 445–81; A. Gupta, 'When Global is Local: Negotiating Safe Use of Biotechnology', in S.S. Jasanoff & M.L. Martello (eds.), *Earthly Politics: Local and Global in Environmental Governance* (MIT Press, 2004), pp. 127–48; S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2007); Y. Devos et al., 'Ethics in the Societal Debate on Genetically Modified Organisms: A (Re)quest for Sense and Sensibility' (2008) 21(1) *Journal of Agricultural and Environmental Ethics*, at pp. 29–61; C. Heller, 'From Scientific Risk to Paysan Savoir-Faire: Peasant Expertise in the French and Global Debate over GM Crops' (2002) 11(1) *Science in Culture*, pp. 5–37.

28 For a further discussion about the societal and ethical implications of nanotechnology, see K.H. David & P.B. Thompson, *What Can Nanotechnology Learn from Biotechnology? Social and Ethical Lessons for Nanoscience from the Debate over Agrifood Biotechnology and GMOs* (Academic Press, 2008); B.V. Lewenstein, 'What Counts as a "Social and Ethical Issue" in Nanotechnology', in D. Baird (ed.), *Nanotechnology Challenges: Implications for Philosophy, Ethics and Society* (World Scientific Publishing, 2006), pp. 201–16.

29 J.P. Holdren et al., 'Memorandum for the Heads of Executive Departments and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials', 9 June 2011, available at: http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

30 Ibid.

31 W. van den Daele, 'Access to New Technology: In Defense of the Liberal Regime of Innovation', in M.E.A. Goodwin, E.J. Koops & R.E. Leenes (eds.), *Dimensions of Technology Regulation* (Wolf Legal Publishers, 2010), pp. 85–105, at 87.

assumes that regulation, which does not determine and justify its objectives scientifically, may hold back technological innovation and economic growth.[32] This concern is based on two separate conceptions: the first is that regulatory authorities run inefficiently and ineffectively with no consideration of regulatory costs, and therefore burden industry. Thus, deregulation and the adoption of private sector management styles are required.[33] The second conception, which is common to all science-based governance approaches (including the precautionary approach), is that the scientific process and scientific knowledge – free from political interests and religious prejudice – provide a rational, objective and universal answer to the problem, and therefore justify regulation and enhance trust in authorities.[34] One consequence of such a regulatory approach is that the burden of proof, and therefore the responsibility to assess the potential risks, falls on the opponents of the technology. Another important consequence is that other social values – such as ethics, religion or culture concerning the development of the technology – cannot justify regulatory action by themselves.

The risk-based approach to regulation adopts a technical conception of risk, which focuses on identifying potential physical harm to human beings or ecosystems, and on analyzing their probabilities of occurring over space and time.[35] Typically, once such risks are found to be severe enough to justify government intervention, standards to minimize the risks are established. However, under conditions of scientific uncertainty, the establishment of quantitative safety goals become challenging. This difficulty supports the development of a flexible and adaptive strategy to risk control that takes account of experience. Because these mechanisms can modify their behaviour in response to new information, they are better suited to conditions of uncertainty than command-and-control or market-based mechanisms that are established to achieve strict goals.[36]

The effectiveness of this approach relies on its ability to acquire the necessary data from experiment and experience monitoring. If it is impossible to monitor data through

[32] See, e.g., the statement of Steve Froggett (Scientific Advisor to the US Department of Agriculture) that 'regulation that is not grounded in sound science could have harmful economic impacts without promoting health or safety': S. Froggett, 'Nanotechnology and Agricultural Trade', OECD Conference on the Potential Environmental Benefits of Nanotechnology: Fostering Safe Innovation-Led Growth, Paris (France), 15–17 Jul. 2009, available at: http://www.oecd.org/science/nanosafety/44029039.pdf.

[33] B.M. Hutter, 'The Attractions of Risk-Based Regulation: Accounting for the Emergence of Risk Ideas in Regulation' *Centre for Analysis of Risk and Regulation (CARR)*, *Discussion Paper DP 33* (2005), available at: http://webfirstlive.lse.ac.uk/researchAndExpertise/units/CARR/pdf/DPs/Disspaper33.pdf.

[34] S. Jasanoff, 'Contested Boundaries in Policy-Relevant Science' (1987) 17(2) *Social Studies of Science*, pp. 195–230; R.K. Merton, 'The Normative Structure of Science (1942)', rpt. in R.K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, 1979), pp. 267–78; T.M. Porter, *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton University Press, 1996). This rationale is embedded so strongly in the hegemonic environmental risk governance paradigm that it is often denied. For example, Ayal, Hareuveny & Perez criticized the Intergovernmental Panel on Climate Change (IPCC) leaders who tend to describe their job as providing policy relevant but not policy prescriptive data: A. Ayal, R. Hareuveny & O. Perez, 'Science, Politics and Transnational Regulation: Regulatory Scientific Institutions and the Dilemmas of Hybrid Authority' (2013) 2(1) *Transnational Environmental Law*, pp. 45–68, at 59–60.

[35] Renn, n. 25 above.

[36] R.J. McLain & R.G. Lee, 'Adaptive Management: Promises and Pitfalls' (1996) 20(4) *Environmental Management*, pp. 437–48, at 438.

experiment, or if the data collected is insufficient for a quantitative risk assessment, the learning process is stuck and the potential risk will be left with a minimum of control, or even completely unregulated.[37] Therefore, some scholars argue that in practice this approach enables agencies to adopt implementation measures and practices that delay compliance or avoid a fully rigorous application of a statutory provision.[38] Stewart, for example, refers to adaptive management as 'a polite term for muddling through'.[39] He further argues that this approach is incompatible with democratic values of transparency, as it is often carried out in a low visibility fashion, and is largely immune, both practically and legally, to judicial review.[40]

3.2. *The Precautionary Approach*

The precautionary approach is commonly applied by the EU. According to the EC's Strategy for Nanotechnology:

> Successful exploitation of nanotechnologies needs a sound scientific basis for both consumer and commercial confidence ... A proactive approach should be taken ... Ethical principles must be respected and, where appropriate, enforced through regulation ... The Precautionary Principle, *as used up to now*, could be applied in the event that *realistic and serious risks* are identified.[41]

In theory, this regulatory approach relies on the perspective that technological innovation is a 'social concession' rather than a private right, and therefore demands sustainability and social responsibility of innovation.[42] This perspective is based on three pillars. Firstly, public views, ethics, and other societal dimensions should be integrated into decisions concerning research and development policy.[43] Secondly, the burden of proof and the responsibility for producing scientific evidence is on the producer, manufacturer

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37 H. Doremus, 'Adaptive Management as an Information Problem' (2011) 89 *North Carolina Law Review*, pp. 1455–98.

38 See, e.g., the US legal debate over the decision of the EPA decision to grant HeiQ Materials conditional registration for its AGS-20 product (nanosilver powder) under s. 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 7 U.S.C. §136a(c)(7)(C) (2012): P. Ambrosio, 'EPA Announces Conditional Registration for Antimicrobial Containing Nanosilver', *Bloomberg BNA*, 5 Dec. 2011; S. Struglinski, 'Lawsuit Seeks to Block EPA's "Free Pass" on Nanosilver', *NRDC Media Center*, 26 Jan. 2012. The EPA issued conditional registration although the company could not show that the product 'will not cause unreasonable adverse effects to the environment', as required by the law. It justified its decision to avoid a competitive disadvantage for HeiQ because other companies already had products containing nanoscale silver on the market without the EPA's knowledge. In response, the Natural Resources Defense Council filed a lawsuit to block the EPA from allowing nanosilver on the market without the legally required data.

39 R.B. Stewart, 'A New Generation of Environmental Regulation?' (2001) 29 *Capital University Law Review*, pp. 21–182, at 54.

40 Ibid., at p. 57.

41 EC, Communication from the Commission: Towards a European Strategy for Nanotechnology, COM(2004)338 final, 12 May 2004 (EC European Strategy for Nanotechnology), available at: http://ec.europa.eu/nanotechnology/pdf/nano_com_en.pdf (emphasis added).

42 Van den Daele, n. 31 above, at p. 88.

43 EC, Commission Working Document: Science, Society and the Citizen in Europe, SEC(2000) 1973, 14 Nov. 2000, available at: ftp://ftp.cordis.europa.eu/pub/rtd2002/docs/ss_en.pdf.

or importer of the potentially risky product.[44] Thirdly, when faced with an unacceptable risk (i.e., a realistic and serious risk), scientific uncertainty and public concerns, governments are obliged to respond in accordance with the precautionary principle.[45]

In practice, however, the precautionary approach still relies on a 'sound science' perspective on risk (i.e., technical risk conception) for its knowledge base. Public concerns based on cultural, religious or ideology preferences are not (implicitly) acknowledged under this approach.[46] According to the EC Communication on the precautionary principle, recourse to the precautionary principle as a risk management tool requires that a scientific evaluation, based on all available data, show a potential unacceptable risk to society.[47] This means that sufficient scientific data should be available to indicate 'realistic and serious risk' before any regulatory action is taken. The precautionary principle, as a legal standard, lowers the burden of proof of adverse effects, but it cannot be used to overturn the sequence of risk analysis altogether.[48]

Importantly, the question of what constitutes *sufficient* scientific data is left open. Because the notions of probability and seriousness of risk under the precautionary principle are too vague to serve as a prescriptive principle for decision-making, some scholars call for a political interpretation of the principle.[49] Under such interpretation, issues such as the benchmark to invoke the precautionary principle should be decided through public deliberation, assuming that the contributions of public participants will be informed and reasoned.[50] Some scholars, however, warn that polarization of the

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44 Unless the industry can prove that the technology and its enabled products are safe, they will not enter the market. See, e.g., the Austrian Nanotechnology Action Plan which states that '[i]n all proceedings that deal specifically with nanomaterials and nanotechnologies, it is important to insist on compliance with the precautionary or polluter-pays-principle. Solid documentation of the inherent properties as well as the risks resulting from the application should be a prerequisite for entering and remaining on the market': Austrian Government, *Austrian Nanotechnology Action Plan* (Vienna (Austria), Dec. 2009), p. 14, available at: http://www.lebensministerium.at/dms/lmat/umwelt/chemie_pestizide_gentechnik/nanotechnologie/Nano-Aktionsplan/Austrian_Nanotechnology_Action-Plan.pdf.

45 The absence of quantifiable scientific proof of risk does not preclude the possibility for real risk, and therefore cannot not be used to justify regulatory inaction under the general duty to refrain from actions that would cause harm to others. See, generally, C. Raffensperger & J.A. Tickner, *Protecting Public Health & the Environment: Implementing the Precautionary Principle* (Island Press, 1999); EC, Communication from the Commission on the Precautionary Principle, COM(2000) 1, 2 Feb. 2000 (EC Precautionary Principle), available at: http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf.

46 See, e.g., A. Gupta, 'Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms' (2001) 9 *Indiana Journal of Global Legal Studies*, pp. 265–81 (interpreting the implementation of the precautionary principle in the Cartagena Protocol, the author argued that the governance architecture of the Protocol does not allow for 'socially precautionary'). See also W. van den Daele, 'Legal Framework and Political Strategy in Dealing with the Risks of New Technology: The Two Faces of the Precautionary Principle', in H. Somsen (ed.), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar, 2007) pp. 118–38, at 124 (arguing that the precautionary principle 'does not provide a carte blanche to reject a technology that gives rise to unsubstantiated fears, or because it is undesirable for other reasons').

47 EC Precautionary Principle, n. 45 above.

48 Van den Daele, n. 46, at p. 122. See also E. Fisher, 'Precaution, Precaution Everywhere: Developing a Common Understanding of the Precautionary Principle in the European Community' (2002) 9 *Maastricht Journal of European & Comparative Law*, pp. 7–28, at 11–12.

49 O. Perez, 'Precautionary Governance and the Limits of Scientific Knowledge: A Democratic Framework for Regulating Nanotechnology' (2010) 28 *UCLA Journal of Environmental Law & Policy*, pp. 29–76.

50 Ibid.

precautionary principle will shift the focus from risk prevention to control of innovation, resulting in arbitrary and inconsistent regulation of new technologies.[51]

Once the precautionary principle is invoked, regulatory action should be taken in response to the projected risk. Yet this does not necessarily mean that legally binding measures must always be adopted. For example, a decision to fund a research programme or to inform the public about the possible adverse effects of a product may also be appropriate under the precautionary principle.[52] The EC's Strategy explicitly rejects the calls for a moratorium on nano-enabled products, alleging that it would not be proportionate given the social benefits expected from nanotechnology.[53]

4. REGULATORY MECHANISMS TO FOSTER GOVERNMENT RATIONALITIES

From the above analysis, it is clear that prior to any risk regulation a 'risk object' linked to a physical harm needs to be defined, based on conventional risk assessment methods. This has special significance in areas of scientific uncertainty regarding potential harms. To define nanomaterials as a 'risk object' under the technical, evidence-based, conception of risk, there is a need to establish first that a hazard exists by identifying an affected organism and the nature of the damage. Secondly, there is a need to estimate the potential exposure from emissions inventories and life-cycle emissions scenarios of the particles.

According to Wiesner et al., currently the nature of the hazard is one of the prominent unknowns for engineered nanomaterials. Further, given the current lack of measurement and nano-specific metrology, emissions scenarios of nanomaterials are bound to have some degree of uncertainty.[54] This conclusion is supported by Grieger et al., who screened 31 publications by leading scientists and authorities on the potential risks of engineered nanomaterials. They concluded, in 2009, that knowledge gaps pervade nearly all aspects of basic environmental, health and safety knowledge.[55] Since 2009, more research has been conducted to identify hazards; however, it is still insufficient for regulatory agencies to initiate evidence-based regulations.[56] Therefore, from a technical, evidence-based conception of risk, the current state of knowledge raises the question of what risk (if any) should be governed in the field of nanotechnologies and, in turn, what information related to it needs to be disseminated and disclosed.

This means that for governments following such risk conception, at the current state of knowledge, regulatory mechanisms should focus on closing knowledge gaps

51 Van den Daele, n. 46 above, at p. 124.

52 EC Precautionary Principle, n. 45 above, at pp. 16–17.

53 EC European Strategy for Nanotechnology, n. 41 above, at p. 19.

54 M.R. Wiesner et al., 'Decreasing Uncertainties in Assessing Environmental Exposure, Risk, and Ecological Implications of Nanomaterials' (2009) 43(17) *Environmental Science & Technology*, pp. 6458–62, at 6461.

55 K.D. Grieger, S.F. Hansen & A. Baun, 'The Known Unknowns of Nanomaterials: Describing and Characterizing Uncertainty within Environmental, Health and Safety Risks' (2009) 3(3) *Nanotoxicology*, pp. 222–33, at 231.

56 R.C. Pleus, 'The State of the Science: Human Health, Toxicology, and Nanotechnology Risks', in J.A. Shatkin (ed.), *Nanotechnology: Health and Environmental Risks* (2nd ed., CRC Press, 2013), pp. 79–116, at 110–11.

until there is sufficient knowledge to justify additional regulatory measures. Such regulatory mechanisms either establish research programmes to directly generate necessary environmental, health and safety data, or request other organizations to generate and submit such data to the agencies. Regulators can collect data from industry through various mechanisms that include voluntary or mandatory reporting programmes, manufacturing notifications, test requirements and hazardous substance reporting. Some already exist in current chemicals regulations, which theoretically apply to nanomaterials. Yet reviews of these programmes have identified many loopholes, allowing nano-objects by themselves or embedded in materials (composites, for example) to avoid regulation and information dissemination.[57]

In response, governments have adopted information-gathering initiatives to address nanomaterials specifically.[58] Still, to date, even the most comprehensive mandatory reporting system under the EU chemical and labelling regulations[59] has yielded very little

[57] J.C. Davies, 'EPA and Nanotechnology: Oversight for the 21st Century', *Project on Emerging Nanotechnologies*, May 2007, available at: http://eprints.internano.org/65/1/EPA_Nano_Oversight.pdf; K. Ludlow, D. Bowman & G. Hodge, 'A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework', *Monash Centre for Regulatory Studies*, Sept. 2007, available at: http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Documents/MonashReport2007.pdf; EC, Nanomaterials in REACH, CA/59/2008 rev. 1, 16 Dec. 2008, available at http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf; The Expert Panel on Nanotechnology, *Small is Different: A Science Perspective on the Regulatory Challenges of the Nanoscale* (Council of Canadian Academies, 2008); S.F. Hansen & A. Baun, 'European Regulation Affecting Nanomaterials – Review of Limitations and Future Recommendations' (2012) 10(3) *Dose-Response*, pp. 364–83.

[58] See, e.g., United Kingdom (UK) Department for Environment, Food and Rural Affairs (Defra), 'UK Voluntary Reporting Scheme for Engineered Nanoscale Materials', 2008 (Defra VRS), available at: http://www.defra.gov.uk/environment/quality/nanotech/policy.htm; US EPA, 'Nanoscale Materials Stewardship Program', 2011 (US EPA MNSP), available at: http://www.epa.gov/oppt/nano/stewardship.htm; J. DiLoreto, 'European Commission Calls for Data on Nanoparticles in Cosmetics', *NanoRegNews*, 19 Sept. 2008; Australian Government. 'Nanomaterials – Call for Information', *Chemical Gazette*, No. C.021, 7 Feb. 2006; Australian Government, 'Industrial Nanomaterials – Voluntary Call for Information' *Chemical Gazette*, No. C 10, 7 Oct. 2008, at p. 8; US EPA, 'Toxic Substances Control Act Inventory Status of Carbon Nanotubes' (2008) 73(212) *Federal Register* 64946; Regulation (EC) No. 987/2008 amending Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V [2008] OJ L 268/163; US EPA, 'Request for Information on Carbon Nanotubes (CNTs) Including Single-Walled Carbon Nanotubes (SWCNTs) and Multi-Walled Carbon Nanotubes (MWCNTs)' (2009) 74(66) *Federal Register* 56880; California Department of Toxic Substances Control (DTSC), 'Carbon Nanotube Information Call-In', 2009 (California DTSC Call-In programme 2009), available at: http://www.dtsc.ca.gov/TechnologyDevelopment/Nanotechnology/CNTcallin.cfm; California DTSC, 'Chemical Information Call-In: Nano Metals, Nano Metal Oxides, and Quantum Dots', 2010 (California DTSC Call-In programme 2010), available at: http://www.dtsc.ca.gov/PollutionPrevention/Round_Two.cfm; Australian Government, 'Adjustment to NICNAS New Chemicals Processes for Industrial Nanomaterials', *Chemical Gazette*, No. C 105, 5 Oct. 2010; US EPA, 'Multi-Walled Carbon Nanotubes; Significant New Use Rule' (2011) 76(88) *Federal* Register 26186; Danish EPA, 'Survey of Nanotechnological Consumer Products', 2007, available at: http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-536-7/pdf/978-87-7052-537-4.pdf; German Federal Institute for Occupational Safety and Health (BAuA), 'Exposure to Nanomaterials in Germany – Results of the Corporate Survey of the Federal Institute for Occupational Health and Safety (BAuA) and the Association of the Chemical Industry (VCI) Using Questionnaires', 24 Apr. 2008 (German BAuA Corporate Survey), available at: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/survey.pdf?__blob=publicationFile&v=2.

[59] Regulation (EC) No. 1907/2006 Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) [2007] OJ L 136/3; Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP) [2008] OJ L 353/1.

risk data on nanomaterials.[60] My online review, presented above, found that of the 36 data collection initiatives, 19 initiatives were adopted in Europe, while only 11 were released in the US, five in Australia, and one in Asia.

This result can be expected in light of previous analysis of the regulatory approach, which assumes that countries adopting the precautionary approach will make more effort to collect data under conditions of scientific uncertainty. Still, in terms of level of obligation, in the US (which follows the risk-based approach) most initiatives were mandatory and only three voluntary, whereas in Europe and Australia (which follow the precautionary approach) the majority of the initiatives were voluntary. While this may indicate some gaps between rhetoric and practice, another explanation may lie in the scope of the initiatives. In Europe and Australia most initiatives were sectorial (such as industrial chemicals, food and feed, consumer products, and occupational health), indicating a systematic approach to data collection. In the US, however, most initiatives focused on specific targeted substances or lists of substances, indicating risk hot spots rather than systematic data collection on nanomaterials. This means that the US uses mandatory tools to collect additional data only on a case by case basis where some evidence of risk already exists.

Under most of these initiatives, industry was asked to report only existing information, and few required generation of additional data. The information requested is mainly on basic data such as information on the company, substance identification, type and quantity of use. Some initiatives also requested more specific data, such as substance characterization, physical-chemical properties, fate and behaviour, measurement and detection techniques, and risk management practices.[61]

In summary, with respect to governance by disclosure, the most important question that regulation should currently address is disclosure of 'what': that is, what kind of information is relevant and meaningful to disclose? Only once this question is answered, is it possible to ask 'by who?' and 'to whom?'. Although both regulatory approaches share the technical, evidence-based risk conception, they differ slightly in the sufficiency

[60] According to interim results of the European Chemicals Agency's (ECHA) search of REACH and CLP submissions for nanomaterials, out of 26,600 REACH registrations, 4,700 distinctive substances and 3.2 million CLP notifications, only three REACH dossiers for three substances, and 15 CLP notifications for 14 substances have been submitted for nanomaterials explicitly. Six additional dossiers, not classified in the International Uniform Chemical Information Database (IUCLID) 5.2 as 'nanomaterials', included nano-scale substances. See Nanotechnology Industries Association, 'Topical Briefing: Interim Results: ECHA's Search of REACH- and CLP-Submissions for Nanomaterials', *NIA Exclusive*, 10 May 2011, available at: http://www.nanotechia.org/nia-internal-news/nia-exclusive—topical-briefing-interim-results-echa-s-search-of-reach–and-clp-submissions-for-nanomaterials.

[61] Working Party on Manufactured Nanomaterials (WPMN), 'Analysis of Information Gathering Initiatives on Manufactured Nanomaterials', *OECD Environment, Health and Safety Publications Series on the Safety of Manufactured Nanomaterials*, ENV/JM/MONO(2009)45 (WPMN (2009)); Milieu Ltd & RPA Ltd, *Proposal for an EU Reporting System for Nanomaterials*, May 2010, available at: http://www.nanomaterialsconf.eu/documents/NanoReportingSystemFinalR; WPMN, 'Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information', *OECD Environment, Health and Safety Publications Series on the Safety of Manufactured Nanomaterials*, ENV/JM/MONO(2011)53 (WPMN (2011)).

thresholds for scientific evidence in support of risk regulation. This variation may anticipate slight differences between the risk-based approach and the precautionary approach with regard to disclosure along the value chain. Under the risk-based approach, information dissemination mechanisms will be adopted only if they can support a *substantive* goal of preventing or mitigating significant environmental harm, for example, by warning workers or consumers to take protective measures when using a nano-product with a known and established risk. When the level of risk is still unknown, governments that follow this approach are unlikely to adopt disclosure mechanisms to facilitate 'right to know' or 'informed choice' goals. Therefore, blanket labelling requirements of nanomaterials in products are unlikely, because they are not grounded in scientific evidence and thus may cause unnecessary fear without promoting health or safety.[62] Indeed, to date no labelling scheme has been adopted by US government agencies.

On the other hand, the precautionary approach may go beyond substantive goals to pursue procedural (and, to a lesser extent, normative) goals if sufficient data exists to indicate realistic and serious risk. Therefore, once the precautionary principle is invoked, regulation may require dissemination of preliminary findings (emphasizing the state of scientific uncertainty) along the value chain. Furthermore, in areas of high public concern (such as food and cosmetics), where there is some indication of severe risk, governments may be willing to require product labelling as a more proportionate measure in lieu of a product ban. However, governments are unlikely to require labelling without a scientific cause for concern.[63]

Indeed, until recently, government initiatives for nano-labelling schemes were based on voluntary compliance, and focused on either 'positive labelling', identifying nanomaterials (for example, nano-enabled), [64] or 'negative labelling', declaring that no

[62] See, e.g., House of Lords, Science and Technology Committee, 'Nanotechnologies and Food, Volume 1: Report', 8 Jan. 2010, available at: http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf (citing the US FDA position that it only requires information to be included on a label if it is necessary in order for the consumer to use the product safely. It does not label on a 'right to know' basis as is sometimes the case in Europe.)

[63] See, e.g., the EC statement regarding food labelling that '[t]he Commission does not also agree with a systematic labelling ... of all foods produced with the aid of nanotechnology. As defined in the common authorization procedure, labelling must be decided on a case by case basis, following the scientific assessment and after consideration of other relevant factors': EC, Commission Communication on the Action Taken on Opinions and Resolutions Adopted by Parliament at the March I and II 2009 Part-Sessions, SP(2009)3060, 4 June 2009, at p. 24, available at: http://www.europarl.europa.eu/oeil/spdoc.do?i=16712&j=0&l=en.

[64] These schemes mainly aim to avoid misleading claims and verify that company statements are correct. They are not intended to ensure health and safety: see Taiwan Ministry of Economic Affairs (MOEA), 'NanoMark', 2004, available at: http://proj3.moeaidb.gov.tw/nanomark/Eng; Iran Nanotechnology Initiative Council, '"Nano mark" Certificate Unveiled in Iran Nano 2009 Exhibit (2009), available at: http://en.nano.ir/index.php/news/show/1415; and Nanotechnology Association of Thailand, 'NanoQ', 2011, available at: http://www.nanoassociation.or.th/th/index.php?status=7.

nanomaterials had been used (for example, nano-free).[65] After 2009, some governments began to adopt mandatory schemes. Since nanomaterials do not have a uniformly accepted definition, each labelling initiative defines them differently for its own purposes. Most notable are the EU's new cosmetic products regulation,[66] new food information to consumers regulation,[67] and new biocidal products regulation,[68] which require cosmetics manufacturers, food business operators responsible for providing food information to consumers, and those authorized to place nanobiocidal products on the market to label all nanoparticles contained in products marketed within the EU with the word 'nano' in brackets.[69]

Still, the effectiveness of these legislative enactments is still in doubt as a result of scientific-technical limitations related to the measurement of nanomaterials. A recent report by the EC Joint Research Centre concluded that '[n]one of the currently available methods can determine whether all kinds of potential nanomaterials meet the regulatory definition or not'.[70] Furthermore, while such blanket labelling requirements aim to foster a normative 'right to know' goal, as the EC recently has admitted: 'nano-ingredient labelling has been introduced [only] in products of relevance to consumers, notably food and cosmetics'.[71] The EC Communication further states that 'current

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65 See, e.g., the Canadian Organic Production Systems General Principles and Management Standards, which also authorizes organic labelling, forbidding completely the use of nanomaterials in organic products: Canadian General Standardization Board, 'Organic Production Systems General Principles and Management Standards', CAN/CGSB-32.310-2006 (CGSB, 2011). For comparison it is interesting to note that the EU's Ecolabel Board rejected the request to exclude nanomaterials in eco-labelling of cleaning products and lubricants, owing to the lack of evidence of risk: see Nanotechnology Industries Association, 'Flowers for Nanomaterials – European Ecolabel Includes Nano-products', 15 Feb. 2011, available at: http://www.nanotechia.org/global-news/flowers-for-nanomaterials—european-ecolabel-includes-nano-products. Furthermore, in Queensland (Australia), the Code of Practice for Labelling of Workplace Hazardous Chemicals recommends that labels be used for all products containing nanomaterials in the workplace, unless there is evidence that the nanomaterials are not hazardous: see Workplace Health and Safety Queensland, 'Labelling of Workplace Hazardous Chemicals Code of Practice 2011', *Queensland Government Gazette*, 2 Dec. 2011.

66 Regulation (EC) No. 1223/2009 on Cosmetic Products (recast) [2009] OJ L 342/59. Following Europe, New Zealand amended its Cosmetic Products Group Standard 2006 to include additional labelling, aligning it with the EU Cosmetics Regulation, Art. 19 (Labelling) and Art. 6 (Obligations of Distributors): see New Zealand EPA, 'Application to Amend the Cosmetic Products Group Standard 2006', ERMA200782, 28 June 2012.

67 Regulation (EC) No. 1169/2011 on Food Information to Consumers [2011] OJ L 304/18. This regulation combines two previous Directives on labelling, presentation and advertising of foodstuffs (2000/13/EC), and nutrition labelling for foodstuffs (90/496/EEC). It was adopted in lieu of the attempt to require labelling in novel food regulation but the regulation was not adopted because of its cloning sections.

68 Regulation (EU) No. 528/2012 concerning the Making Available on the Market and Use of Biocidal Products [2012] OJ L 167/1.

69 For additional discussion on worldwide national nano-labelling schemes, see, e.g., G.P. Gruère, 'Labeling Nano-Enabled Consumer Products' (2011) 6 *Nano Today*, pp. 117–21; and R. Falkner et al., 'Consumer Labelling of Nanomaterials in the EU and US: Convergence or Divergence?', Briefing Paper, Chatham House, Oct. 2009, available at: http://eprints.lse.ac.uk/25422/1/Consumer_labelling_of_nanomaterials_in_the_EU_and_US(LSERO).pdf.

70 EC Joint Research Centre, 'Requirements on Measurements for the Implementation of the European Commission Definition of the Term "Nanomaterial"', July 2012, available at: http://publications.jrc.ec.europa.eu.

71 EC, Communication on Second Regulatory Review on Nanomaterials, COM(2012)572 final, at p. 9.

knowledge about nanomaterials does not suggest risks which would require information about all products in which nanomaterials are used'.[72] Their scope is therefore very limited.

5. DEMOCRATIC IMPLICATIONS OF CURRENT APPROACHES TO DISCLOSURE

Having discussed the rationale behind the two major government approaches to risk management, and the regulatory mechanisms adopted to foster them, this section now considers their democratic implications. The analysis focuses on the lessons that can already be drawn from the worldwide implementation of information-gathering initiatives since 2006. While a few initiatives to facilitate disclosure along the value chain have also been adopted, they have not yet been fully implemented, and it is therefore too early to draw any conclusions on their effectiveness.

The discussion starts by investigating whether the information-gathering initiatives were effective in achieving their own goals, and then analyzes their democratic implications. In 2009, the Working Party on Manufactured Nanomaterials (WPMN) of the Organisation for Economic Co-operation and Development (OECD) conducted its first analysis of information-gathering initiatives for manufactured nanomaterials.[73] This report concluded that the overall objectives of such initiatives are:

(1) to provide governments with a baseline of information that will inform the development or adequacy of regulatory programmes to address potential risks; and
(2) to provide the public and stakeholders with the maximum information available, while protecting legitimate confidential information, to allow their engagement in discussions and decisions concerning such materials.[74]

The first objective explicitly states that the output of the information-gathering initiative should be to support additional regulatory actions. The second acknowledges the importance of broad stakeholder engagement in decision-making on the future development of these technologies (that is, not only technical expert opinion matters, but also those of the public). This section now addresses the question of whether the implemented initiatives have achieved these objectives.

5.1. *Objective 1: Developing Baseline Information for Regulatory Development*

Based on the stated purposes of the information-gathering initiatives adopted to date, governments have focused their efforts almost exclusively on the first objective, namely

[72] Ibid., at p. 10.
[73] WPMN (2009), n. 61 above.
[74] Ibid., at p. 17.

https://doi.org/10.1017/S2047102513000034 Published online by Cambridge University Press

building baseline information to assist the development of adequate regulation.[75] However, no indication has been given as to how governments have used or intend to use the collected data in the development of regulation. A minor exception is the 2006 German Corporation Survey,[76] aimed at and followed by the publication of guidance for the handling and use of nanomaterials in the workplace.[77] Among the various reasons for the failure of the information-gathering initiatives in the field of nanotechnologies to achieve this goal, the main two are low participation and the quality of information.

Participation

The ineffectiveness of the voluntary information-gathering initiatives may be linked to the low rate of participation in these programmes. In the United Kingdom (UK), for example, only 11 companies and two academic institutes signed up to a two-year programme (2006–08).[78] In the US, only 31 organizations submitted information to a two-year programme (2008–10) covering about 132 nanoscale materials under the basic phase, and only four companies agreed to participate in the in-depth phase.[79] In Australia's Information Call-In, 20 companies responded in 2006,[80] and only seven in 2008.[81]

In its analysis, the OECD WPNM recommended that 'in the case of voluntary information-gathering initiatives, authorities should clearly indicate how they intend to measure progress and the success of the programme, when and how they will be assessed, and the steps that will be taken if objectives are not met'. Additionally,

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75 See, e.g., UK Defra, n. 58 above, at p. 2 ('The Government is aiming to develop appropriate controls in respect of any risks to the environment and human health from free engineered nanoscale materials. In order to move towards appropriate controls, there is a need to build evidence on potential risks. This Voluntary Reporting Scheme is one strand of the Government's approach to gathering this evidence'); US EPA NMSP, n. 58 above, at p. 4861 ('The Nanoscale Materials Stewardship Program is intended to: [h]elp the Agency gather existing data and information from manufacturers, importers, processors, and users of existing chemical nanoscale materials to build EPA's knowledge base in this area; [i]dentify and encourage use of risk management practices in developing and commercializing nanoscale materials; [e]ncourage the development of additional test data needed to provide a firmer scientific foundation for future work and regulatory/policy decisions; [e]ncourage responsible development of nanoscale materials').

76 German BAuA Corporate Survey, n. 58 above.

77 German BAuA & German VCI, 'Guidance for Handling and Use of Nanomaterials at the Workplace', 27 Aug. 2007, available at: http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/guidance.pdf?__blob=publicationFile&v=2.

78 UK Defra, 'Update on the Voluntary Reporting Scheme for Engineered Nanoscale Materials: June 2009', 2009, available at: http://archive.defra.gov.uk/environment/quality/nanotech/policy.htm.

79 US EPA NMSP, n. 58 above.

80 Australian Government, 'NICNAS Information Sheet – Summary of Call for Information on the Use of Nanomaterials', Jan. 2007 (NICNAS Information Sheet Summary 2007), available at: http://www.nicnas.gov.au/publications/information_sheets/general_information_sheets/nis_call_for_info_nanomaterials.pdf.

81 Australian Government, 'NICNAS Information Sheet – Summary of 2008 Call for Information on the Use of Nanomaterials', Nov. 2010 (NICNAS Information Sheet Summary 2010), available at: http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Results_Call_for_Information_2008_Nov_2010_PDF.pdf. For additional figures, see WPMN (2011), n. 61 above.

'consideration should be given to supplementing voluntary initiatives with mandatory reporting'.[82] None of the nanomaterials voluntary reporting schemes threatened mandatory reporting requirements if the objectives were not met. Yet, after evaluating the disappointing results, the governments leading all three initiatives indicated that they are to consider additional means to collect data.[83]

In May 2011 the US Environmental Protection Agency (EPA) issued a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA)[84] for the chemical substance identified generically as multi-walled carbon nanotubes (MWCNT).[85] SNURs aim to provide the EPA with a basic set of information on MWCNT, to help to evaluate the intended uses of this nanoscale material and take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment. In January 2011, Australia adjusted the New Chemical processes under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to require all producers or importers of nano-forms of new chemicals (even of small amounts of nanomaterials) to go through a full risk assessment process and provide all information required by the law for conventional chemicals. NICNAS may require additional information on a case by case basis as necessary for the assessment of the chemical.[86]

From a review of the documents relevant to the development and implementation of information-gathering schemes, it is evident that countries watch and mimic each other's steps. Whilst no government sets out to burden the nanotechnology industry in a particular country over another, the ineffectiveness of information-gathering programmes has led governments to consider mandatory requirements.

The information call-in programme in California (US), for example, is mandatory, and all viable companies and research organizations responded. Yet, no further indication has been given so far as to how the collected data is evaluated and used for regulatory or other purposes.[87] This leads to questioning whether lack of participation

82 WPMN (2009), n. 61 above, at pp. 17–18.

83 UK Department for Business, Innovation and Skills (DBIS), 'UK Nanotechnologies Strategy: Small Technologies, Great Opportunities', Mar. 2010, available at: http://www.bis.gov.uk/assets/goscience/docs/u/10-825-uk-nanotechnologies-strategy.pdf ('The Government's preference is for a voluntary scheme, but it may be that a mandatory scheme will be the only way of ensuring that the necessary information is supplied'); US EPA. n. 58 above ('Although the NMSP provided EPA with useful information regarding a limited number of nanoscale materials in commerce, a significant number of the environmental health and safety data gaps remain. To address these gaps and prevent potential risks that may be posed by nanoscale materials, EPA is taking a number of regulatory actions under the Toxic Substances Control Act'); Australian Government, n. 58 ('NICNAS is progressing a regulatory strategy for nanomaterials that is expected to be progressed in a staged manner and includes administrative and legislative amendments to the regulation of these substances'). According to NICNAS, 'Proposal for Regulatory Reform of Industrial Nanomaterials' (2009), more adjustments to the scheme are under way, including a mandatory notification and assessment scheme for nano-forms of existing chemicals.

84 15 U.S.C. §2604(a)(2) (2013).

85 US EPA NMSP, n. 58 above.

86 Australian Government, n. 58 above.

87 California DTSC, 'Carbon Nanotube Information Call-In', 2009, available at: http://www.dtsc.ca.gov/PollutionPrevention/Round_One.cfm.

really is a significant obstacle, and whether mandatory participation would lead to sufficient data collection to enable the assessment of health and environmental risk.

Quality of information

The Californian example suggests another explanation for the failure of reporting programmes (voluntary or mandatory) in achieving their objectives; this relates to the quality of the information submitted. Beaudrie and Kandlikar found that the California DTSC Information Call-In programme has not been successful in acquiring the full range of nanomaterial property and toxicology data required to permit a full risk assessment.[88] Similarly, the OECD WPMN survey of nine information-gathering schemes found that 'even those with higher response rates indicated that the data received was not as detailed as originally hoped, or was incomplete'.[89] Variability in the level of reporting and quality of information makes the submitted information insufficient to support informed decision.[90] Further, with respect to nanomaterials, even with quality assurance mechanisms, the lack of or inadequate nanomaterial characterizations make it almost impossible to determine the potential hazards.[91]

The absence of sufficient scientific data appears also to be true for the new EU chemical legislation on Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) and Classification, Labelling and Packaging of Substances and Mixtures (CLP).[92] It has been suggested that current reporting under REACH–CLP is unlikely to provide the full range of information needed by regulators to assess the potential risks to public health and the environment from nanomaterials.[93] This is because current test guidelines that support REACH do not require nano-specific information and the information collected, based on conventional chemicals, may not be appropriate for the assessment of risks associated with nanomaterials. Recently, the European Chemicals Agency (ECHA) has begun to update guidance on information requirements specific to nanomaterials for REACH.[94]

While some progress has been made in terms of nanomaterials characterization, many uncertainties remain in this area, making it very complicated to conduct risk assessment for nanomaterials. It is therefore somewhat unrealistic to expect that, at a time of such major scientific uncertainty, data collected under information-gathering initiatives would provide a sound scientific basis for policy.

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88 C.E.H. Beaudrie & M. Kandlikar, 'Horses for Courses: Risk Information and Decision Making in the Regulation of Nanomaterials' (2011) 13(4) *Journal of Nanoparticle Research*, pp. 1477–88.

89 WPMN (2011), n. 61 above, at p. 14.

90 S.F. Hansen & J.A. Tickner, 'The Challenges of Adopting Voluntary Health, Safety and Environment Measures for Manufactured Nanomaterials: Lessons from the Past for More Effective Adoption in the Future' (2007) 4 *Nanotechnology Law & Business*, pp. 341–59, at 353–4 (citing the example of the High Production Volume (HPV) Challenge Program in the US).

91 Ibid.

92 REACH–CLP, n. 59 above.

93 Milieu Ltd. & RPA Ltd, n. 61 above, at pp. 39–40.

94 European Chemicals Agency, 'Updated Guidance on Information Requirements and Chemical Safety Assessment for Nanomaterials', available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

5.2. *Objective 2: Enhancing Public and Stakeholder Engagement*

The second objective of information-gathering initiatives is to provide the public and stakeholders with the most information available while protecting legitimate confidential information to allow their engagement in discussions and decisions concerning such materials. Two elements are incorporated in this objective: the public's right to know and the public's right to engage in the decision-making process, which means that not only technical expertise is necessary but also a wide range of stakeholders should also be included in the process to build trust in the agency programme. Although most government rhetoric has leant towards transparency and openness all along,[95] as discussed below in practice very few attempts have been made to incorporate public views in the decision-making process.

Public Right to Know

The principle of the public's 'right to know' is embodied in many laws, and it is based on the democratic theory that 'the public, as a sovereign, must have all information available in order to instruct its servants, the government'.[96] Placed in the nanotechnology context, people have, for example, the right to know what nano-based chemicals they may be exposed to from the products they use, not only for making informed consumer choices but also for deciding upon the future of this technology.

According to the analysis of information-gathering initiatives by the OECD WPMN, 'authorities should identify clearly how information collected under the initiative will be made public'.[97] Hansen and Tickner argue that a key part of any effort to improve and ensure transparency is giving the public and other stakeholders access to raw data.[98] Yet, in most information-gathering initiatives in the field of nanotechnology, companies were allowed to protect confidential information, and subsequently governments published only a summary of the information available to the public.[99] Even where raw data was published, much of the submitted information was not released to the public under the Confidential Business Information (CBI) provisions.[100] Some argue that

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95 See, e.g., J.P. Holdren et al. (n. 29 above) who state that one of the US policy principles is to 'develop relevant information in an open and transparent manner, with ample opportunities for stakeholder involvement and public participation'. Australian Government, 'Australian Government Approach to the Responsible Management of Nanotechnology', 11 July 2008, available at: http://www.innovation.gov.au/Industry/Nanotechnology/NationalEnablingTechnologiesStrategy/Documents/ObjectivesPaper.pdf (states an objective to foster informed community debate by ensuring decision-making processes are open, transparent and engage stakeholders). The EC (n. 41 above) states that 'an effective two-way dialogue is indispensable, whereby the general public's views are taken into account and may be seen to influence decisions concerning R&D policy').

96 T.I. Emerson, 'Legal Foundations of the Right to Know' (1976) *Washington University Law Quarterly*, pp. 1–24, at 14.

97 WPMN (2009), n. 61 above, at p. 19.

98 Hansen & Tickner. n. 90 above, at p. 357.

99 See German BAuA Corporate Survey and UK Defra VRS, both n. 58 above, and Australia NICNAS Information Sheet Summary 2007, n. 80 above; and NICNAS Information Sheet Summary 2010, n. 81 above.

100 See, e.g., US EPA NMSP and California DTSC Information Call-In programme 2009 and 2010, both n. 58 above.

even if the public were to be given access to raw data, this would have no real meaning to the lay person.[101] Nevertheless, availability provides a step towards building trust, and some NGOs employ experts to evaluate and translate data to the public. Environmental and community organizations have played a significant role in the US Toxic Release Inventory (TRI)[102] data, generating reports and profiles of toxic pollution and leading polluters.[103] While arguing that more transparency of raw data is important, transparency may empower and work as a transformative mechanism only when the disclosed information is valuable, accessible, comprehensible and comparable.[104] Otherwise, there is a risk of 'drowning in disclosure' of misinformation and disinformation.[105] So, for example, while the ECHA is compiling an inventory of nanomaterials included in REACH registration dossiers and CLP notifications at the request of the EC,[106] according to Otto Linher of the EC's Directorate General (DG) Enterprise, 'the Commission doesn't have a position on whether there should be a harmonised inventory at the EU level'.[107] Meanwhile, inventories are developed independently by various organizations, collecting nano-related information in an inconsistent way with limited usefulness.

Public Right to Engage

In one of his early reports on *Managing the Effects of Nanotechnology*, Davies notes that 'social values, apart from scientific questions, are an inextricable part of assessing risks [citation omitted], and the public needs to be involved in assessing [nanotechnology's] risks, as well as in defining the measures to be taken to deal with the risks'.[108] In the same line of thought, Hansen and Tickner propose that representatives of the public should be involved in the design of the reporting format, as well as in reviewing submissions, reviews and reports.[109] However, under the technical, evidence-based approach to risk

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101 O. Perez, 'Complexity, Information Overload and Online Deliberation' (2009) 5(1) *I/S: A Journal of Law and Policy for the Information Society*, pp. 43–85.

102 The TRI was established as part of the Emergency Planning and Community Right to Know Act (EPCRA) of 1986, §§ 301–330. The TRI requires manufacturing and certain other industrial facilities to disclose releases of hundreds of toxic chemicals. The information is available in a publicly accessible computerized database, in a standardized form enabling any interested party to aggregate the data in a variety of ways, and to generate inter-temporal, inter-facility, inter-firm, inter-sectoral, and inter-community comparisons: see B.C. Karkkainen, 'Information as Environmental Regulation: TRI and Performance Benchmarking, Precursor to a New Paradigm?' (2001) 89 *Georgetown Law Journal*, pp. 257–370, at 286–7.

103 Ibid., at pp. 318–19.

104 K. Dingwerth & M. Eichinger, 'Tamed Transparency: How Information Disclosure under the Global Reporting Initiative Fails to Empower' (2010) 10(3) *Global Environmental Politics*, pp. 74–96.

105 A. Gupta, 'Transparency under Scrutiny: Information Disclosure in Global Environmental Governance' (2008) 8(2) *Global Environmental Politics*, pp. 1–7.

106 L.L. Bergenson, 'ECHA Preparing Nano Inventory from REACH and CLP Submissions', *Nano and Other Emerging Chemical Technologies Blog*, 17 May 2011, available at: http://nanotech.lawbc.com/2011/05/articles/international/echa-preparing-nano-inventory-from-reach-and-clp-submissions.

107 European Chemical Industry Council, 'Cefic's First Nano & REACH Workshop a Success', 27 Jun. 2011, available at: http://www.cefic.org/newsroom/2011/Cefics-first-Nano–REACH-workshop-a-success.

108 J.C. Davies, *Managing the Effects of Nanotechnology* (Project on Emerging Nanotechnologies, 2006), at p. 29.

109 Hansen & Tickner, n. 90 above, at pp. 357–8.

assessment, only technical experts are considered to be eligible sources of data for the construction of the risk object of nanomaterials. This excludes social-cultural expertise in risk evaluation, as well as the voice of the lay public.[110]

Although stakeholders have been given the opportunity to comment on the design of some of the information-gathering initiatives, in many cases it is difficult to track whether comments have been implemented.[111] For example, in relation to the US EPA Nanoscale Materials Stewardship Program, Richard Dension, representing Environmental Defense, argued for the need to determine specific deadlines for data submission (three months) as well as regulatory backstops (mandatory rules).[112] Dension further argued against the possibility to claim CBI extensively and to submit the information in any form and format. While the importance of these comments to building public trust is obvious, they seem to have been ignored.

Once information-gathering schemes have been initiated, representatives of public interest groups are often not included to evaluate the submitted data. Lacking the ability to review the scientific data on which risk assessments are based leaves the public disengaged from the process.[113] The lack of broad stakeholder engagement may have negative impacts on the future development of this technology.

Firstly, the technology may not account for overall social prosperity. As Feenberg argues, 'public intervention may actually improve technology by addressing problems ignored by vested interests entrenched in the design process'.[114] By accounting for social dimensions of the technology at the start, the public may affect the very definition of the function that ought to be fulfilled by the technology and the quality of the environment associated with the production and use of the devices, avoiding future public rejection of the technology.[115]

Secondly, it may lead to mistrust in the nanotechnology industry and in the ability of governments to protect the public from potential risks. It is well documented in the literature of public perception and risk communication that the general climate of distrust that exists between the public, industry and risk management professionals is the result of ineffective risk communication efforts.[116] This 'trust deficit' can be avoided by facilitating more public engagement in the decision-making process.[117]

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110 See generally, Renn, n. 25 above, at pp. 58–61; Wynne, n. 27 above; J. Kuzma & J.C. Besley, 'Ethics of Risk Analysis and Regulatory Review: From Bio- to Nanotechnology' (2008) 2(2) *Nanoethics*, pp. 149–62.

111 Hansen & Tickner, n. 90 above, at pp. 357–8.

112 US EPA, 'Meeting Summary Report: Nanoscale Materials Stewardship Program', 8 Aug. 2007, at pp. 2–8, available at: http://www.epa.gov/oppt/nano/mtgsummary080207.pdf.

113 M. Stebbing, 'Avoiding the Trust Deficit: Public Engagement, Values, the Precautionary Principle and the Future of Nanotechnology' (2009) 6(1) *Journal of Bioethical Inquiry*, pp. 37–48, at 41.

114 A. Feenberg, *Questioning Technology* (Routledge, 2002), at p. 89.

115 Ibid., at p. 90.

116 P. Slovic, 'Trust, Emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield' (1999) 19(4) *Risk Analysis*, pp. 689–701, at 697.

117 Ibid., at p. 334; Stebbing, n. 113 above.

6. CONCLUSION

Examining current government rhetoric and practices to oversee the development of nanotechnologies indicates more convergence than divergence in transnational policy approaches. This is the result of the evidence-based approach for risk assessment, which is shared by the EU and US. Yet, as this article demonstrates, this approach has fundamental limitations to effectively overseeing the development of emerging technologies under scientific uncertainty. This is not only because of faults in design and implementation or power inequalities, but also because of an inherent limitation of current knowledge. At this time, the premise that 'a more data-intensive world will facilitate qualitative performance measurement, comparative analysis, and the benchmarking of result'[118] does not seem to hold true for nanotechnology.

Information-gathering initiatives have not achieved their objectives to date. While the low rate of participation in voluntary programmes has been the most frequently mentioned reason for their failure, this article argues that this is not accurate. Even systematic mandatory schemes have limited ability to collect the whole range of risk data necessary for quantitative risk assessment. The main reason for the failure of the information-gathering initiatives in the field of nanotechnology is their unrealistic objectives. Any attempt to effectively oversee the development of nanotechnologies using an evidence-based approach is unlikely to succeed because of the major scientific uncertainties in this field. Another reason for the failure of these programmes is that they have the potential to create mistrust instead of building trust in the technology. To date, scientific data provision to the government is an opaque process and the relevant stakeholders cannot assess its accuracy and relevance.

Nevertheless, experience has shown that technological innovation sometimes has latent adverse effects (as in the cases of asbestos, dichlorodiphenyltrichloroethane (DDT) and polychlorinated biphenyls (PCBs)).[119] Furthermore, public concerns that are not addressed on time may significantly affect the future market of the new technologies (as in the case of GMOs).These lessons suggest that in formulating public policy for nanotechnologies, the risk assessment process should not only be structured in narrow scientific terms but should also include other relevant societal dimensions.[120]

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118 Esty, n. 8 above, at p. 120; see also Perez, n. 101 above.

119 See, e.g., P. Harremoes et al. (eds.), *Late Lessons from Early Warnings: The Precautionary Principle 1896–2000* (European Environment Agency, 2001).

120 In the EU, the concept of 'other legitimate factors' in risk management was recognized in the GMO food regulation context a decade ago. See Art. 3(12) of Regulation (EC) No. 178/2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002] OJ L 31/1. Still, in the context of nanotechnology regulation the EU does not seem to have gone in the same direction: see M. Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation', in C. O'Cinneide (ed.), *Current Legal Problems 2009* (Oxford University Press, 2010). In the US, a recent effort was made to apply the US EPA Comprehensive Environmental Assessment approach, to identify and prioritize research directions for engineered nanomaterials, incorporating input from diverse stakeholder perspectives to support environmental decision-making; the second phase of the implementation will focus on prioritization of 'risk trade-offs' for risk management: see C.M. Powers et al., 'Comprehensive Environmental Assessment: A Meta-Assessment Approach' (2012) 46(17) *Environmental Science & Technology*, pp. 9202–8.

Challenges remain in democratizing the regulatory decision-making process, especially in highly technical areas.[121] This article attempts neither to solve these challenges nor to call for such comprehensive public deliberation. Rather, it argues that information disclosure has a normative role to change the rules of the game and engage more stakeholders in the fundamental societal decisions regarding the development of new technologies. Information disclosure should not only describe mechanisms to ensure access to information to enable informed decision-making and to protect consumers' right to know, as it has mainly done so far. Instead of being viewed as a vehicle for the transfer of scientific knowledge to support informed decision-making, it should also be viewed as a medium to enhance responsible development through transparency and open public dialogue.

To this end, information must flow in two directions and not only top-down from regulatory agencies/industry, in order to 'educate' the public. 'Democratizing' disclosure mechanisms means including a wider segment of society in deciding the scope of disclosure. This includes accounting for social views when deciding *what* to disclose and not only *how*, *by who* and *to whom*. It might be less ambitious than democratizing the entire risk management process in terms of architecture, but it may be more challenging in terms of political will. In addition to reorganization and financial and human resources, it requires a values change in our risk conception. It requires including not only technical-scientific parameters, but also societal aspects in the definition of the risk object.

Disclosure mechanisms should act as an intermediate medium, which transfers knowledge among all stakeholders through nets of 'epistemic communities'.[122] In this way, diverse social, cultural and ethical viewpoints that are brought to the table may yield a better understanding of society's views. The accumulation of different points of view would facilitate production of a better definition of the regulatory risk object and a more refined prioritization of regulatory objectives.[123] Prioritization would not necessarily be based on the level of scientific risk, but would reflect the kind of potential risks that society is willing to take to enjoy the potential benefits of technological advancement. For example, this process can reveal that society is willing to take significant environmental, health and safety risks for the benefit of finding a cure

121 Perez (n. 49 above, at pp. 56–75) highlights five challenges in the democratization of risk regulation in the context of nanotechnology, relating to the development of institutional structures for participatory processes.

122 P.M. Haas, 'Introduction: Epistemic Communities and International Policy Coordination' (1992) 46(1) *International Organization*, pp. 1–35, at 3 (defines an epistemic community as 'a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area').

123 Public deliberation results should be binding for regulators in developing the risk management approach and not a mere practice of transparency: see, e.g., A. Hullmann, 'European Activities in the Field of Ethical, Legal and Social Aspects (ELSA) and Governance of Nanotechnology, European EC DG Research, Brussels, 2008, available at: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/elsa_governance_nano.pdf (discussing the EC's funded projects for public deliberation in the field of nanotechnology).

for currently incurable diseases, but is unwilling to take any risk for the benefit of having transparent sunscreen lotion or longer-lasting food.[124]

This movement towards a more deliberative process should not be seen as an obstacle to technological innovation; on the contrary, technology may find more society-friendly directions in which to evolve, while reducing future public objection.

[124] See, e.g., Kirmizidis, n. 14 above. In the biotechnology context, see also TNS Opinion & Social, Eurobarometer 73.1: Biotechnology, Oct. 2010, available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.