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Trends in Global Nanotechnology Regulation: The Public-Private Interplay

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ABSTRACT

Over the last decade, concerns regarding potential exposure to nanomaterials gave rise to substantial new regulation intended to ensure safe development of nanotechnology applications. This Article examines the resultant regulatory system through empirical analysis of trends and patterns in global development of nanotechnology regulatory initiatives. It argues that rather than a government-driven process, it was private actors who set the regulatory wheels in motion. This Article shows that under conditions of scientific uncertainty, governments lacking technical and scientific knowledge to support risk-based regulation often leave a regulatory void. Consequently, businesses apply self-risk-management strategies to fill the gap, leading the way for public regulation to follow. Thus, it is the continual interplay between public and private regulations that shapes the current landscape and drives the regulatory innovation. This Article further shows that, while formal partnerships are rare, an informal and self-organized collaboration is occurring through reciprocal signals of intent and tacit understanding of the internal and external factors that drive both public and private regulations. It concludes that, due to some unique aspects of nanotechnology, private

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regulation has (and is likely to continue to have) a prominent role in regulating nanotechnologies.

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I. INTRODUCTION

Today, with over 1,800 nano-enabled consumer products or product lines already on the market (including textiles, food packaging, cosmetics, luggage, children's toys, floor cleaners, and wound dressings),[1] addressing the possible exposure to nanomaterials[2] has become a subject of increasing regulatory concern. Over the last decade, many actors worldwide have developed specific regulatory initiatives to oversee the safety of nanotechnology[3] applications under

1. *See* Project on Emerging Nanotechnologies, *All Products*, CONSUMER PRODS. INVENTORY (2014), http://www.nanotechproject.org/cpi/products/.

2. The term "nanomaterial" is difficult to define. Institutes around the world define "nanomaterial" and other related terms such as "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 mainly sought to identify an inclusive size range of 1–100 nanometers, that helps to understand the terminology that uses the prefix "nano." For example, the International Organization for Standardization (ISO) definition is a "material with any external dimension in the nanoscale" (between 1 and 100 nanometers (nm)) "or having internal structure or surface structure in the nanoscale." *See* Int'l Org. for Standardization [ISO], *Nanotechnologies—Vocabulary—Part 1: Core Terms*, ISO/TS 80004-1:2010 (2010), *available at* https://www.iso.org/obp/ui/#iso:std:iso:ts:80004:-1:ed-1:v1:en. The European Commission (EC) was the first to publish its recommended definition on nanomaterials for regulatory purposes in October 2011. *See Commission Recommendation of 18 October 2011* . However, as discussed in the paper, the implementation of this definition is still problematic due to technical constraints.

3. There is a great variety of technologies for manipulating materials in the nanoscale, all of which are coined "nanotechnology" as a generic term. *See, e.g.*, ISO, *supra* note 2.

conditions of scientific uncertainty.[4] The rise of diverse nanospecific regulatory arrangements, some of which operate simultaneously at different scales, created a dense global nanotechnology regulatory landscape devoid of central coordination. This situation raises questions regarding the way in which new global regulatory norms are formed: who the leading actors are, at what level they operate, where around the world decisions are made, how certain norms gain global supremacy over others, and whether there are legitimate grounds for overall governance.

This Article examines the emerging regulatory system through empirical analysis of trends and patterns and the interaction between public and private regulations. In doing so, it discusses the underlying drivers of regulation as well as its regional distribution, highlighting differences in regulatory approaches, tools, and scope worldwide. An understanding of past and current trends in nanotechnology regulation can provide some insight into the future of nanotechnology regulation and the challenges it must face. It may also serve as a case study for understanding modern regulatory dynamics in areas of scientific uncertainty.

This Article contributes to the growing literature studying the fragmentation of global governance by highlighting the role of private regulation in shaping global regulatory systems under conditions of scientific uncertainty.[5] It raises several observations and arguments.

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4. This Article uses the term "scientific uncertainty" to mean the general inability to make reliable scientific predictions of events or damages. *See* EUROPEAN SCI. & TECH. OBSERVATORY, ON SCIENCE AND PRECAUTION IN THE MANAGEMENT OF TECHNOLOGICAL RISK 12 (Andrew Stirling, ed. 2001) [hereinafter ESTO, ON SCIENCE], *available at* http://ftp.jrc.es/EURdoc/eur19056IIen.pdf. The author includes complex and ambiguous scientific conditions under the umbrella of this term. Scientific complexity refers to the cognitive component of risks that provide specific constraints and challenges for data collection and interpretation. It is characterized by a major scientific dispute about complex dose-effect relationships or the alleged effectiveness of measures to reduce vulnerability. ORTWIN RENN, RISK GOVERNANCE: COPING WITH UNCERTAINTY IN A COMPLEX WORLD 178, 192 (2008). Scientific ambiguity is characterized by intense controversy among different stakeholders in society about the interpretation of risk information and the values and priorities of what should be protected. *Id.* at 179.

5. The main focus of the literature has been on public regulatory arrangements as the center and driver of regulatory systems and interactions. *See, e.g.*, THOMAS GEHRING & SEBASTIAN OBERTHÜR, *Interplay: Exploring Institutional Interaction, in* INSTITUTIONS AND ENVIRONMENTAL CHANGE: PRINCIPAL FINDINGS, APPLICATIONS, AND RESEARCH FRONTIERS 187 (Oran R. Young et al. eds., MIT Press 2008); Kenneth. W. Abbott & Duncan Snidal, *Strengthening International Regulation through Transnational New Governance: Overcoming the Orchestration Deficit*, 42 VAND. J. TRANSNAT'L L. 501, 503 (2009); Robert O. Keohane & David G. Victor, *The Regime Complex for Climate Change* 2 (Harvard Project on Int'l Climate Agreements, Discussion Paper No. 10-33, 2010), *available at* http://belfercenter.ksg.harvard.edu/files/Keohane_Victor_Final_2.pdf. More recent exceptions include, for example, Peer Zumbansen, *Neither 'Public' Nor 'Private', 'National' Nor 'International': Transnational Corporate Governance from a Legal Pluralist Perspective*, 38 J. LAW & SOC. 50 (2011); Graeme Auld & Jessica F. Green,

First, in the case of nanotechnology regulation, it was private actors who set in motion the regulatory "wheels" rather than a government-driven process. Under conditions of scientific uncertainty, governments lack the technical and scientific knowledge to support risk-based regulation, and are often satisfied with results from minimal data-collection requirements. However, this has left a significant gap in regulation. Consequently, businesses apply self-risk-management strategies to fill that gap, leading the way for public regulation to follow. The continual interplay between public and private regulation is what shapes the current landscape and drives regulatory innovation.

Second, while formal partnerships are rare, informal collaboration frequently occurs through reciprocal signals of intent and tacit understanding of the internal (organizational) and external (social, economic, and political) factors that drive both public and private regulations. Given this dynamic, it is clear that the public-private interplay does not result from a governmental strategy or orchestration as commonly argued,[6] but instead is self-organized.

Third, under conditions of scientific uncertainty, businesses opt to go beyond compliance for two main reasons. One reason is that, in unregulated domains, businesses have incentives to influence future regulatory requirements.[7] In this way, they are able to avoid being faced with overly burdensome regulations and can reduce the risk of policy divergence among jurisdictions. Secondly, scientific uncertainty, complexity, and ambiguity regarding the technological risks pressure businesses to apply multiple strategies concurrently for addressing new risks and uncertainties. This may include going beyond compliance as a way to build public trust and regulatory support.

This Article concludes with the author's view that, due to some unique aspects of nanotechnology, including the diversity and complexity of nanobased materials, the pace of innovation, and information asymmetry, private regulation is likely to continue to have a prominent role in the future. Unlike traditional command-and-control regulation, which is a "one size fits all" approach, private regulation can more easily accommodate differences in materials and manufacturing processes, thus allowing the

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Unbundling the Regime Complex: The Effects of Private Authority (Osgoode CLPE, Research Paper No. 15/2012, 2012), *available at* http://dx.doi.org/10.2139/ssrn.2116296.

6. *See, e.g.*, IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (Oxford Univ. Press 1992); Abbott & Snidal, *supra* note 5.

7. This incentive may be limited by the resources the firm has to invest in the voluntary program and the shield to liability it can get for such activity.

regulation to be more specific, relevant, and proportionate. Private arrangements, when implemented, also often allow greater flexibility (addressing scientific and regulatory gaps with professional judgment), and can therefore incorporate new knowledge regarding potential risks more quickly.

Part II of this Article briefly outlines the relevant conceptual framework. Part III describes the methodology used by the author to create the Global Nanotechnology Regulatory Initiative (GNRI) database. Part IV is an overview of the results of an analysis of this database. Part V then discusses trends in the GNRI evolution in more depth, analyzing the major social-economic and political factors influencing these trends, including the cultural differences in environmental health and safety (EHS) risk perception and risk regulation across the globe. Part VI concludes this Article with insights about the future of nanotechnology regulation and its challenges, highlighting the need for further investigation of private authorities' role in shaping global nanotechnology regulatory norms.

II. CONCEPTUAL FRAMEWORK

This Article examines the empirical data[8] using three theoretical prisms, which jointly and severally help explain the observed global trends in nanotechnology regulation. The first prism, risk governance under scientific uncertainty, will provide the overall context in which nanotechnology is being developed and regulated. The second theoretical lens is proposed by the greening of industry, which seeks to explain the motivations of private firms to go beyond compliance and develop regulation that specifically addresses the environmental and human health implications of nanotechnologies. The third theoretical lens, discussing the fragmentation of global governance, provides a perspective for understanding the proliferation of decentralized nanotechnology regulatory initiatives globally, and the diversity of institutions involved in setting regulation. These theoretical prisms contextualize the regulatory situation in which nanotechnology regulation is being developed and for understanding the other two regulatory phenomena, greening and fragmentation, that are observed in the field.

8. *See* discussion *infra* Part III.

A. *Risk Management Under Conditions of Scientific Uncertainty*

Risk management involves reducing risks to a level deemed acceptable by society.[9] The literature often refers to three main strategies for managing technological risks:[10]

(1) *Risk-based approach.* Identifies potential physical harm to human beings or ecosystems and analyzes the probability that these events will occur over space and time.[11] Typically, once such risks are severe enough to justify government intervention, qualitative safety goals, exposure limits, or standards are established to minimize the risks. However, under conditions of scientific uncertainty, establishing these measures becomes challenging. The effectiveness of this approach lies in its ability to acquire the necessary data for the risk evaluation process.

(2) *Precautionary-based approach.* Justifies regulatory intervention based on a scientific conclusion of a "realistic and serious risk" to society (and thereby lowers the burden of proof of adverse effects).[12] Typically, under this approach, regulation adopts "activity reduction" measures such as production limits through permits, control banding, exposure limit standards set at "as low as reasonably achievable" (ALARA),[13] and constant monitoring of the potentially harmful side effects.

(3) *Discursive-based approach.* Frames the risks and decides on the means to address them through roundtables, mediation, citizen panels or other deliberative processes that engage multiple stakeholders. The regulatory outcome of such an approach often includes self-enforced codes of conduct aimed at strengthening the long-term

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9. *See* RENN, *supra* note 4, at 185.

10. *See, e.g.*, ESTO, ON SCIENCE, *supra* note 4; Andreas Klinke & Ortwin Renn, *A New Approach to Risk Evaluation and Management: Risk-Based, Precaution-Based, and Discourse-Based Strategies*, 22 RISK ANALYSIS 1071 (2002).

11. *See* Ortwin Renn, *Concepts of Risk: A Classification, in* SOCIAL THEORIES OF RISK, 53, 59 (Sheldon Krimsky & Dominic Golding eds., 1992).

12. The absence of quantifiable scientific proof of risk does not preclude the possibility for real risk, and therefore cannot be used to justify regulatory inaction under the general duty to refrain from actions that would cause harm to others. *See generally* PROTECTING PUBLIC HEALTH & THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE (Carolyn Raffensperger & Joel A. Tickner, eds. 1999); *Communication from the Commission on the Precautionary Principle* COM (2000) 1 final (Feb. 2, 2002) [hereinafter, *Commission on the Precautionary Principle*], *available at* http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf.

13. *Commission on the Precautionary Principle*, *supra* note 12, at 15.

responsibility of the regulated entity and international coordination.

Choosing among these strategies depends on the type of risk problem addressed—problems can range from a routine risk, which can be addressed through traditional cost-benefit analysis, to a risk with scientific complexity, unresolved scientific uncertainty, or scientific ambiguity requiring a strategy more tailored to the specific conditions.[14] For example, Renn notes that because the main obstacle of managing complex risk is obtaining the best information to resolve the complexity in a scientific and reliable way, the regulatory approach should be expert deliberation—what he terms "epistemic discourse." On the other hand, highly uncertain risks cannot be resolved through more sophisticated scientific data; they require the employment of proxy variables that refer to the nature of the risk in question. In addition, resilience strategies and the development of substitutes should be adopted. Finally, because the main problem with managing ambiguous risks is reaching consensus on the content, regulatory strategy should focus on ways and means to prioritize the objectives and the regulatory options that are acceptable for most stakeholders in society.[15]

In the context of nanotechnology, however, the line between one type of risk problem and another is not always clear; thus, the optimal regulatory strategy to address such risks is value-laden. The literature on risk governance acknowledges both the value-laden component of risk management and the fact that regulatory intervention to oversee technological risks may vary between fields, countries, and individuals, depending on their risk conception and their construction of the "risk object"[16] that requires control. A good illustration for this point is the international debate over the regulation of genetically modified organisms (GMOs) in food. The literature documents that the European Union (EU) objections to biotechnology are based not only on the potential health risk (physical harm) that this technology might cause but also on cultural, ethical, religious, ideological, and competitive grounds.[17]

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14. RENN, *supra* note 4, at 177–80.

15. *Id.* at 191–200.

16. 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 the regulatory intervention to control its impact on society, and the way it is defined determines how it should be managed. *Id.*

17. 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. Thus, it was not a precautionary principle decision per se, rather a

Similar to GMOs, nanotechnology-enabled applications also raise societal, legal, and ethical concerns, including issues of privacy, human enhancement, intellectual property, and international power-relationships.[18] To avoid the implications of the transatlantic policy divergence over GMO regulation, which includes significant technological development barriers, both public and private actors have changed their traditional strategy.

B. The Greening of Industry: Moving Beyond Compliance

For many years, industrial businesses regarded environmental regulation as an unjustified economic burden that threatened their profitability and competitiveness. However, over the last two decades, leading businesses began viewing environmental reputation as a strategic business case. The move towards "greening" was justified by cost-reduction, competitive advantage, and reputational enhancement in the eyes of regulators and the public.[19] Gradually, businesses also shifted from talking about environmental management and pollution prevention to talking about sustainability and environmental stewardship, indicating a more proactive approach that goes beyond simply avoiding negative consequences.[20] Hence, regardless of the

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multi-faceted decision not to support the development of such technology. *See, e.g.*, SHEILA S. JASANOFF, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES (2005); Yann Devos et al., *Ethics in the Societal Debate on Genetically Modified Organisms: A (Re)Quest for* Sense and Sensibility, 21 J. AGRIC. & ENVTL. ETHICS 29 (2007); Aarti Gupta, *When Global is Local: Negotiating Safe Use of Biotechnology, in* EARTHLY POLITICS: LOCAL AND GLOBAL IN ENVIRONMENTAL GOVERNANCE 127–48 (Sheila Jasanoff & Marybeth Long Martello eds., 2004); Chaia Heller, *From Scientific Risk to Paysan Savoir-Faire: Peasant Expertise in the French and Global Debate Over GM Crops,* 11 SCI. AS CULTURE 5 (2002); Brian Wynne, *Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs,* 10 SCI. AS CULTURE 445 (2001).

18. For a further discussion on societal and ethical implications of nanotechnology, see WHAT CAN NANOTECHNOLOGY LEARN FROM BIOTECHNOLOGY?: SOCIAL AND ETHICAL LESSONS FOR NANOSCIENCE FROM THE DEBATE OVER AGRIFOOD BIOTECHNOLOGY AND GMOS (Kenneth H. David & Paul B. Thompson eds., 2008); Bruce V. Lewenstein, *What Counts as a 'Social and Ethical Issue' in Nanotechnology, in* NANOTECHNOLOGY CHALLENGES: IMPLICATIONS FOR PHILOSOPHY, ETHICS AND SOCIETY 201 (Davis Baird & Joachim Schummer eds., 2006).

19. *See* ENVIRONMENTAL STRATEGIES FOR INDUSTRY 3 (Johan Schot & Kurt Fischer eds., 1993) (discussing the evolutionary process of industry's greening); Robert A. Kagan et al., *Explaining Corporate Environmental Performance: How Does Regulation Matter?*, 37 LAW & SOC'Y REV. 51 (2003) (explaining the external and internal shapers of corporate environmental behavior); Aseem Prakash, *Why do Firms Adopt 'Beyond-compliance' Environmental Policies?*, 10 BUS. STRATEGY & THE ENV'T 286 (2001); Forest Reinhardt, *Market Failure and the Environmental Policies of Firms: Economic Rationales for "Beyond Compliance" Behavior*, 3 J. INDUS. ECOLOGY. 9 (1999) (arguing that environmental practices can be used as part of the firm's overall business strategy).

20. *See* DANIEL J. FIORINO, THE NEW ENVIRONMENTAL REGULATION 90–116 (2006) (discussing the overall logic and trends); NEIL A. GUNNINGHAM ET AL., SHADES OF GREEN: BUSINESS, REGULATION, AND ENVIRONMENT (2003) (discussing beyond-compliance in terms of a socially constructed "license to operate"); Jennifer Howard-Grenville et al., *Constructing the*

motivations, many businesses now advance environmental practices with no direct government pressure.

Several factors influence businesses to go beyond compliance:

(1) *The shadow of regulation.* Anticipating the need to comply with more stringent rules later, businesses are motivated to address the issue before government sets potentially inflexible rules.[21]

(2) *Reducing risk and regulatory uncertainty.* According to Fiorino, "Much of the behavior associated with the greening of industry may be explained as efforts by firms to manage risk and uncertainty."[22] Adopting product stewardship programs or similar mechanisms allows companies to lower their economic and political liabilities if they can show that they did their best to prevent the harm. This may also serve as evidence of their environmental responsibility for their suppliers.[23]

(3) *Building reputational capital.* Participating in voluntary government programs helps businesses deal with public pressure and maintain good relationships with regulators. This, in turn, often grants businesses more flexible regulatory compliance requirements, such as being at a lower priority for routine agency inspections, being eligible to file pollution reports less frequently, or being eligible for expedited permitting and delisting petition processes.[24]

(4) *Enhancing competitive position.* Businesses use their environmental quality operations, their open relationship with communities and others, and the environmental attributes of their products to gain market share and create a positive public image, which will enhance the company's long-term business success. In addition, businesses with greater capacities use environmental practices to gain a first-mover advantage over their competitors that have

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License to Operate: Internal Factors and Their Influence on Corporate Environmental Decisions, 30 LAW & POL'Y 73 (2008); Michael E. Porter & Claas van der Linde, *Toward a New Conception of the Environment-Competitiveness Relationship*, 9 J. ECON. PERSP. 97 (1995) (raising the argument of the economic-environmental relationship's win-win situation).

21. *See, e.g.*, FIORINO, *supra* note 20, at 108, 113; Kagan et al., *supra* note 19, at 88; Porter & van der Linde, *supra* note 20, at 111; Reinhardt, *supra* note 19, at 13.

22. FIORINO, *supra* note 20, at 112.

23. *See, e.g.*, *id.* at 105; FOREST L. REINHARDT, DOWN TO EARTH: APPLYING BUSINESS PRINCIPLES TO ENVIRONMENTAL MANAGEMENT (2000); David Dana, *When Less Liability May Mean More Precaution: The Case of Nanotechnology*, 28 UCLA J. ENVTL. L. & POL'Y 153, 154–55 (2010).

24. *See, e.g.*, FIORINO, *supra* note 20, at 113–15; Howard-Grenville et al., *supra* note 20, at 86; Kagan et al., *supra* note 19, at 74–75.

fewer capacities. By making the first move, lead firms can unilaterally influence government policy choice. In turn, this change in regulatory status quo (and the adoption of higher standards) raises the cost of entry for their rivals.[25]

(5) *Internal managerial factors.* Corporate culture, mediated by available corporate financial resources, influences management decisions on environmental policy. Kagan et al. constructed five "ideal" management categories that display incrementally more dedication to compliance (or beyond compliance) with regulatory requirements—environmental laggards, reluctant compliers, committed compliers, environmental strategists, and true believers.[26] Later on, Howard-Grenville et al. identified five internal organizational factors that shape businesses' environmental practices: "managerial incentives, organizational culture, organizational identity, organizational self-monitoring, and personal affiliations and commitments . . . ."[27]

Part V examines some of the drivers for businesses to go beyond compliance in the field of nanotechnology regulation considered through the lens of emerging technologies under conditions of scientific uncertainty. The author found that the most significant drivers for nanomaterial businesses to go green are the shadow of regulation, reducing risk, and regulatory uncertainty, and, to a lesser extent, enhancing competitive position and building reputational capital. Nevertheless, as no personal interviews were conducted to gain systematic insight on these drivers, this Article only highlights those drivers that could be observed in the general data. This discussion, therefore, does not preclude the influence of additional drivers.

C. The Fragmentation of Global Governance

A broad body of literature in the legal, international relations, political science, and sociology disciplines addresses the phenomena of global governance fragmentation and decentralization under

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25. *See, e.g.*, Scott Barrett, *Environmental Regulation for Competitive Advantage*, 2 BUS. STRATEGY REV. 1 (1991); Chad Nehrt, *Maintainability of First Mover Advantages When Environmental Regulations Differ Between Countries*, 23 ACAD. OF MGMT. REV. 77, 91–93 (1998); Porter & van der Linde, *supra note* 20, at 104–05; Reinhardt, *supra* note 19; Steven C. Salop & David T. Scheffman, *Raising Rivals' Costs*, 73 AM. ECON. REV. 267, 267 (1983); ENVIRONMENTAL STRATEGIES FOR INDUSTRY, *supra* note 19.

26. Kagan et al., *supra* note 19, at 56–58.

27. Howard-Grenville et al., *supra* note 20, at 75.

conditions of rising institutional density. The concepts of new governance[28] and legal pluralism[29] developed to describe an emerging governing style that challenges the Westphalian sovereignty of the state as the exclusive source of norm making. Instead, they highlight the increasing influence of non-state actors and the blurring of boundaries between public and private rulemaking. These concepts imply a shift in the authority to regulate EHS problems from formal institutions of the state to self-organizing and inter-organizational networks. Moreover, contrary to the command-and-control approach—which relies on bureaucratic expertise and applies a "one size fits all" mandatory ruling and enforcement strategy—these concepts focus on the engagement of dispersed expertise, decentralized standard setting and enforcement, and voluntary ruling.[30]

From a global perspective, this also means that the exercise of control occurs at multiple levels and has "transnational repercussions."[31] Likewise, the influence of transnational private decision-making institutions is growing in many areas of regulation at all levels.[32] The consequences of institutional density and multiple, uncoordinated coexisting regulatory arrangements may be both negative and positive. For instance, some scholars have emphasized the potential for competing claims of authority and conflicting demands or norms.[33] On the other hand, others have pointed out that regulatory diversity may lead to the creation of a more democratic, tolerant, and creative society.[34] Nevertheless, it is important to

28. *See, e.g.*, Orli Lobel, *The Renew Deal: The Fall of Regulation and The Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342 (2004); R. A. W. Rhodes, *The New Governance: Governing Without Government*, 44 POL. STUD. 652 (1996); James N. Rosenau, *Governance in the Twenty-first Century*, 1 GLOBAL GOVERNANCE 13 (1995); Gerry Stoker, *Governance as Theory: Five Propositions*, 50 INT'L SOC. SCI. J. 17 (1998).

29. *See, e.g.*, Oren Perez, *Legal Pluralism, in* OXFORD ENCYCLOPEDIA OF AMERICAN POLITICAL AND LEGAL HISTORY 97–98 (Donald T. Critchlow & Philip R. VanderMeer eds., Oxford Univ. Press 2012); Brian Z. Tamanaha, *Understanding Legal Pluralism: Past to Present, Local to Global*, 30 SYDNEY L. REV. 375 (2008); Zumbansen, *supra* note 5.

30. *See* Abbott & Snidal, *supra note* 5, at 520–23.

31. *See* Rosenau, *supra* note 28, at 13, 15.

32. *See, e.g.*, TIM BÜTHE & WALTER MATTLI, THE NEW GLOBAL RULERS: THE PRIVATIZATION OF REGULATION IN THE WORLD ECONOMY (2011); Kenneth W. Abbott & Duncan Snidal, *Taking Responsive Regulation Transnational: Strategies for International Organizations*, 7 REG. & GOVERNANCE 95, 97 (2013); Oren Perez, *International Environmental Law as a Field of Multi-Polar Governance: The Case of Private Transnational Environmental Regulation*, 10 SANTA CLARA J. INT'L L. 285, 286–87 (2013).

33. *See, e.g.*, Abbott & Snidal, *supra* note 5, at 542; David M. Trubek & Louise G. Trubek, *New Governance & Legal Regulation: Complementarity, Rivalry, and Transformation*, 13 COLUM. J. EUR. L. 539, 547 (2007); Tamanaha, *supra* note 29, at 400.

34. *See, e.g.*, Elinor Ostrom, *Polycentric Systems for Coping with Collective Action and Global Environmental Change*, 20 GLOBAL ENVTL. CHANGE 550, 552 (2010); Oren Perez,

empirically study how coexisting regulatory arrangements interact with one another to assess governance effectiveness and legitimacy in a certain domain.

In recent years, many scholars have identified steering mechanisms to promote desired transnational governance. Proposed concepts range from top-down, state-strategic orchestration to bottom-up citizen sovereignty. Between these two extremes lies a third concept, rough consensus and running code, used to describe a more deliberative experimental process.

The orchestration concept views the government or inter-governmental organization as the orchestrator that "pursues public goals by promoting and empowering a network of public, private-sector, and civil society actors and institutions, all of which are encouraged to engage in various 'regulatory' (including self-regulatory) activities."[35] Abbott and Snidal specify "a wide range of directive and facilitative techniques" applied by the state to propel this network. These include "initiating voluntary and cooperative programs; convening and facilitating private collaborations; persuading and providing incentives for firms to self-regulate; building the capacities of private actors; negotiating regulatory targets with firms; providing incentives to exceed mandated performance levels; and ratifying or scaling up successful approaches."[36]

Another concept views the erosion of the national sovereignty as an opportunity for the enhancement of "citizen sovereignty" through "webs of influence."[37] According to Braithwaite and Drahos, "[P]ower is not a matter of imposing a sovereign will, but of enrolling the cooperation of chains of actors." Therefore, cross-national alliances of non-governmental organizations (NGOs) that capture the imagination of the public in powerful states can strategically influence the forum in which the global business regulation occurs and can counter forum-shifting by stronger actors.[38] This allows NGOs to influence the dialogue that builds the regulatory regime through "defining issues as a concern, creating contracting spaces where complex interdependency can induce cooperation, constituting normative commitments, nurturing habits of compliance that are then institutionalized into bureaucratic routines, [and] communicating

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Normative Creativity and Global Legal Pluralism: Reflections on the Democratic Critique of Transnational Law, 10 IND. J. GLOBAL LEGAL STUD. 25, 26, 29 (2003).

35. Abbott & Snidal, *supra* note 5, at 521.

36. *Id.* at 511.

37. JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 31 (2000).

38. *Id.*

informal praise and shame that are then institutionalized, and building capacity."[39]

The final concept proposes a decentralized dynamic in which the regulator (public, private, or hybrid), drawing on experts and stakeholders' knowledge, "seek[s] to identify an evolving—rough—consensus in light of which it will put forward an experimental draft body of norms. These, in turn, will receive feedback and remain open to adaptation and change, constituting a running code."[40] From this perspective, transnational norms formation is a process of constant deliberation and consensus-seeking combined with regulatory instruments for experimentation and adaptation.[41]

Over the years, several regulatory models have been proposed to describe how public and private actors interplay, or should interplay, in the field of nanotechnology. One seminal work that served as a model for several nanotechnology regulation scholars is Ayres and Braithwaithe's responsive regulation and the pyramid of regulatory strategies, which argues for a "symbiosis between state regulation and self-regulation."[42] The pyramid presents the range of regulatory strategies (see Figure 1)—from self-regulation at the bottom, through supervised or enforced self-regulation and other forms of public-private interaction in the middle, to standard forms of command-and-control regulation at the top. With this tool at hand, the authors argue that regulators can play a tit-for-tat strategy: They allow firms to self-regulate so long as the firms respond with responsible action. If not, then the regulator intervenes with stronger regulation.[43]

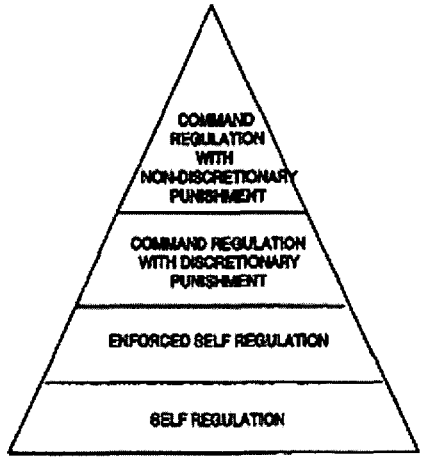

Figure 1—Pyramid of Regulatory Strategies

39. *Id.* at 32.
40. Zumbansen, *supra* note 5, at 69.
41. *Id.*
42. AYRES & BRAITHWAITE, *supra* note 6, at 3.
43. . at 6.

Several scholars adapted this model to the field of nanotechnology regulation.[44] Of particular interest is Marchant et al.'s model, which attempts to account for the scientifically uncertain conditions under which nanotechnology regulation is developed. Their model extends the regulatory pyramid through time, viewing these strategies as sequential. They propose that, in the near future, regulation should focus on softer and more decentralized measures, which will produce the greatest information, coupled with mechanisms for learning from them. Over time, as society learns about the actual risks and benefits of nanotechnology from its early experiences, a more command-and-control based regulatory structure can be gradually built up.[45]

In reality, as discussed in Part V, there has been no strategic incremental development of nanotechnology regulation. Rather, regulation has been a fluid mixture of soft-hard law that evolved differently in each sector and region of the world based on traditional regulatory culture and public perception of nanotechnology. Furthermore, as previously commented in the literature, the pyramid of regulatory strategies—static or incremental—neither represents the activities of both regulated entities and third parties, nor accounts for the complexity of social engineering in a multifaceted and fragmented regulatory system.[46] It also fails to address a globalized regulatory system characterized by multiple regulators (both public and private) with limited regulatory capacities, jurisdictional authority, information access, and sanctioning ability.[47]

Another regulatory model that has been adapted to the field of nanotechnology is Abbott and Snidal's model of the regulatory triangle. This model assumes there are three actor groups—states, businesses, and NGOs—who act as regulators in agenda setting, negotiation, implementation, monitoring, and enforcement of

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44. *See, e.g.*, Diana M. Bowman & Graeme A. Hodge, *Nanotechnology: Mapping the Wild Regulatory Frontier*, 38 FUTURES 1060 (2006); David Levi-Faur & Hanna Comaneshter, *The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology*, *in* NEW GLOBAL REGULATORY FRONTIERS IN REGULATION: THE AGE OF NANOTECHNOLOGY 154–55 (Graeme A. Hodge et al. eds., 2007); Gary E. Marchant et al., *Risk Management Principles for Nanotechnology*, 2 NANOETHICS 43, 51 (2008).

45. Marchant et al., *supra* note 44, at 52.

46. *See, e.g.*, Robert Baldwin & Julia Black, *Really Responsive Regulation*, 71 MOD. L. REV. 59, 60–61 (2008); Peter N. Grabosky, *Inside the Pyramid: Towards a Conceptual Framework for the Analysis of Regulatory Systems*, 25 INT. J. SOC. L. 195, 197 (1997); Oren Perez, *Responsive Regulation and Second-Order Reflexivity: On the Limits of Regulatory Intervention*, 44 U.B.C. L. REV. 743, 745–46 (2011); Colin Scott, *Regulation in the Age of Governance: The Rise of the Post Regulatory State*, *in* THE POLITICS OF REGULATION: INSTITUTIONS AND REGULATORY REFORMS FOR THE AGE OF GOVERNANCE 145–74 (Jacint Jordana & David Levi-Faur eds., 2004).

47. Abbott & Snidal, *supra* note 5.

environmental, health, and safety standards.[48] Analyzing the strategic positions of each of the actors, as well as the limitations on their ability to act separately, offers a valuable explanation of the social-political dynamic of standard setting. Still, this theory does not adequately explain the ongoing interaction among the various regulatory schemes that operate simultaneously.

Indeed, while using the regulatory triangle model to analyze global nanotechnology regulations, Abbott et al. found that the most effective form of regulation is formal public-private collaboration. This argument was based on their conclusion that "nearly half of the mechanisms on the triangle are collaborative."[49] However, their analysis focuses on a limited number of nanotechnology oversight initiatives, which do not represent the entire nanoregulatory landscape. Furthermore, it ignores the broader informal collaboration between public and private schemes in the entire regulatory web.

Given the range of models discussed above to promote desired transnational governance outcomes, there is room for further theoretical investigation in the field of nanotechnology regulation. To find the most appropriate model, we must first gain a better understanding of real life interactions among coexisting regulatory arrangements. We need to know what the drivers, mechanisms, and pathways of interactions are, who the leading actors are, at what level they operate, where around the world decisions are made, and how certain norms gain global supremacy over others. The concept of risk governance, which looks at the complex web of actors, the rules they develop, and the mechanisms they employ for collecting, analyzing, and communicating risk information,[50] is valuable for understanding the global nanotechnology regulatory landscape.

III. DATABASE METHODOLOGY AND CLASSIFICATION

The GNRI database is a comprehensive catalogue capturing most nanospecific regulatory initiatives[51] introduced between 2000

48. Kenneth W. Abbott & Duncan Snidal, *The Governance Triangle: Regulatory Standards Institutions and the Shadow of the State, in* THE POLITICS OF GLOBAL REGULATION 44 (Walter Mattli & Ngaire Woods eds., 2009).

49. Kenneth W. Abbott et al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS J. 279, 300 (2012).

50. RENN, *supra* note 4, at 9.

51. Regulatory initiatives are documents that set principles, rules, or laws designed to control or govern conduct. It does not include literature reviews of best practices or policy statements, which do not have a normative call. Regulatory initiatives included in the GNRI database are regulatory programs that address nanomaterial specifically, either as an amendment, supplement, or implementation to existing regulatory programs, or as an

and 2012. The database documents 203 GNRIs led by different organizations, involving data collection, labeling and disclosure, general guidelines, risk management processes, product control, emission standards, and regulatory coordination. These initiatives are taking place at a range of scales, from company and business sector-specific to location-specific (cities, states, and countries; and federal and regional) levels in different regions of the world.

The database was developed by analysis of documents and electronic materials mostly available in English on publicly accessible websites, conducted between October 2009 and December 2012. The data was collected from European countries and the EU, the United States, Canada, Australia, and to the extent possible, from Asian and Middle Eastern countries. It was corroborated using information reported in official Organisation for Economic Co-operation and Development (OECD) reports,[52] the External Liaison Report to the International Organizations for Standardization International Organization for Standardization-Technical Committees (ISO-TC) 229 Nanotechnologies,[53] and other independent reviews such as ObservatoryNANO.[54] The information was collected, filed, and analyzed according to date, the actors involved, the geographic region in which it originated, the aim of the initiative, the level of obligation, the scale of the initiative, and its scope.[55] The results were entered into the database and the analysis is presented below.

It is important to note some limitations of the database. First, there are initiatives taking place that the author could not review due to language or access barriers. Second, the database indicates only when the initiative was first introduced and it does not reflect continuity over time. Third, the database does not make any statements on the effectiveness of the initiatives in achieving their goals.

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independent one. It does not take into account existing regulatory programs that may cover nanomaterials under their regulatory umbrella but have not been adapted for that purpose.

52. *Safety of Manufactured Nanomaterials*, OECD, http://www.oecd.org/env/ehs/nanosafety/ (last visited Dec. 20, 2014).

53. On file with author.

54. ObservatoryNANO Individual Focus Reports, BAX & WILLEMS, http://bwcv.es/observatorynano/observatorynano-individual-focus-reports (last visited Dec. 20, 2014).

55. See full classification and description of the categories in Table 1.

Category	Code	Description
Issued Date	Year	This field includes the year in which the regulatory initiative was introduced for the first time.
Actor Type	Public	Regional, federal, national, state, and local government agencies; inter-governmental organizations.
	Private	Non-governmental organizations—i.e., corporations, industry associations, civil society organizations, and research institutions.
	Hybrid	A combination of both public and private actors.
Geographic Region	Europe North America Australia Asia Middle East Global	Regulatory initiatives introduced by any organization from the region. The Global level includes either international organizations or a multi-region collaboration between organizations.
Regulatory Obligation	Mandatory	Affected organizations have to comply with the rules.
	Voluntary	Relevant organizations can choose to comply with the instructions.
Regulatory Tool	Data Collection	Any requirements (obligatory) or requests (voluntary) by government authorities for information on production, handling, use, risk assessment, control measure methods, and surveillance practices regarding nanomaterials. Such regulatory initiatives can collect existing data, or require or request the gathering and submission of new data. Such data is usually collected to serve as a basis for future regulation or regulatory guidance.
	Labeling & Disclosure	Any requirements, recommendations, or certification systems for labeling products containing ingredients obtained through nanotechnology. It also includes any requirements or recommendations for third party information disclosure regarding nanomaterials, such as preparation of material safety data sheets (MSDSs).
	General Guidelines	Any documents providing general policy principles for risk assessment, risk management, and risk communication of

Category	Code	Description
		nanomaterials or for health surveillance. Such documents may include corporate codes of conduct, regulatory guidelines, etc. The main distinction between these initiatives and the ones classified as "risk management processes" is the level of abstractness or specificity of the regulatory initiative.
	Risk Management Processes	Any requirements or recommendations for a holistic approach to responsible development, handling, use, and disposal of engineered nanomaterials, as well as approaches for occupational health and safety measures. Unlike the General Guidelines documents, which only lay out the principles, these documents provide more elaborate descriptions and technological measures to ensure the safety of products and a safe working environment.
	Product Control	Any requirements or recommendations to restrict, condition, or ban the distribution and use of nano-enabled products or substances in the market. This includes conditional registration, quantity limitations on production and selling, product bans, etc.
	Emission Standards	Any requirements or recommendations for environmental exposure limits, including occupational exposure limits, effluent discharge levels, air and water emission levels, etc.
	Regulatory Coordination	Any regulatory program aiming at facilitating transnational policy coordination.
Regulatory Scope	Occupational Health	Any regulatory initiative targeting the health and well-being of people employed in the work environment.
	General	All industry sectors manufacturing, processing, handling, using, and disposing of nano-objects that may be affected by the regulatory initiative.
	Industrial Chemicals	Any regulatory initiative targeting the manufacture, processing, handling, use, and disposal of chemical substances intended for industrial use other than for agriculture, pesticides, veterinary use, food, drugs, or

Category	Code	Description
		cosmetics.
	Food, Drugs & Cosmetics	Any regulatory initiative targeting the manufacture, processing, handling, use, and disposal of chemical substances intended for use as food additives, therapeutic devices, or cosmetics.
	Agriculture, Pesticide & Veterinary use	Any regulatory initiative targeting the manufacture, processing, handling, use, and disposal of chemicals that can be used to: (a) regulate plant growth; (b) prevent, destroy, or mitigate any pest; or (c) prevent, cure, or alleviate a disease or injury of an animal.
	Textile, Paint & Electronics	Any regulatory initiative targeting the manufacture, processing, handling, use, and disposal of materials used in textile, paint, and electronic devices.
	Consumer Products	Any regulatory initiative targeting the manufacture, processing, handling, use and disposal of commonly-used merchandise (including their components, parts, accessories or packaging) that is ordinarily bought by individuals or households for private consumption (including for domestic, recreational, and sporting purposes).
	Organic Products	Any regulatory initiative targeting the manufacture of products made from organic raw materials (including food, textile, or cosmetics).

Table 1—Database Categories, Codes & Description of Data Collected

IV. OVERVIEW OF FINDINGS

This Part presents the findings from the analysis of the GNRI database. The results are presented in Figures 2 to 7 and Tables 2 to 6 in the Appendix. Note that each initiative is counted only once under the year it was first introduced and under the most appropriate classification in each category.

Figure 2 presents the annual development of total GNRIs between 2000 and 2012. The number of new GNRIs introduced each year is represented by a black line, and the total number of GNRIs

that have been introduced by the end of each year is represented by a grey line. The cumulative numbers do not reflect whether the regulatory initiatives have continuity over time (e.g., short period initiatives such as "calls for information"). Initiatives that expired or have not been fully implemented are still counted as an indication of the extent of regulatory activity. From the cumulative figures it is clear that a considerable effort has been made toward regulating this field. While these data only cover the initial years of nanotechnology regulation and the future may look distinctly different, some early observations can be noted. First, GNRIs, in general, developed slowly between 2000 and 2005. Faster growth in the number of GNRIs released began in 2006 and increased significantly in 2008 (an approximate three-fold increase between 2005 and 2006, and a ten-fold increase between 2005 and 2008). Factors relevant to this increase will be discussed in Part V. Between 2008 and 2012, the number of new GNRIs released annually remained relatively steady, at about 35 new GNRIs every year, suggesting a continual growth of regulatory activity in subsequent years.

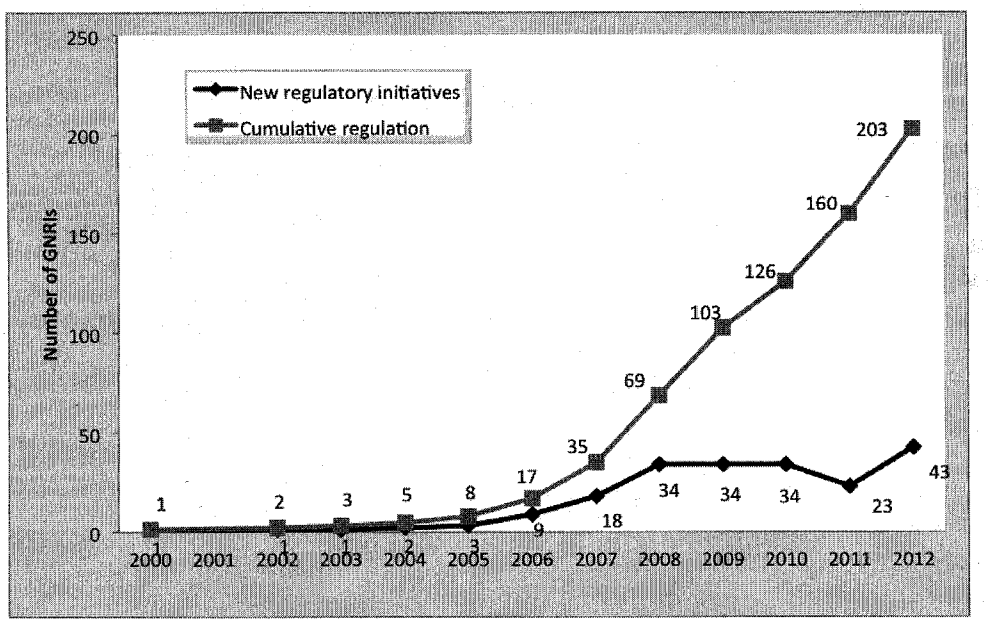

Figure 2—The annual distribution of GNRIs during 2000–2012 by the number of GNRIs introduced in each year (black line) and the cumulative number of total GNRIs introduced in each year (grey line).

Moreover, as indicated in Figure 3, which shows the annual development of new GNRIs (as shown by the black line in Figure 2) separated by actor type, until 2008 private regulation was more dominant, whereas public regulation seems to have emerged mainly after that year. *Prima facie*, the influence of public and private regulators appears relatively equal until 2006, with a major peak in private activity during 2007. De facto, however, Tables 2 and 3, which break down Figure 3 by the regulatory tools implemented and the scope of regulation, show that private actors proactively set up risk management and general guidelines and procedures, with general and occupational safety and health (OSH) scopes. In contrast, public actors lagged behind, focusing on understanding the nature and boundaries of the nanotechnology field through data collection on the nanotechnology industry, substance identification, nanomaterial uses, and quantity of use before taking regulatory action.

It is therefore possible to conclude that the private sector took the first proactive approach and was the driving force for the development of nanotechnology regulation, while the public sector came on board in 2008 taking more of a leadership role thereafter, especially in the areas of industrial chemicals and food, drugs, and cosmetics. Compared with other areas of scientific uncertainty, such as biotechnology and climate change, this trend indicates a shift from government-driven regulation to industry-driven regulation. For example, Auld and Green conclude that, "[A]lthough the climate regime complex had been developing for some twenty years, private authority does not assume a position of prominence until efforts at intergovernmental cooperation hit their first sizeable obstacle."[56] Part V suggests some possible explanations as to why private actors set the regulatory wheels in motion and what led to the shift that occurred in 2008. It also discusses why private regulations tend to focus on OSH and general issues, while public regulations tend to be sector-specific in their scope.

Another interesting observation is the insignificant number of hybrid GNRIs (10), suggesting little formal collaboration between public and private actors during the period in question. This is noteworthy given the growing literature that suggests "nanotechnology should be subject to a mixture of civil, state and

56. Auld & Green, *supra* note 5, at 17; *see, e.g.*, Chris Cocklin et al., *Competitiveness Versus 'Clean and Green'? The Regulation and Governance of GMOs in Australia and the UK*, 39 GEOFORUM 161 (2008) (discussing the central role of public regulation of GMOs in Australia and the UK).

hybrid forms of regulation."[57] Part VI will suggest some possible explanations for the lack of public-private partnerships. Still, as discussed below, this finding does not exclude informal forms of public-private collaboration and reciprocal learning.

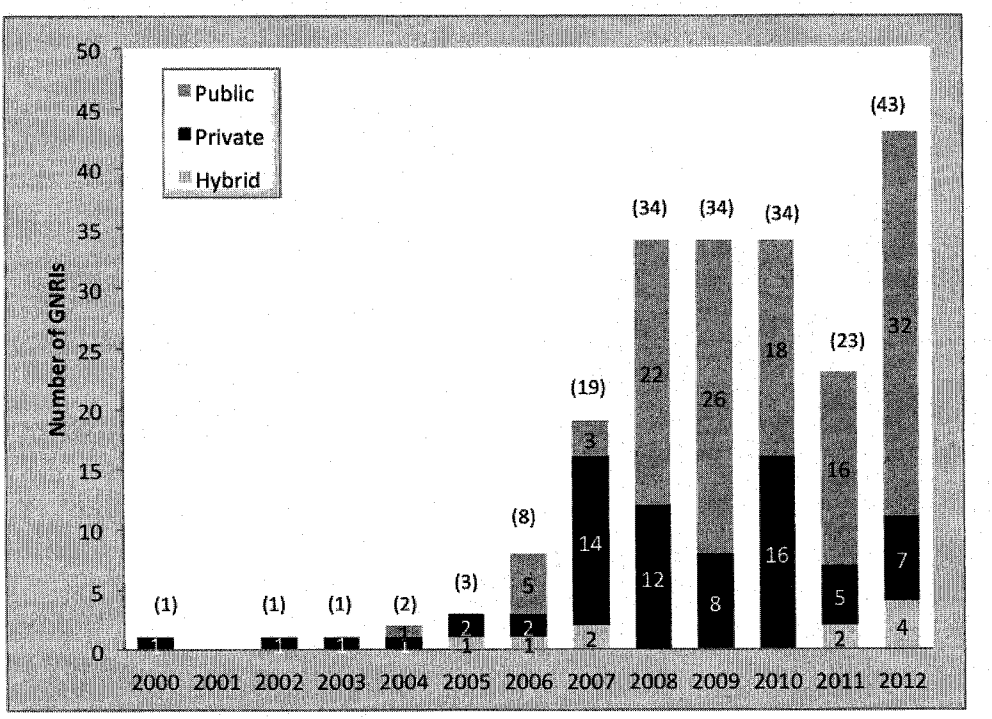

Figure 3—The annual distribution of new GNRIs between 2000 and 2012 separated by actor type (public, private, or hybrid).

The results presented above are at a global scale; however, some geographic regions are more active than others in the development of GNRIs. Figure 4, which shows the geographic regional distribution of GNRIs by the various actors, shows that during the time period examined, Europe (in terms of both public and private action) has been most dominant in advancing new regulatory initiatives (90); followed by North America with 68 regulatory initiatives (mostly led by the public sector). All other regions are considerably less active. Furthermore, Figure 5, which presents the

57. Levi-Faur & Comaneshter, *supra* note 44, at 160; *see, e.g.*, Abbott et al., *supra* note 49, at 300; John Howard & Vladimir Murashov, *National Nanotechnology Partnership to Protect Workers*, 11 J. NANOPARTICLE RES. 1673 (2009).

level of obligation of public GNRIs for each geographic region, indicates that most public regulatory initiatives in Europe are voluntary (60 percent), while in North America there are proportionately more mandatory regulatory initiatives (about 73 percent). Other regions of the world such as Australia, Asia, and the Middle East clearly focus on voluntary mechanisms. This is also the case globally. While this Article only briefly discusses governments' preference to adopt voluntary mechanisms, the author has previously elaborated on this issue elsewhere.[58]

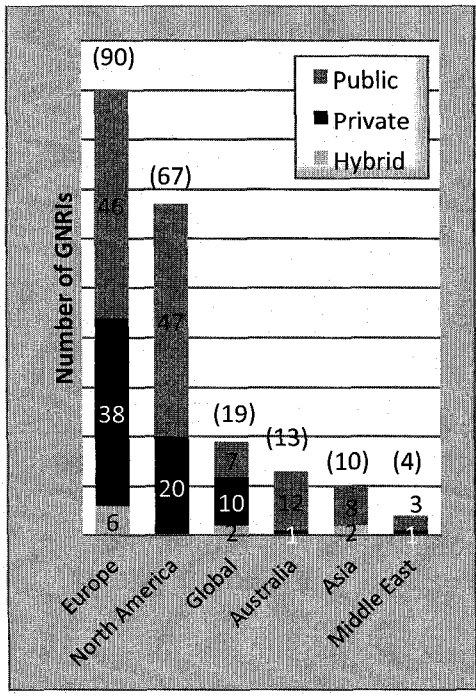

Figure 4—The distribution of total GNRIs between 2000 and 2012 by geographic region (Global, Europe, North America, Australia, Asia and the Middle East), separated by actor type (public, private, or hybrid).

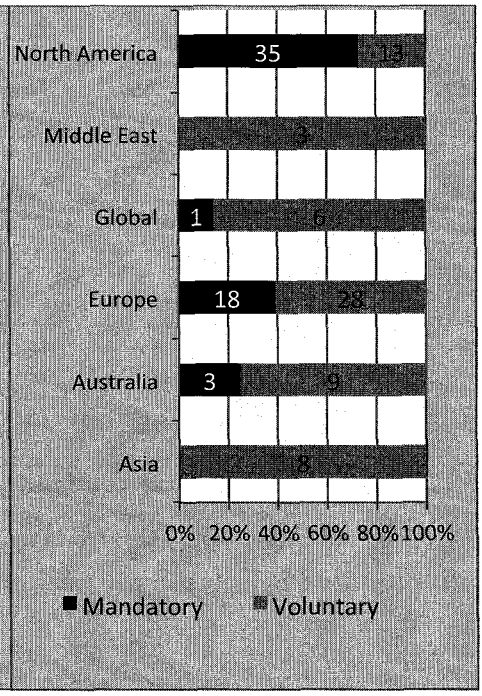

Figure 5—The distribution of total public GNRIs between 2000 and 2012 by geographic region (Global, Europe, North America, Australia, Asia and the Middle East), separated by the level of regulatory obligation (mandatory or voluntary).

58. Reut Snir, *Governance by Disclosure: Transnational Convergence in the Field of Nanotechnology*, 2 TRANSNAT'L ENVTL. L. 69 (2013).

Looking more closely, Figures 6 and 7 and Tables 4–6 highlight the tools and scope of regulation promoted by the various actors in each geographic region. Figure 6, which shows the distribution of total GNRIs developed between 2000 and 2012 by the regulatory tool adopted, indicates that overall, most GNRIs adopted risk management processes (72); followed by data collection (56) and general initiatives (35). Breaking the numbers down by actor type, it is clear that, while most private GNRIs indeed adopted risk management processes (about 61 percent), most public GNRIs adopted data collection tools (about 42 percent) and fewer risk management processes (about 19 percent). Table 4, which breaks down Figure 6 into the geographic regions of GNRIs, further reveals that this trend in actor preference is shared across the globe, particularly in Europe, North America, and Australia. In Asia and the Middle East, however, a slightly different public regulatory approach is preferred, focusing on risk management processes. This finding may suggest a difference in regulatory culture and public-private relationships between Western and Eastern countries.

According to Figure 6, product control, labeling, and disclosure are less frequently used regulatory tools (16 GNRIs each). Overall, private actors prefer labeling and disclosure mechanisms over product control ones while public regulators prefer the opposite. However, Table 4 shows that this finding varies depending on the geographic region. For example, in Australia, Asia, and the Middle East it is the other way around. In fact, only in North America do public actors clearly adhere to traditional product control mechanisms under existing chemicals regulation, and even there the tool is a preliminary one used to drive information gathering.[59] This variance in regulatory tool preference may also suggest differences in regulatory culture and public risk perception between geographic regions.

Next, Figure 6 indicates preliminary efforts to establish emission standards (7 GNRIs). According to Table 4, emission standards have so far been promoted only in Europe (by both public and private actors) and North America (by public actors only). It is also evident from Table 6—which describes the distribution of total GNRIs developed between 2000 and 2012 by regulatory tool, scope, and level of obligation—that these emission standards are focused exclusively on the workplace environment and were published as voluntary recommendations. Nevertheless, as elaborated in Part V, this trend suggests the direction of future regulatory activity.

59. *Id.* at 81–82.

Lastly, Figure 6 shows even less activity in promoting transnational regulatory coordination (beginning only in 2012). This is particularly interesting given that legal scholars on both sides of the Atlantic have expressed concerns that urgent action is required to avoid the regulatory divergence and international trade barriers to nanotechnology.[60] The author elaborates on this point in Part V.

A longitudinal analysis of these results, as presented in Table 2, reveals that globally there was no "tit-for-tat" strategic or incremental development of regulation as suggested by some legal scholars.[61] First, private regulations that adopt general guidelines and risk management processes (commonly referred to as multi-stakeholder norms or self-regulation) have been developed since 2000 without any governmental guidance and before the first data collection initiative was introduced in 2006. Second, mandatory product-control mechanisms under chemical regulations have been in place since as early as 2008, the same year in which the implementation of most data-collection programs began. These trends are observed in both Europe and North America, but less so in Australia, where both private and public actors have been relatively inactive.

One caveat to the last point is that some of these product-control initiatives incorporate in their process a first stage of massive mandatory data collection—with only marginal risk management requirements focusing on personal exposure control—while more substantive control actions come, if at all, only after the data is reviewed.[62] Still, these initiatives prohibit the commercialization of the product subjected to the process until all data is submitted and reviewed. Furthermore, the data-collection component and the risk-management component follow one another and, therefore, have elements of both short and long-term approaches. Thus, these trends indicate a fluid, dynamic evolution between soft and hard law rather than a governmental strategic approach to regulation. They also suggest that a combination of economic and social forces (such as public pressure and market competitiveness),

60. *See, e.g.*, LYNN BREGGIN ET AL., SECURING THE PROMISE OF NANOTECHNOLOGIES: TOWARDS TRANSATLANTIC REGULATORY COOPERATION (Chatham House 2009), *available at* http://eprints.lse.ac.uk/25425/1/Securing_the_promise_of_technologies_towards_transatlantic_regulatory_cooperation(LSERO).pdf; Matthew Kearnes et al., *From Bio to Nano: Learning Lessons from the UK Agricultural Biotechnology Controversy*, 15 SCI. AS CULTURE 291 (2006); Michael D. Mehta, *From Biotechnology to Nanotechnology: What Can We Learn from Earlier Technologies?*, 24 BULL. SCI. TECH. & SOC. 34 (2004); Debra M. Strauss & Melanie C. Strauss, *Globalization and National Sovereignty: Controlling the International Food Supply in the Age of Biotechnology*, 15 J. LEGAL STUD. BUS. 75 (2009).

61. *See supra* text accompanying note 47.

62. *See* discussion *infra* Part V.B.4.b.

and not pure risk-based legal logic, drove the development of GNRIs. Finally, they imply that risk-based approaches to regulation might not be sufficient (or even desirable) to oversee the development of emerging technologies under scientific uncertainty.

In terms of the scope of regulation, Figure 7, which shows the distribution of total GNRIs developed between 2000 and 2012 according to their regulatory scope, indicates that globally, both public and private actors are most interested in occupational-health related issues (76). The next most common issues are industrial chemicals (53) and general applications (39), both of which are mainly driven by public regulators, followed by initiatives related to food, drugs, and cosmetics (18), which are almost exclusively European and public-led. Finally, other areas of concern are: agriculture, pesticide, and veterinary use (5); textile, paint and electronics (4); consumer products (3); and organic products (3), with a mix of public and private regulation.

Nevertheless, Table 5, which breaks down Figure 7 into the geographic regions of GNRIs, shows that while private GNRIs across the globe are indeed focused on occupational health issues, the public GNRI scope varies between regions. For example, in Europe, most public activity is focused on food, drugs, and cosmetics applications; in North America, it is focused on industrial chemicals; and at the global level, on general applications. In addition, Table 6 indicates a relatively significant number of mandatory GNRIs for industrial chemicals (16) and food, drugs, and cosmetics (12)—adopting various regulatory tools, including data-collection, product control, and labeling and disclosure. These trends may suggest differences in public risk perception and regulatory culture between geographic regions, which drive regulatory activities in different sectors. They may also relate to each region's historical experience with harmful exposure or concerns about harmful exposure that have been publicized in the media, leading to pressure on governments to regulate in different areas. For example, the European experience with the epidemic of madcow disease in the mid-80s influenced European public opinion on GMO food, on the one hand;[63] and the US experience with recurring adverse outcomes of environmental exposure incidents such as Love Canal, Times Beach, asbestos, polychlorinated biphenyls (PCBs), and others influenced US public

63. *See, e.g.*, Lisbet Berg, *Trust in Food in the Age of Mad Cow Disease: A Comparative Study of Consumers' Evaluation of Food Safety in Belgium, Britain and Norway*, 42 APPETITE 21, 21 (2004).

opinion on industrial chemicals, on the other hand.[64] The lack of private activities in areas such as food, drugs, and cosmetics, in which public regulators have been relatively active, is also noteworthy. The food and drug industries' inexperience with self-regulation might explain this. However, it is a surprising finding for the cosmetics industry given their long-lasting tradition of self-regulation combined with the strong public demand to ban the use of nanomaterials in cosmetics products.

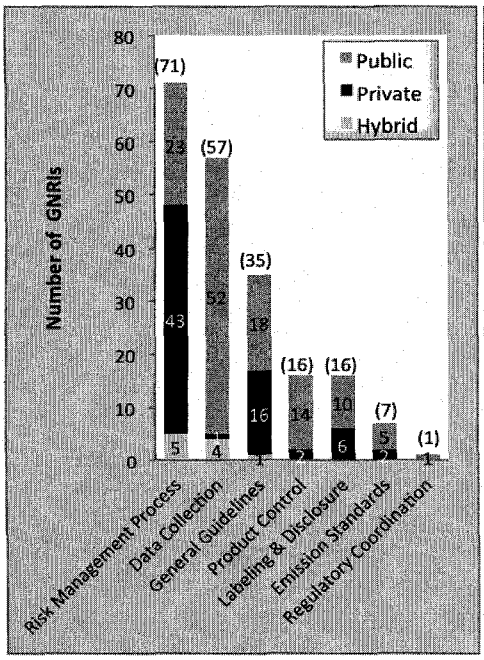

Figure 6—The distribution of total GNRIs between 2000 and 2012 by regulatory tool (Risk Management Process, Data Collection, General Guidelines, Product Control, Labeling & Disclosure, Emission Standards, and Regulatory Coordination), separated by actor type (public, private, or hybrid).

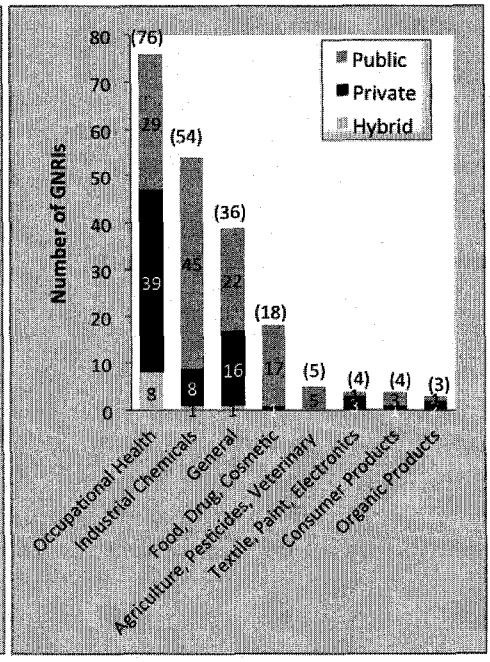

Figure 7—The distribution of total GNRIs between 2000 and 2012 by regulatory scope (General, Occupational Health, Industrial Chemicals, Food, Drugs & Cosmetics, Agriculture, Pesticides & Veterinary Use, Textile, Paint & Electronics, Consumer Products, and Organic Products), separated by actor type (public, private, or hybrid).

64. *See, e.g.*, John M. Gillroy & Robert Y. Shapiro, *The Polls: Environmental Protection*, 50 PUB. OPINION Q. 270, 270 (1986).

Viewed together, it is evident that the strongest trend in GNRI development between 2000 and 2012 was the growth in initiatives addressing risk management processes in occupational settings. It is also evident that the leading force for such regulations was the private sector, which was more active until 2008, the year when public sector activity finally began. This was followed by significant public interest in industrial chemicals and food, drug, and cosmetics applications. These are potentially due to public pressure and previous experience with technological problems. Furthermore, the difference in regulatory approaches adopted by each actor is noticeable. While the private sector has been focused on developing practical risk management mechanisms and general guidelines from the very start, the public sector appears to have been more hesitant, initially focusing on data collection. Still, growing public activity in the area of industrial chemicals and food, drugs, and cosmetics, as well as in setting emission standards for the workplace, indicates the direction that more substantive formal regulation will take.

V. DISCUSSION OF THE GLOBAL REGULATORY TRENDS

This Part turns to a more detailed discussion of the trends in the development of nanotechnology regulation before and after the turning point in 2008, highlighting several regulatory initiatives and the role they played in shaping the global landscape of nanotechnology regulatory norms. Attention is given to both the regions and type of actors from which these initiatives originate, highlighting trends in policy diffusion around the world and between types of actors. This Part also suggests some explanations for: (1) the emergence of private regulation in an unregulated domain and the shift that occurred in 2008; (2) the dynamics between public and private regulations; (3) the overall lack of formal public-private partnerships; and (4) the differences in EHS risk regulation approaches across the globe.

A. Trends Until 2008: The Private Regulation "Big Bang"

1. Deliberation First: Third Party Codes of Conduct for Responsible Development

Think-tanks and other third-party private organizations first raised the issue of responsible development of nanotechnology and developed codes of conduct (CoCs) to direct companies in assessing

and managing the risks of nanomaterials.[65] These were developed through a multi-stakeholder deliberative process and are characterized by a holistic approach that examines the entire life cycle of product manufacture, handling, use, and disposal. These initiatives sent the first signal to both industry and regulators that, in order to realize the potential of nanotechnology, applications should be developed in a socially and environmentally responsible manner. Their main goal was to inspire the development of self-regulation in a responsible way according to certain principles and procedures.

For example, in 2000, the Foresight Institute, a US-based think-tank focused on transformative future technologies, introduced their draft *Guidelines for Responsible Nanotechnology Development*.[66] These guidelines were based on analysis and discussions starting in the late 1970s, when K. Eric Drexler first brought to public attention the profound impact that these future technologies could have on the human condition.[67] The guidelines include assumptions, principles, and some specific recommendations intended to provide a basis for the responsible development of nanotechnology. The goal was for the guidelines to be adopted by organizations sponsoring nanotechnology research and development projects, and to inspire effective self-regulation.[68] Over the years, the guidelines were modified and revised and their latest version (the sixth) was released in 2006.[69] According to some commentators, while not having a direct impact on nanotechnology regulation, the guidelines have been effective in raising awareness and fostering debate on nanotechnology regulation, particularly with respect to ethical concerns related to self-replicating autonomous nanodevices.[70] Other examples exist to support the NGOs' influence on driving nanotechnology regulation, in which a key element was transparency about the nanomaterial content in the product.[71]

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65. *See, e.g.*, NANOACTION PROJECT, INT'L CTR. FOR TECH. ASSESSMENT, PRINCIPLES FOR THE OVERSIGHT OF NANOTECHNOLOGIES AND NANOMATERIALS (2007), *available at* http://www.centerforfoodsafety.org/files/final-pdf-principles-for-oversight-of-nanotechnologies_80684.pdf; Neil Jacobstein, Foresight Inst., Foresight Guidelines for Responsible Nanotechnology Development (draft version 6) (Apr. 2006), *available at* http://www.foresight.org/guidelines/ForesightGuidelinesV6.pdf.

66. Jacobstein, *supra* note 65, at 14.

67. *Id.*

68. *Id.*

69. *Id.*

70. Abbott et al., *supra* note 49, at 287.

71. *See, e.g.*, NANOACTION PROJECT, *supra* note 65, at 3.

2. The Response to Public Demand for Disclosure: Product Information Communication

As the prospect of commercialization of nanotechnology became more realistic, the importance of ethics in the development grew. Consequently, both proponents and opponents of nanotechnology have called for more transparency and information disclosure on the products. In response, since 2004, governments in several Asian countries and third-party organizations in Europe began developing voluntary certification schemes that ensure the quality or safety of the product. While some of the disclosure and labeling schemes indeed attempt to provide a certain level of assurance on the safety of the product, many have instead aimed to address the risk of fraud and abuse in selling and marketing products. This indicates that these governments are generally in favor of nanotechnology and are thus implementing market controls to ensure product effectiveness rather than to control EHS risks.

a. Product Quality Certification and Labeling

In 2004, the Taiwan Industrial Development Bureau (IDB) and Ministry of Economic Affairs (MOEA) entrusted the Industrial Technology Research Institute (ITRI) Center for Measurement Standards (CMS) with executing the "Nano-product Certification System Plan"—nanoMark.[72] The goal of nanoMark is to build "nano brand" credibility through the confirmation of the new functions generated due to the nanoscale. In this manner it intends to highlight quality products and promote competition in the market. According to the center's website, obtaining the nanoMark certification can help companies enhance their corporate image, gain customer trust, and promote market sales—including increasing the selling price of their products by 20 percent.[73] From 2004 to August 2013, the Taiwan nanoMark Certification System certified 1,257 products from thirty-seven companies. This certification approach was followed by several similar schemes introduced in other countries around the world such as the Hohenstein Quality Label (2005) and Quality Seal Nano-Inside (2008) in Germany, the Nano Mark Certificate in Iran (2009),[74] and the NanoQ in Thailand (2011).

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72. *Introduction*, NANOMARK, http://www.nanomark.org.tw/Eng/About/ (last visited Dec. 20, 2014).

73. *Id.*

74. From a global market perspective, it is interesting to note that unlike its counterparts, the Iranian Nano Mark Certificate is mandatory for government-funded applications. This requirement is somewhat puzzling given that it is related to positive labeling,

These schemes, however, focus on the accuracy of the manufacturer's claims on the product label with respect to the incorporation of nanoparticles in the product, and only to a lesser extent, if at all, on the life-cycle implications of the products. Therefore, they should be best viewed as efforts to promote local and global commercialization of nanobased products. In subsequent years, these initiatives may find themselves competing with other product labeling schemes on the accepted global approach to labeling of nano-enabled products.

b. Product Risk Management Certification

A different approach has been applied in Europe, where in 2006, the German TÜV SÜD and the Swiss Innovation Society have introduced CENARIOS®, a full certifiable risk management and monitoring system specifically adapted to nanotechnologies.[75] CENARIOS® provides a "structured methodology for the industry and commercial enterprises to identify, analyze, and assess potential risks and opportunities in products and processes."[76] It combines the elements of traditional risk assessment and analysis with future-oriented risk monitoring and communication tools specifically adapted to the characteristics of new technologies. The first company granted CENARIOS® certification was Bühler Partec in 2007.[77]

More recently, TÜV SÜD and the Innovation Society have also started offering additional services such as a NanoRisk Check, which gives companies an overview of their risk position regarding the handling and use of nanomaterials in products.[78] It is unclear whether this initiative has taken off at all and whether its semi-quantitative risk assessment module has been adopted by others. Still, it implies that, even with the lack of current scientific data regarding the actual risks of nanomaterials, it is possible to prioritize levels of risks and respond to them accordingly. Therefore, it serves as a pioneering example for a precautionary regulatory approach to deal

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which is in the economic interest of the developer and allegedly does not require a government regulatory intervention. Tsung-Tsan Su, Presentation at the Plenary of ISO/TC 229 14th Meeting, *ISO/TC 229 ANF Liaison Report*, at slide 5 (June 11–15, 2012) (on file with author).

75. Fact sheet, *CENARIOS® Certifiable Nanospecific Risk Management and Monitoring System*, INNOVATION SOC. & TÜV SÜD (2006), http://innovationsgesellschaft.ch/wp-content/uploads/2014/10/Factsheet_CENARIOS_english.pdf.

76. *Id.* at 3.

77. Bühler AG, *Bühler Partec's Risk Management System Certified*, NANOWERK NEWS (Sept. 11, 2007), http://www.nanowerk.com/news/newsid=2544.php.

78. *NanoRisk Check—The Risk Screening*, TÜV SÜD, http://www.tuev-sued.com/uploads/images/1213944684881447630384/NanoRiskCheck_e.pdf (last visited Dec. 20, 2014).

with scientific uncertainty by employing proxy variables that refer to the nature of the hazardous characteristics of nanomaterials.

3. Industry Going Green: Self-Implementation of Risk Management Programs

During the early years, large organizations also took up the gauntlet and started developing in-house approaches to responsible development of nanotechnologies. These approaches include best-practices guidelines for working safely with nano-objects as well as CoCs and product stewardship programs covering the following: protection of employees, customers and business partners; protection of the environment; participation in safety research; and open communication and dialogue. By doing so, the industry sent a strong signal to both the public and regulators that the nanotechnology industry is up for the challenge and wants to get the technology right. This is a twenty-first century industry that has learned the lessons of historical failures.

Over the years, such self-regulatory initiatives account for at least 25 percent of the total number of GNRIs.[79] Note that not all companies dealing with nanomaterials publish their internal activities for promoting safe working environments on their websites. It is thus likely that some initiatives at the company level have not been included in the database and their actual number may be even higher.

a. Life-Cycle Risk Management Framework

The first organization to develop an in-house holistic risk management approach tailored specifically to the development of nanomaterials was Luna Innovations Inc., a US-based business focused on developing and manufacturing new-generation products for the healthcare, telecommunications, energy, and defense markets.[80] In 2003, Luna introduced its NanoSAFE program, a best-practices approach to minimizing EHS risk in nanotechnology manufacturing based on a five-point strategy that includes: facility management, product stewardship, workforce protection, environmental management, and emerging technologies and strategies.[81] It was the first effort by a private company to strategically assess and manage

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79. *See supra* Part IV.

80. *About Luna*, LUNA, http://lunainc.com/about-luna/ (last visited Dec. 20, 2014).

81. Matthew Hull, *Nanotechnology Risk Management and Small Business: A Case Study on the NanoSafe Framework*, *in* NANOTECHNOLOGY ENVIRONMENTAL HEALTH AND SAFETY: RISKS, REGULATION AND MANAGEMENT 248 (Matthew Hull & Diana Bowman eds., 2010).

the environmental, health, and safety implications of its nanotechnology-related activities along the life cycle of the product.

Some explanation of the early actions by the private sector can be found in *EHS Today*'s interview with the developer of the NanoSAFE program in 2005:

> The proactive aspect of NanoSAFE is as much about good business sense as it is about environmental and human health and safety. Hull explained that NanoSAFE is driven by the business need to prepare for the federal safety and environmental nanotechnology standards that are sure to come sooner or later. For those companies that aren't ready when federal regulators get a handle on nanotechnology, the cost of compliance could be steep.[82]

Thus, it is clear that at least some firms see self-regulation that goes beyond compliance as a risk mitigation strategy that makes good business sense. As discussed earlier, such EHS stewardship programs may prepare firms for "rainy days"—not only in case of future government regulations but also in case of future liability for harm to public health and the environment. Reducing risk amid regulatory uncertainty allows companies to lower their economic and political liabilities by showing that they did their best to prevent harms.[83]

In the same year, another well-known risk management process scheme—the NanoRisk Framework—was introduced by DuPont, a large US-based chemical company, and Environmental Defense Fund (EDF), a US-based environmental NGO.[84] In 2005, the heads of both organizations jointly stated in the *Wall Street Journal*: "An early and open examination of the potential risks of a new product or technology is not just good common sense—it's good business strategy."[85] Following this statement, the collaboration between the two organizations yielded a risk assessment and management guide that provides a procedure for the development of data profiles of nanomaterials properties, inherent hazards, and exposure potential.[86] The procedure is based on six steps: describe material and expected application; profile life cycles; evaluate life cycle risks; assess risk management; decide, document, and act; and review and adapt.[87]

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82. Josh Cable, *A Best Practices Approach to Minimizing EHS Risk in Nanotechnology Manufacturing*, EHS TODAY (Oct. 6, 2005), http://ehstoday.com/news/ehs_imp_37825.

83. *See supra* Part II.B.

84. Project Archive, *DuPont–Safer Nanotech*, EDF + BUSINESS, http://www.nanoriskframework.com (last visited Dec. 20, 2014).

85. Fred Krupp & Chad Holliday, *Let's Get Nanotech Right*, WALL ST. J., June 14, 2005, http://www.edf.org/sites/default/files/5177_OpEd_WSJ050614.pdf.

86. *See* Project Archive, *supra* note 84.

87. *Id.*

Here again, going beyond compliance is this top firm's business strategy: adopting such a risk management program provides DuPont with a better competitive position based on its environmental quality operations, their open relationship with communities and others, and the environmental attributes of their products. As discussed above, such a business strategy goes beyond risk mitigation to gain market share and creates a positive public image, which will enhance the company's long-term business success.[88] This move, with all the substantive resource investment it implies, makes a lot of business sense given the amount of public criticism DuPont has faced for endangering the health of both its employees and the public in previous years.[89]

Subsequently, the NanoRisk Framework served as the starting point for an ISO technical report on Nanotechnologies—*Nanomaterial Risk Evaluation*, published in 2011.[90] While it has undergone some changes during the ISO negotiations, the basic logic behind the NanoRisk Framework is retained in the ISO document. In turn, the ISO document was adopted (or is in the process of being adopted) as a national standard by various countries.[91] This development shines a light on additional potential drivers for the nanotechnology industry to go beyond compliance. It demonstrates the power of a "first mover" to influence global regulatory norms that are later adopted by national governments. In this way, DuPont may ultimately raise the cost of entry for its rivals.

b. Occupational Safety and Health Best Practices

Approaches to overseeing OSH issues have proliferated in the past few years. Between 2000 and 2007, OSH GNRIs accounted for about 52 percent of total GNRIs developed, of which about 71 percent were private-led. Given that the workplace has historically been where the highest levels of exposure to chemical agents occur, focusing initial efforts on OSH appears to be adaptive to past experience. Examples of such regulatory initiatives are numerous and include Texas A&M Engineering (2005), BASF (2006), and Bayer (2007),

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88. *See supra* Part II.B.

89. Corporate Profile of *DuPont (E.I. DuPont de Nemours and Company)*, CORPORATE WATCH (Nov. 2002), http://www.corporatewatch.org/?lid=170.

90. ISO, *Nanotechnologies—Nanomaterial Risk Evaluation*, ISO/TR 13121:2011 (May 12, 2011).

91. *See, e.g.*, BUREAU OF INDIAN STANDARDS, DRAFT INDIAN STANDARD: NANOTECHNOLOGIES—NANOMATERIAL RISK EVALUATION MTD 33 (5110) (2011) (noting that the draft Indian Standard is "identical with ISO/TR 13121:2011 'Nanotechnologies—Nanomaterial risk evaluation' issued by the International Organization for Standardization (ISO)").

which played a leading role in developing best practices at the organizational level.

The self-regulatory mechanisms introduced by businesses and other private organizations did not necessarily invent new ways of managing workplace risks; rather, the new mechanisms relied primarily on EHS programs already implemented by the organization, adapting the procedures to address the new materials. When developing new materials, there is always a level of uncertainty regarding potential EHS risks, and programs include mechanisms to address this knowledge gap. The same process is also applied to nanomaterials, although the margin of safety and the precautionary measures that are applied for each material may change based on professional judgment regarding the likelihood of the risk. Such professional judgment may later become the subject of negotiation when developing national and international risk management approaches that are often reliant on industry best practices.

While some firms and academic institutions were moving forward, not waiting for the advice of government agencies, there was a growing demand by the broader nanotechnology community for an authoritative guideline on approaches to safe nanotechnology. To address this call, the US National Institute for Occupational Safety and Health (NIOSH) published a non-policy information exchange on approaches to safe nanotechnology in 2005.[92] This document was out in draft form for four years, during which it was revised several times, and in 2009 the agency's official recommendations were published.[93] NIOSH was followed by other agencies such as the US Department of Energy, which set guidance for its in-house research labs.

4. Public-Private Partnership: The Way to Go?

In light of the spontaneous and informal collaborations that have started to intertwine public and private actors in setting regulatory initiatives to address market needs, the question that comes to mind is whether partnerships and coregulations are the best way to go. The early days of collaborations between private companies or industry associations and government agencies have yielded some

92. Dept. of Health & Human Servs., U.S. Nat'l Inst. for Occupational Safety and Health (NIOSH) & Ctrs. for Disease Control (CDC), Approaches to Safe Nanotechnology: An Information Exchange with NIOSH, (Oct. 1, 2005), *available at* http://www.cdc.gov/niosh/topics/nanotech/pdfs/Approaches_to_Safe_Nanotechnology.pdf.

93. DEPT. OF HEALTH & HUMAN SERVS, U.S. NAT'L INST. FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH) & CTRS. FOR DISEASE CONTROL & PREVENTION, APPROACHES TO SAFE NANOTECHNOLOGY: MANAGING THE HEALTH AND SAFETY CONCERNS ASSOCIATED WITH ENGINEERED NANOMATERIALS (2009), *available at* http://www.cdc.gov/niosh/docs/2009-125.

important lessons, which highlight the benefits and limitations of hybrid initiatives. For example, in 2005, the Nanoparticle Occupational Safety and Health (NOSH) Consortium was formed by a group of sixteen members—including multi-national corporations (such as DuPont, Dow Chemical, Intel, and Boeing), government agencies from the US (NIOSH) and the UK (HSE), and NGOs (such as EDF)—to "answer specific questions which would benefit a broad global audience in terms of helping to define what would be best practice to protect workers with respect to handling engineered nanoparticles."[94] The consortium's objectives were to develop a portable aerosol monitor and a test method to measure filtration efficiency for commercially available filter media.[95] In addition to meeting its objectives, the consortium is regarded as a successful approach to transatlantic public-private collaboration:

> [T]he NOSH Consortium has been viewed by a wide audience to be an excellent demonstration of the technical and professional progress that can be achieved as part of a *successful collaboration between diverse and interested professionals.* The fact that the NOSH Consortium was able to *identify common goals, navigate through complex technical results, and find common ground to present findings to the technical community* is a testament to the value of people working together to achieve exciting results.[96]

This statement raises questions about what made this collaboration successful and why the GNRI landscape is not abundant with such initiatives. While the motivation to enroll and to invest substantial resources in such collaboration sounds simple—common goals—it hides a "tacit understanding" of the interests that drive both public and private actors. Methods to monitor exposure and determine filtration efficiency are essential for the development of technology-based emission standards. Such standards are often developed based on industrial best practices.[97] In emerging fields, the industry may not have experience in all aspects necessary for regulation; thus, these best practices are not fully developed.

Public regulators need the industry's money and expertise in order to develop best practices. This explains the motivation for public regulators' involvement in such a project. Large businesses, on the other hand, have a strategic business interest in being a "first

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94. Nanoparticle Occupational Safety and Health (NOSH) Consortium, Executive Summary, at 1 (Dec. 13, 2007), *available at* http://www.hse.gov.uk/nanotechnology/consortiumsummary.pdf.

95. *Id.*

96. Michele L. Ostraat, *Industry-Led Initiative for Occupational Health and Safety*, *in* NANOTECHNOLOGY ENVIRONMENTAL HEALTH AND SAFETY: RISKS, REGULATIONS AND MANAGEMENT 234 (Matthew Hull & Diana Bowman eds., 2010) (emphasis added).

97. Timothy F. Malloy, *Soft Law and Nanotechnology: A Functional Perspective*, 52 JURIMETRICS 347, 352 (2012).

mover." Regulation that adopts technically-based emission standards using a business's in-house technology saves the business money in new control-technologies implementation and puts it in a better position compared to its competitors. This explains the motivation for private firms' voluntary investment of substantial resources in such a project.

Thus, although the interests of the partners might be different, understanding and agreeing to pursue other partners' interests makes the partnership successful. It is the economic, social, and political forces, not "the value of people working together," that attract interested stakeholders to come together and yield a technical consensus in a contested field. Today, the ambivalent nature of technical matters and the value-laden nature of the consensus process of technical matters are widely understood.[98] Statements on the success of the technical consensus process should therefore be read with more scrutiny, as there is often a tacit understanding underlining public-private collaboration and the consensus may benefit some more than others.[99] Thus, while broad stakeholder collaboration may be ideal from a governance normative point of view, it does not always make business or political sense—the "free rider dilemma"—and it is definitely not a commonplace practice.

This conclusion can be supported by reviewing another collaborative effort in this area. In 2006, the German Federal Institute for Occupational Safety and Health (BAuA) and the German Chemical Industry Association (VCI) jointly collected data on methods currently applied in chemical industry OSH for the handling and use of nanomaterials.[100] This survey resulted in the joint publication of

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98. The neutrality of technical matters has been challenged by many academic studies that deconstruct the process in which "scientific facts" have been produced and consolidated, showing how the result was influenced by social and political judgment. This was also acknowledged by those involved directly with producing them. *See, e.g.*, SHEILA S. JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 229 (1990) (noting that they are "aware that what they are doing is not 'science' in any ordinary sense, but a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgment").

99. Another example is the OECD's Working Party of Manufactured Nanomaterials (WPMN) Sponsorship Programme for the Testing of Manufactured Nanomaterials (SPTMN), which funds the safety testing of a priority list of thirteen manufactured nanomaterials which are already in use or will be soon, for an agreed list of endpoints. The outcomes of this Sponsorship Programme will provide information on the "intrinsic properties" that determine the appropriate risk evaluation and management strategies. *See Sponsorship Programme for the Testing of Manufactured Nanomaterials*, OECD, http://www.oecd.org/science/nanosafety/sponsorshipprogrammeforthetestingofmanufacturednanomaterials.htm (last visited Dec. 20, 2014).

100. *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*, BAUA: BUNDESANSTALT FÜR ARBEITSSCHUTZ UND

the *Guidance for Handling and Use of Nanomaterials at the Workplace*, which contains recommendations and operating instructions for handling nanomaterials.[101] After a second survey, it was updated in 2012 by the new *Recommendations for the Risk Assessment for Activities Involving Nanomaterials in the Workplace*.[102]

In this series of initiatives, however, the public-private collaboration was between a regulatory agency and a business association, not individual private businesses. Thus, the regulated businesses were not directly involved in developing the recommendations and have less influence over the negotiation process. This may result in less motivation for businesses to participate in the data collection program. Indeed, of the 656 businesses approached to answer the survey, the return rate was 33 percent, of which 79 percent claimed not to have performed any activities involving nanomaterials.[103] Thus, despite the hybrid nature of the regulatory initiative, the involvement of a business representative in the design and implementation of the program, and the relatively non-burdensome data request (businesses were not asked to generate new information), the participation rate was low. There was no strategic business incentive for firms to participate, partially because the survey was anonymous and firms undertaking efforts regarding nanotechnologies would not even be recognized for such activities.

Beginning in 2007, the outcomes of national and international standard-setting bodies' work in the field of nanotechnology became more evident. Nanotechnology-specific technical committees have been established within many standardization bodies around the globe since 2005, but they only started releasing documents in 2007. In the area of ESH, the first to publish a guidance document was the American Society for Testing and Materials (ASTM) International with its *Standard Guide for Handling Unbound Engineered Nanoparticles in Occupational Settings*.[104] It was followed by the British Standards Institution (BSI), which published

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ARBEITSMEDIZIN (Apr. 24, 2008), http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/survey.pdf [hereinafter *Exposure to Nanomaterials in Germany*].

101. *Guidance for Handling and Use of Nanomaterials at the Workplace*, BAUA: BUNDESANSTALT FÜR ARBEITSSCHUTZ UND ARBEITSMEDIZIN (Aug. 12, 2007), http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/guidance.pdf?__blob=publicationFile&v=2.

102. *Nanotechnology*, BAUA: BUNDESANSTALT FÜR ARBEITSSCHUTZ UND ARBEITSMEDIZIN, http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/Nanotechnology.html (last visited Dec. 20, 2014) (providing link to updated 2012 report in German).

103. *See Exposure to Nanomaterials in Germany*, *supra* note 100.

104. ASTM Int'l, *Standard Guide For Handling Unbound Engineered Nanoscale Particles in Occupational Settings*, E2535-07 (2007) (reapproved 2013).

Nanotechnologies—Part 2: Guide to Safe Handling and Disposal of Manufactured Nanomaterials.[105] A year later, in 2008, the ISO published its technical report, *Nanotechnologies—Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies.*[106]

While regulatory initiatives issued by standardization bodies are mostly classified as private regulatory initiatives in the GNRI database (unless the legal structure of the specific national body is public or hybrid), there are hybrid attributes to the consensus process that are worth noting in this context. All of these regulatory initiatives have an open, voluntary, and consensus based process through which they have been developed; and the negotiations were done by designated experts from multiple stakeholders representing public, private, civil society, or academic organizations, under the orchestration of the standard-setting body's secretariat. The negotiation process follows strict procedural rules set by the standard-setting body, which aim to facilitate an open dialogue with a consensual outcome. Over the years, such organizations have become very influential players in transnational governance, awarding them the title of "The New Global Rulers."[107] *Prima facie*, such a rule-making framework represents an ideal model for public and private collaboration; de facto, however, many scholars have criticized these organizations for being captured by Western countries' industry interests and for not allowing a "real" equal opportunity to participate in the standard-setting process. Their effectiveness at promoting societal goals has therefore been challenged.[108] Nevertheless, they have promoted progressive precautionary risk management approaches to deal with the current lack of scientific knowledge, each in its own way.[109] Therefore, public-private partnerships are successful if both parties have a tangible incentive to participate. If

105. British Standards Inst. [BSI], *Nanotechnologies—Part 2: Guide to Safe Handling and Disposal of Manufactured Nanomaterials*, PD 6699-2:2007 (Dec. 2007).

106. ISO, *Nanotechnologies—Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*, ISO/TR 12885:2008 (2008).

107. *See* BÜTHE & MATTLI, *supra* note 32; *see also*, BRAITHWAITE & DRAHOS, *supra* note 37.

108. *See, e.g.*, Jennifer Clapp, *The Privatization of Global Environmental Governance: ISO 14000 and the Developing World*, 4 GLOBAL GOVERNANCE 295 (1998); Robert W. Hamilton, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329 (1977); Spencer J. Henson, *The Role of Public and Private Standards in Regulating International Food Markets*, 4 J. INT'L AGRIC. TRADE & DEV. 63 (2007).

109. *See, e.g.*, ISO, *Nanotechnologies—Nanomaterial Risk Evaluation*, *supra* note 90, § 7.3.5. ("[I]n situations where there is risk uncertainty, a precautionary approach (i.e. assuming higher levels of risk) should be utilized.").

they do not, any such partnership is likely to be ineffective, or worse, not representative of all interests.

5. Closing Data-Asymmetry: Data Collection Programs

During the first phase of regulation, public regulators kept relatively quiet. Initially, governments' focus was on acquiring information for their various needs, including obtaining an overview of the nanotech industry or workplace condition, obtaining available data for risk assessment and risk management purposes, guiding research programs, and supporting the development of new policy. Most programs required information only regarding existing basic information on the company, substance identification, use, and quantity of use. Some initiatives also requested more specific information such as substance characterization, physical-chemical properties, effects, fate and behavior, measurement and detection techniques, and risk management practices.[110] Nevertheless, such programs sent a signal to both industry and the public that the government is in the picture and is likely to act upon any finding of actual risk for human health or the environment. These programs received a significant boost in 2008 and continued to grow thereafter.[111]

B. Trends after 2008: Public Regulation Enters High Gear

In 2008 and thereafter, private organizations maintained their rate of introduction of workplace safety measures, CoCs and life-cycle risk management processes of nanomaterials. On the other hand, there was a dramatic increase in activities in the public sector. Although most of the public regulatory initiatives after 2008 still focus on data collection, there are some efforts in other directions such as risk management processes, regulatory guidance, product labeling, product control and codes of conduct.[112]

This awakening could have been the result of various factors acting together and independently. First, it is likely that some bottlenecks opened up after 2008 when public initiatives that had

110. Org. for Econ. Co-operation & Dev. [OECD], *Analysis of Information Gathering Initiatives on Manufactured Nanomaterials*, ENV/JM/MONO(2009)45 (Nov. 24, 2009).

111. *See infra* Part V.B.1.

112. The author discusses this light-touch government approach—"governance-by-disclosure"—elsewhere, explaining why governments worldwide have been slow in promoting regulations in the field of nanotechnology and why they tend to focus on information disclosure mechanisms. The author further explains why data collection approaches have been similar around the world and that when implementing other regulatory tools, a greater diversity can be expected and indeed observed. *See* Snir, *supra* note 58.

been in the pipeline for a long time finally came into effect. This may also explain the private sector's early expectation for future regulation and its desire to make the first move. Second, as public awareness of nanotechnology and its potential implications grew over the years, so too did public demands for governments to oversee nanotechnology development. Third, in the early years, nanotechnology was still at the research and development stage and the ability to mass produce nano-objects was (and still is) the greatest challenge in fulfilling the promises of the new technologies; therefore nanotechnology has gone under the radar of the regulatory threshold. Over the years, however, new production methods have resulted in the production of various nano-objects in larger quantities, making them a gradually more pressing regulatory issue.[113] In addition, in 2008, the first Toxic Substances Control Act (TSCA) Section 8(e) adverse effects report for nanomaterials and "For Your Information" (FYI) Submissions were submitted. Notices were submitted by several corporations, including BASF and Bayer, for their Carbon Nanotube (CNT) materials, indicating a more concrete risk from some nano-objects.[114]

1. Boosting Data Collection Programs: From Voluntary to Mandatory Schemes

After 2008, governments started pursuing more systematic—and in some cases mandatory—data-collection mechanisms. Overall, these initiatives account for about 42 percent of total public and hybrid GNRIs. As presented in Table 4, out of 57 data-collection regulatory initiatives, 30 originate in North America, 19 in Europe, 5 in Australia, 2 at the Global level, and 1 in Asia. In addition, 6 initiatives classified as "product control" focus primarily on additional testing requirements as a pre-condition for manufacturing and importing permits, and 9 initiatives classified as "general guidelines" provide companies with guidance on how to develop the necessary data for compliance with data-collection requirements. In

113. For illustration, while graphene was discovered in 2004, researchers have been searching for an easy method to produce it in large quantities for many years, and not until mid-2010 was a breakthrough technique developed that works at room temperature and needs little processing, paving the way for cost-effective mass production of graphene. *See New Method for Producing Graphene Paves Way for Mass Production of Nanomaterial*, SCIENCE DAILY (June 22, 2010), http://www.sciencedaily.com/releases/2010/06/100621122132.htm.

114. *See, e.g.*, Letter from Janet Cerra, BASF Corp. to U.S. EPA, Notice in Accordance with Section 8(e): Results of Subchronic Inhalation Study in Wistar Rats with Carbon Nano Tube (July 8, 2008), *available at* http://www.epa.gov/oppt/tsca8e/pubs/8ehq/2008/aug08/8ehq_0808_17208a.pdf; Letter from Richard A. Jourdenais, Director, chemicals division Bayer MaterialScience LLP to U.S. EPA, Multiwalled Carbon Nanotube Toxicity Information (July 9, 2008), *available at* http://www.epa.gov/oppt/tsca8e/pubs/8ehq/2008/jul08/fyi_0708_01611a.pdf.

terms of levels of obligation, most initiatives in North America are mandatory, whereas in Europe and Australia the majority of initiatives are voluntary. Yet, in Europe and Australia, most initiatives are sectorial (e.g., industrial chemicals, food and feed, consumer products, and occupational health) while in North America, most initiatives focus on specific targeted substances or lists of substances, indicating risk hot-spots rather than systematic data collection on nanomaterials.

During 2013, several European notification schemes came into force. For example, Article 13 of the new EU cosmetics regulation requires cosmetics manufacturers to notify the European Commission (EC) of any nanoparticles contained in products before the start of marketing activities within the EU and to submit the information specified in the regulation.[115] In January 2012, the EC established the Cosmetics Product Notification Portal (CPNP), a central system into which distributors will have to submit information, including the presence of nanomaterials, on cosmetics placed on the market. Direct access to the database will be limited to authorities only.[116]

As another example, the French mandatory annual declaration of nanoparticles scheme (R-Nano.fr) requires French manufacturers, importers, and distributors of substances intentionally manufactured in nano size, and in volumes of more than 100 grams per year, to submit an annual declaration to the French Ministry of Ecology, Sustainable Development and Energy (MEDDE).[117] Information required in the declaration includes: (1) personal information of the registrant; (2) chemical identity; (3) chemo-physical properties of the substance (such as composition, distribution, size, aggregation, agglomeration, shape, crystalline state, specific surface area, surface charge, surface chemistry, and coating); and (4) manufacturing,

115. Regulation 1223/2009, art. 16, of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products (recast), 2009 O.J. (L342) 59, 70 (EC).

116. *Cosmetics Product Notification Portal (CPNP)*, EUROPEAN COMM'N (2012), http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/cpnp_new_en.pdf.

117. Article 185 on Prevention of Risks to Health and the Environment from Exposure to Substances in the State of Nanoparticle, made under Law No 2010-788 of July 12, 2010 on National Commitment to the Environment, amending Title II of the French Environmental Code, OJRF 0160/12 905 (2010); Décret 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement [Decree 2012-232 of February 17, 2012 On the Annual Declaration on Substances at Nanoscale in Application of Article R. 523-4 of the Environment Code], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE, [J.O.][OFFICIAL JOURNAL OF THE FRENCH REPUBLIC], Feb. 19, 2012, p. 2863; Ministerial Order of 6 August 2012 on the Content and the Conditions for the Presentation of the Annual Declaration on Substances at Nanoscale, in application of Articles R. 523-12 and R. 523-13 of the Environment Code, OJRF 18/112 (2012); *Declaration of Nanomaterials*, R-NANO.FR, https://www.r-nano.fr/?locale=en (last visited Dec. 20, 2014).

distribution and uses information.[118] As of June 30, 2013, 670 companies have made 3,400 declarations representing 500 thousand tons of substances placed on the market in France in 2012. This amount is estimated to reflect only a partial picture of the market;[119] therefore the effectiveness of this approach is still questionable.[120]

Nevertheless, to date, no indication has been given as to how governments have used or intend to use the collected data in the development of regulation, and even the most comprehensive mandatory reporting system under the EU chemical and labeling regulations[121] has yielded very little risk data on nanomaterials.[122] According to interim results of the European Chemicals Agency's (ECHA) search of Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labelling and Packaging of Substances and Mixtures (CLP) submissions for nanomaterials at the end of June 2011—out of 26,600 REACH registrations, 4,700 distinctive substances, and 3.2 million CLP notifications, only 3 REACH dossiers for 3 substances, and 15 CLP notifications for 14 substances have been explicitly submitted for nanomaterials. Six additional dossiers, not classified in the International Uniform Chemical Information Database 5.2 (IUCLID) as "nanomaterials," included nanoscale substances.[123] This picture has not changed dramatically in the review carried out at the end of February 2012.[124]

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118. SAFENANO, QUESTIONS AND ANSWERS ON THE FRENCH DECLARATION OF NANOPARTICULATE SUBSTANCES (2013) (English translation).

119. FRANCE MINISTRY OF ECOLOGY, SUSTAINABLE DEV. & ENERGY (MEDDE), RESULTS OF THE FIRST YEAR OF REPORTING.

120. See Snir, *supra* note 58, at 85–91 for discussion on the limitations of nano-information reporting schemes.

121. Council Regulation 1907, 2006 O.J. (L 396) (EC); Council Regulation 1272, 2008 O.J. (L 353) (EC).

122. See Snir, *supra* note 58, at 86–87 for additional discussion on level of participation in data collection programs.

123. *See Topical Briefing: Interim Results: ECHA's Search of REACH- and CLP-Submissions for Nanomaterials*, NIA NANOTECHNOLOGY INDUSTRIES ASS'N (May 10, 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; Snir, *supra* note 58, at 82 n. 60.

124. *Commission Staff Working Paper on Types and Uses of Nanomaterials, Including Safety Aspects*, at 26, COM (2012) 288 final (Oct. 3, 2012), *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF.

2. Extending Responsible Development Codes of Conduct: From NGOs to Business Organizations and Government Agencies

From 2008 onwards, an increasing number of CoCs have been developed by third-party private organizations, business associations, and government agencies. Most CoCs specify general principles for responsible Research and Development of nanotechnology, allowing for greater flexibility in actual performance when implemented. An example of a business association's CoC is the Swiss retailers' association's (IG DHS) CoC,[125] which was implemented by some of its members: Charles Vögele, Coop, Manor, Migros, and Valora.[126] Similarly, the German government published the NanoKommission, a framework of five basic principles for responsible use of nanomaterials, which are expected to be further developed into sector-specific guidelines that provide guidance on practical implementation.[127] Several companies, such as Evonik and sectoral industry associations such as VCI and the German Paint Industry Association, have referred to the NanoKommission principles in their guidelines; however its implementation in general falls short of expectations, and efforts are being made in Germany to increase the level of awareness and implementation of the CoC.[128]

A more ambitious approach was taken in the UK through collaboration between the Royal Society, Insight Investment, the Nanotechnology Industries Association, and the Nanotechnology Knowledge Transfer Network in developing the Responsible Nanocode.[129] This initiative specifies seven principles, accompanied by examples of good practice, which organizations need to address with respect to the economic and societal effects of their activities in nanotechnology. These principles cover: (1) board accountability; (2) stakeholder involvement; (3) worker health and safety; (4) environment, health and safety risks; (5) social, environmental,

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125. IG DHS INTERESSENGEMEINSCHAFT DETAILHANDEL SCHWEIZ, CODE OF CONDUCT: NANOTECHNOLOGIES (Feb. 5, 2008), *available at* http://nanotech.law.asu.edu/Documents/2011/06/CoC_Nanotechnologies_english_544_3536.pdf.

126. *Id.*

127. RESPONSIBLE USE OF NANOTECHNOLOGIES: REPORT AND RECOMMENDATIONS OF THE GERMAN FEDERAL GOVERNMENT'S NANOKOMMISSION 2008 (Wolf-Michael Catenhusen & Antje Grobe eds., 2009), *available at* http://www.bmu.de/fileadmin/bmu-import/files/english/pdf/application/pdf/nanokomm_abschlussbericht_2008_en.pdf.

128. ANTJE GROBE, RESPONSIBLE USE OF NANOTECHNOLOGIES: REPORT AND RECOMMENDATIONS OF THE GERMAN FEDERAL GOVERNMENT'S NANOKOMMISSION 2011, 28 (Wolf-Michael Catenhusen ed., 2010), *available at* http://www.bmu.de/fileadmin/bmu-import/files/english/pdf/application/pdf/nano_schlussbericht_2011_bf_en.pdf.

129. INSIGHT INV. ET AL., INFORMATION ON THE RESPONSIBLE NANO CODE INISITATIVE (May 2008), *available at* http://www.nanoandme.org/downloads/The%20Responsible%20Nano%20Code.pdf.

health, and ethical implications; (6) engaging with partners; and (7) transparency and disclosure.[130] To date, the Responsible NanoCode has not been fully implemented due to limited resources and the lack of a central organization that can oversee its implementation. However, its principles are shared by other private and public CoCs.

At the EU level, the voluntary CoC for responsible research calls on governments to encourage all entities under their jurisdiction that conduct nanotechnology research to follow the principles and guidelines set forth in the Code.[131] Thus far, the only European country to set a general contractual obligation to comply with the EU CoC in grant agreements is the Netherlands.[132] Interestingly, outside of Europe, the South Korean Ministry of Knowledge and Economy published *Guidance on Safe Management of Nanotechnology Based Products* that follows the principles of the EU CoC.[133] To improve the level of awareness and implementation of the Code, in 2010 the EC launched the NanoCode project, which resulted in the development of a Master Plan for revision and implementation of the Code, as well as the CodeMeter, a tool to help firms determine whether they are complying with its principles.[134]

Overall, similar to the CoCs in the early years, the post-2008 CoCs had relatively minor influence because of, *inter alia*, the proliferation of competing CoCs in this field. As some commentators note, an organization facing competing CoCs that require different courses of action tends to harmonize them rather than choose one over the other, thereby adhering to the lowest common denominator.[135] It is also likely that the incentive for firms to implement these codes—building reputational capital—is not strong enough given their

130. *Id.*

131. *Commission Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*, COM (2008) 424 final (Feb. 7, 2008), *available at* http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf.

132. DAVID BENNETT & SERENE CHI, DELFT UNIV. OF TECH., SURVEY RESULTS: COUNTRY REPORT "THE NETHERLANDS" (2010).

133. OECD, *Current Developments/Activities on the Safety of Manufactured Nanomaterials*, at 39 ENV/JM/MONO(2009) 45 (May 23, 2011), *available at* http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2011)12&doclanguage=en.

134. CHRISTOPH MEILI ET AL., NANOCODE PROJECT, NANOCODE MASTERPLAN: ISSUES AND OPTIONS ON THE PATH FORWARD WITH THE EUROPEAN COMMISSION CODE OF CONDUCT ON RESPONSIBLE N&N RESEARCH (2011), *available at* http://www.nanotec.it/public/wp-content/uploads/2014/04/NanoCode_MasterPlan.pdf; CHRISTOPH MEILI ET AL., NANOCODE PROJECT, REPORT ON THE NANOCODE CODEMETER TOOL: CONCEPTS, OBJECTIVES & APPLICATION (2011), *available at* http://www.nanotec.it/public/wp-content/uploads/2014/04/NanoCode-CodeMeterToolReport.pdf.

135. Malloy, *supra* note 97, at 354.

limited resources and constant struggle to survive in an emerging and competitive market. Therefore, it is unclear whether current efforts to raise awareness of the codes will have any impact. Both the lack of implementation and the merely cosmetic efforts to change that indicate some limitations for the principle-based, self-regulation approach when it is introduced by the government without concrete rewards for participating in the program.

3. Scaling Up Risk Management Programs: From Bottom-Up to Top-Down

a. Life-Cycle Risk Management Frameworks

The limitations of the principles-based CoCs led to the development of more specific, process-based approaches to life-cycle risk management in 2008 and thereafter. Some initiatives address each stage of the life cycle of the product separately, while others apply one holistic process. Some have been published in the form of guidance documents, while others developed more sophisticated computer-based tools. However, these initiatives, unlike earlier efforts, are no longer bottom-up, company-specific approaches; rather, they are institutionalized, top-down approaches advanced by business associations, government agencies, and insurance companies.

For example, VCI has issued a series of documents that provide guidance on all aspects of good product stewardship on nanomaterials: from implementing Responsible Care® for nanomaterials to regulatory documents on complying with REACH, globally harmonized system (GHS), to material data safety sheet (MSDS) requirements for nanomaterials.[136] In the public sector, a similar attempt was made by the Japanese Ministry of the Environment, which published *Guidelines for Preventing the Environmental Impact of Manufactured Nanomaterials*.[137] This document provides information that allows manufacturers to choose a proper control policy for environmental conservation throughout the life cycle of the manufactured nanomaterial.[138]

A more sophisticated approach was introduced by Zurich Financial Services Ltd., a Swiss-based insurance company, and

136. GERMAN CHEM. INDUS. ASS'N [VCI], RESPONSIBLE PRODUCTION AND USE OF NANOMATERIALS (2008).

137. JAPAN MINISTRY OF ENV'T, GUIDELINES FOR PREVENTING THE ENVIRONMENTAL IMPACT OF MANUFACTURED NANOMATERIALS (ABSTRACT) (June 2009), *available at* http://www.env.go.jp/chemi/nanomaterial/eibs-conf/guideline_0903_enab.pdf.

138. *Id.*

Intertox, Inc., a US-based toxicological research firm, in 2009. This trans-Atlantic joint venture has developed the Zurich Nanotechnology Exposure Protocol™ (ZNEP™), a web-based computer software product capable of quantitatively assessing potential risks of nano-objects and nanomaterials using a standard risk assessment approach for Zurich customers. The science-based program relies on nano-object characteristics such as size, shape, solubility, and other properties, as well as reliable scientific studies reported in the literature, to assist in determining the level of potential hazard of nanomaterials. ZNEP™ is designed to add updated scientific content as new studies are reported. Customer procedures, product uses, and disposal issues are then factored into the equation to produce an in-depth risk analysis of the potential toxicity of the nanoparticles used in the product.[139]

Besides serving as an innovative approach for risk assessment and risk management, this example indicates the arrival of a new regulatory force into the nanotechnology field—insurance companies. As observed in recent years in other environmental fields, the shadow of liability law moves insurers to require the implementation of rigorous internal control systems as a condition for underwriting pollution liability insurance. Accordingly, insurers require sound environmental practices before a policy is issued.[140] Third-party regulators, such as insurance companies, may be in a position to exercise more coercive power over a regulated entity than a state regulatory agency,[141] and their entrance into the nanotechnology field sends a clear signal to the industry that good-will is not enough and adequate performance is expected.

b. Occupational Safety and Health Best Practices

From 2008 onwards, the number of new OSH regulatory initiatives, which include OSH best practices guidance, precautionary risk mitigation tools, workers' health surveillance practices, and exposure limits, has grown constantly. Unlike the OSH GNRIs introduced before 2008, which were mostly voluntary, private, and organization-specific, the OSH GNRIs introduced after 2008 are

139. Zurich Fin. Servs., *Insight on Nanotechnology*, INDUSTRY INSIGHT 2–3 (Jonathan Tin ed., June 2009), *available at* http://www.zurich.com/NR/rdonlyres/19B26BAF-B2AB-4CAA-B8D6-7A20A2A77B1A/0/Insight_Nano_webfinal3.pdf.

140. *Id.*; *see, e.g.*, STEPHAN SCHMIDHEINY & FEDERICO ZORRAQUÍN, FINANCING CHANGE: THE FINANCIAL COMMUNITY, ECOEFFICIENCY, AND SUSTAINABLE DEVELOPMENT 117–30, (1996); Andrew J. Hoffman, *Linking Organizational and Field-Level Analyses: The Diffusion of Corporate Environmental Practice*, 14 ORG. & ENV'T 133 (2001).

141. Grabosky, *supra* note 46, at 197.

carried out at a much broader scale by both public and private actors, some on a mandatory basis. This shift indicates the future direction of OSH GNRIs, but more importantly, it reveals some underlying dynamics in transnational public-private interplay.

i. OSH Best Practices Guidance

OSH guidance has been published with varying levels of detail by various actors. For example, in the private sector, the Producers Association of Carbon NanoTubes in Europe (PACTE)[142] and the French Union of Chemical Industries[143] have published information on risk mitigation best practices. In the public sector, UK Health and Safety Executive (HSE), Environment Canada, and Work Safe Australia (WSA) have published similar voluntary informative guidance.[144] There are also several collaborations between public and private sectors, such as the UK NanoSafety Partnership Group.[145] As nanosafety is an emerging field, these documents are being updated constantly as new knowledge arises.

Nevertheless, all these guidance initiatives have been introduced on a voluntary basis, and there are only a few mandatory occupational risk management standards. Mandatory initiatives include, for example, the Japanese Ministry of Health, Labor and Welfare's (MHLW) *Notification on Present Preventive Measures for the Prevention of Exposure at Workplaces Manufacturing and Handling*

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142. Producers Ass'n of Carbon nanoTubes in Europe (PACTE), *Code of Conduct for the Production and Use of Carbon Nanotubes* (2008), http://www.nanocyl.com/en/content/download/219/1544/file/PACTE%20Code%20of%20conduct.pdf.

143. FÉDÉRATION FRANÇAISE POUR LES SCIENCES DE LA CHIMIE (FFC) & UNION DES INDUSTRIES CHIMIQUES (UIC), CELLULE INNOVATION: GOOD PRACTICE GUIDE NANOMATERIALS AND HSE (2009).

144. *See* ENV'T CANADA, SCI. & TECH. BRANCH, GUIDE FOR THE SAFE HANDLING OF NANOTECHNOLOGY-BASED PRODUCTS (2009), *available at* http://publications.gc.ca/collections/collection_2010/ec/En84-79-2010-eng.pdf; GREG HAYWOOD, SAFE WORK AUSTRALIA, SAFE HANDLING AND USE OF CARBON NANOTUBES (2012), *available at* http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Documents/664/Safe%20Handling%20and%20Use%20of%20Carbon%20Nanotubes.pdf; HEALTH & SAFETY EXEC. (HSE), RISK MANAGEMENT OF CARBON NANOTUBES (2009), *available at* http://www.steptoe.com/assets/htmldocuments/UK%20HSE%20Risk%20Mgmt%20Carbon%20Nanotubes.pdf; HEALTH & SAFETY EXEC. (HSE), USING NANOMATERIALS AT WORK: INCLUDING CARBON NANOTUBES (CNTS) AND OTHER BIOPERSISTENT HIGH ASPECT RATIO NANOMATERIALS (HARNS) (2013), *available at* http://www.hse.gov.uk/pubns/books/hsg272.pdf; *Work Health and Safety Assessment Tool for Handling Engineered Nanomaterials*, SAFE WORK AUSTRALIA, http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Publications/Documents/547/Work_health_safety_tool_handling_engineered_nanomaterials.pdf (last visited Dec. 20, 2014).

145. UK NANOSAFETY P'SHIP GRP. (UKNSPG), WORKING SAFELY WITH NANOMATERIALS IN RESEARCH & DEVELOPMENT (2012), *available at* http://www.fan.org.ar/es/wp-content/uploads/nanosustentable/WorkingSafelywithNanomaterials-Release10-Aug2012.pdf.

Nanomaterials.[146] The notification, first issued in 2008 and updated in 2009,[147] instructs how "nanomaterial-related work" should be carried out, including using technical exposure control and personal protective equipment, measurement of nanomaterial concentration in the working environment, and procedures for waste disposal and cleaning. It also provides specific procedures for emergency response, health surveillance, and worker training.

Another example of mandatory requirements is the US Environmental Protection Agency (EPA) Pre-Manufacturing Notice (PMN) Consent Order and Significant New Use Rules (SNURs) under the TSCA of 1976, which applies to various nanomaterials on a case-by-case basis since 2008. Under these authorities, the EPA requires companies to follow specific personal exposure control measures approved by NIOSH.[148]

More interesting, however, is the way in which these seemingly independent regulatory initiatives, both public and private, have interacted with and helped shape one another over the years. For example, the aforementioned US NIOSH draft document, *Approaches to Safe Nanotechnology*, served to kick off the international work and to help achieve transnational consensus on the equivalent ISO technical report, *Health and Safety Practices in Occupational Settings Relevant to Nanotechnologies*. Once the ISO document was finalized in 2008, sections of it were incorporated in the final 2009 version of the NIOSH recommendations. In addition, the ISO report was adopted as a national standard by various countries (e.g., Canada, India, Indonesia, South Korea, and soon China), facilitating a broader, complementary ,rather than conflicting, transnational governance. This evolution and diffusion of global OSH best practices reveals

146. JAPAN MINISTRY OF HEALTH, LABOUR & WELFARE (MHLW), RE: NOTIFICATION ON PRECAUTIONARY MEASURES FOR PREVENTION OF EXPOSURE ETC. TO NANOMATERIALS (LSB Notification No.0331013) (2009), *available at* http://www.jniosh.go.jp/joho/nano/files/mhlw/Notification_0331013_en.pdf.

147. *Id.*

148. *See, e.g.*, Significant New Use Rules on Certain Chemical Substances, 77 Fed. Reg. 61124 (Oct. 5, 2012) (discussing potassium titanium oxide); Significant New Use Rules on Certain Chemical Substances, 77 Fed. Reg. 20296, 20299–300 (Apr. 4, 2012) (to be codified at 40 C.F.R. pts. 9, 721) (discussing carbon nanostructures, generic); Multi-Walled Carbon Nanotubes; Significant New Use Rule, 76. Fed. Reg. 26186-92 (May 6, 2011) (to be codified at 40 C.F.R. pts. 9, 721; Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules, 75. Fed. Reg. 56880, 56880–89 (Sept. 17, 2010) (to be codified at 40 C.F.R. pts. 9, 721); Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65743, 65751–52 (Nov. 5, 2008) (to be codified at 40 C.F.R. pt. 721) (discussing silica and alumina particles); U.S. EPA, OFFICE OF POLLUTION PREVENTION & TOXICS, *Regulation of a New Chemical Substance Pending Development of Information; Consent Order and Determinations Supporting Consent Order*, P-08-0177, *available at* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.

dynamics of constant dialogue and mutual learning between public and private regulatory arrangements at multiple levels, which eventually leads to regulatory innovation. It also shows transnational private organizations and their consensus-based standards building a framework that provides government agencies the confidence to issue guidance for new technology. By doing so, these private organizations enhance international collaborations and transnational governance integration faster and more effectively than traditional inter-governmental organizations such as the World Health Organization (WHO).[149]

ii. Precautionary Risk Mitigation Tools

In addition to the best practice guidance, several methods were developed to assist the assessment and management of potential exposure to nanoparticles, and the nanospecific health and environmental risk of nanoproducts under conditions of scientific uncertainty. These methods are based on the precautionary principle and recommend extra control measures when there is insufficient data to determine the level of risk. For example, in 2008 the Swiss Federal Office for Public Health and the Swiss Federal Office for the Environment published the first version of the Precautionary Matrix for Synthetic Nanomaterials.[150] The matrix is a screening tool to estimate the nanospecific potential risk of nanomaterials and their applications for workers, customers, and the environment based on selected evaluation parameters. It also helps in identifying possible sources of risk in the development, production, use, and disposal of synthetic nanomaterials. Risk potential is classified and matched with appropriate measures to protect health and the environment.[151] The matrix is a voluntary tool introduced as part of the first phase in the Swiss Action Plan Synthetic Nanomaterials to create a regulatory framework for responsible handling of synthetic nanomaterials.[152]

Furthermore, since 2009 several GNRIs were developed to apply a Control Banding Approach[153] to workers' exposure to

149. The WHO started developing its guidelines only in 2012 and it is a work in progress. *See WHO Guidelines on Nanomaterials and Worker's Health*, WORLD HEALTH ORG., http://www.who.int/occupational_health/topics/nanotechnologies/en/ (last visited Dec. 20, 2014).

150. .

151. *Id.* at 7.

152. *Id.* at 5.

153. Control Banding is a complementary approach to protecting worker health by focusing resources on exposure controls. Since it is not possible to assign a specific Occupational Exposure Limit to every chemical in use, a chemical is assigned to a "band" for control measures, based on its hazard classification according to international criteria, the amount of chemical in use, and its volatility or dustiness. BENJAMIN O. ALLI, FUNDAMENTAL PRINCIPLES OF

nanoparticles. For example, Workplace Health and Safety Queensland (WHSQ) has developed a Nanomaterial Control Banding Tool Worksheet to assist with risk management of nanomaterials, particularly at research facilities where small quantities of nanomaterials are likely to be used. This tool can also be applied at all nanotechnology workplaces.[154] Similarly, the Dutch Ministry of Social Affairs and Employment developed the Stoffenmanager Nano module, an online tool to qualitatively assess occupational health risks from inhalation exposure to manufactured nano-objects (MNOs).[155] It is designed as a tool for small and medium enterprises to prioritize potential health risks occurring as a result of exposure to MNOs at the workplace and to find effective measures to manage these risks. Risk management measures may be included in the facility's workplace risk assessment, evaluation, and action plan. The Module is a work in process that reflects the current knowledge on risks related to working with nanomaterials, and it puts the precautionary principle into practice and is a good example of an innovative way to deal with current scientific uncertainty.[156] As of 2013, Stoffenmanager Nano is available in three languages—English, Finish, and German—and it has more than six hundred users.[157] More recently, the Stoffenmanager approach has been implemented in the ISO Technical Specification, *Nanotechnologies—Occupational Risk Management Applied to Engineered Nanomaterials—Part 2: Use of the Control Banding Approach.*[158]

OCCUPATIONAL HEALTH AND SAFETY 119–20 (2d ed. 2008), *available at* http://www.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/---publ/documents/publication/wcms_093550.pdf.

154. *See Nanomaterial Control Banding Tool Worksheet*, WORKPLACE HEALTH & SAFETY QUEENSLAND (WHSQ) (last updated Apr. 7, 2010), https://www.engineersaustralia.org.au/sites/default/files/shado/Learned%20Groups/National%20Committees%20and%20Panels/Nanotech/Newsletters%20and%20Publications/Nanomaterial%20Control%20Banding%20Tool%20Worksheet.pdf.

155. STOFFENMANAGER NANO MODULE 1.0, http://nano.stoffenmanager.nl/ (last visited Dec. 20, 2014).

156. DUUREN-STUURMAN ET AL., STOFFENMANAGER NANO: DESCRIPTION OF THE CONCEPTUAL CONTROL BANDING MODEL, TNO REPORT V9216, 4 (2011), *available at* https://nano.stoffenmanager.nl/public/factsheets/STMNano_%20Bevindingendocument.pdf.

157. Email from Dr. Henri Heussen, Senior Consultant, Arbo Unie, to Reut Snir, Ph.D. Candidat, Bar Ilan University (Sept. 12, 2013, 15:37 IDT) (on file with author).

158. ISO, *Nanotechnologies—Occupational Risk Management Applied to Engineered Nanomaterials: Use of the Control Banding Approach*, ISO/PRF 12901-2 (Aug. 30, 2013) (on file with author).

iii. Worker Health Surveillance and Exposure Limits

In terms of worker health surveillance, US NIOSH published guidance concerning specific medical tests recommended for asymptomatic workers exposed to engineered nanomaterials until additional research either supports or negates the need for this type of screening.[159] In addition, several organizations have started developing numerical occupational exposure limits (OELs) for nanosubstances. For example, US NIOSH recommends a reference exposure limit (REL) for TiO2,[160] and for carbon nanotubes and carbon nanofibers.[161] Similarly, other OSH research institutes in Germany[162] and in the Netherlands[163] have introduced RELs, benchmark exposure limits (BELs), or derived no-effect levels for specific manufactured nanomaterials. Although none of these have been adopted by regulatory agencies to date, the growing interest in this area suggests that more regulation is soon to follow.

During this time, several private companies (such as BASF, Nanocyl, and Bayer) have also established OELs as part of the implementation of a product stewardship program to ensure the safe use of their products. These OELs appear on the safety data sheet of the relevant products. More recently, ISO has approved a New Work Item Proposal (NWIP), *General Framework for the Development of Occupational Exposure Limits for Nano-Objects and their Agglomerates and Aggregates* (NOAA), which intends to describe a general framework for the development of OELs for individual NOAAs

159. *See* DEPT. OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL (CDC) & U.S. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH (NIOSH), INTERIM GUIDANCE FOR MEDICAL SCREENING AND HAZARD SURVEILLANCE FOR WORKERS POTENTIALLY EXPOSED TO ENGINEERED NANOPARTICLES (2009), *available at* http://www.cdc.gov/niosh/docs/2009-116/pdfs/2009-116.pdf.

160. DEPT. OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL (CDC) & U.S. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH (NIOSH), OCCUPATIONAL EXPOSURE TO TITANIUM DIOXIDE (2011), *available at* http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf.

161. *Id.*; DEPT. OF HEALTH & HUMAN SERVS,, CTRS. FOR DISEASE CONTROL (CDC) & U.S. NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH (NIOSH), OCCUPATIONAL EXPOSURE TO CARBON NANOTUBES AND NANOFIBERS (2013), *available at* http://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf.

162. Inst. for Occupational Safety & Health of the German Soc. Accident Ins., *Criteria for Assessment of the Effectiveness of Protective Measures: Limit Values in Germany*, IFA, http://www.dguv.de/ifa/Fachinfos/Nanopartikel-am-Arbeitsplatz/Beurteilung-von-Schutzma%C3%9Fnahmen/index-2.jsp (last visited Dec. 20, 2014).

163. DUTCH SOC. & ECON. COUNCIL (SER), PROVISIONAL NANO REFERENCE VALUES FOR ENGINEERED NANOMATERIALS (2012), http://www.ser.nl/~/media/Files/Internet/Talen/Engels/2012/2012_01/2012_01.ashx.

and categories of NOAAs for different levels of available data.[164] Time will tell which of the national approaches have "won" in the international negotiation process.

To keep pace with the development of new workplace practices, a collaboration of several organizations introduced a beta version of the *GoodNanoGuide* in 2010. This is an Internet-based collaboration platform specially designed to enhance the ability of experts to exchange ideas on how best to handle nanomaterials in an occupational setting. It creates an interactive forum that fills the need for up-to-date information about current good workplace practices, highlighting new practices as they develop.[165] The *GoodNanoGuide* provides both OSH Protocols and a Reference Manual. The *OSH Reference Manual* outlines the various approaches taken by professionals to develop appropriate protocols and guidelines. The Manual is organized into six sections intended to conform with general industrial processes and is open for editing.

4. Governments Push Harder: Product-Specific Regulation

As discussed above, after 2008, governments started exploring product-specific oversight approaches. In North America, the focus of regulation is on traditional product case-by-case control mechanisms under existing chemicals regulations; other countries around the globe have developed new sectorial regulatory initiatives to address nanomaterial in products, mainly by facilitating product information. In addition, the scope of regulatory initiatives has seemed to vary—industrial chemicals in North America, and food, drugs, and cosmetics in Europe. These differences in regulatory approaches may indicate differences in public risk perception and regulatory culture. They may also relate to the region's historical experience with harmful exposure, leading to pressure on governments to regulate in different areas as discussed above.

a. Product Information Communication

After 2008, much development has been made in the area of product information communication. While more product quality schemes have been introduced in Asia and Iran—Europe, Australia and New Zealand have moved fast in the direction of product safety schemes, including nanospecific safety data sheets and new

164. ISO, GENERAL FRAMEWORK FOR THE DEVELOPMENT OF OCCUPATIONAL EXPOSURE LIMITS FOR NANO-OBJECTS AND THEIR AGGLOMERATES AND AGGREGATES (2013) (on file with author).

165. GOODNANOGUIDE, http://goodnanoguide.org/ (last visited Dec. 20, 2014).

mandatory labeling requirements. Still, many technical and scientific uncertainties present challenges to the effective implementation of these schemes.

i. Safety Data Sheet

Guidance on nanospecific information for a Safety Data Sheet (SDS) was published over the years by various institutions such as the German VCI,[166] the Swiss State Secretariat for Economic Affairs (SECO),[167] Safe Work Australia (SWA),[168] Queensland's state authorities,[169] and ISO.[170]

These initiatives provide some guidance on the necessary data on physical and chemical properties unique to nanomaterials[171] cautionary statements for use on an SDS when data is insufficient, as well as specific recommendations for control measures, particularly engineering controls and personal protective equipment for nanosized particulates. While the Australian Code of Practice recommends that labels be prepared for all products containing nanomaterials in the workplace unless there is evidence that the nanomaterials are not hazardous, no government is currently requiring the preparation of an SDS for nanomaterials. Consequently, very few nanobased products actually have an SDS that specifically addresses their nano-enhanced properties.

ii. Product Labeling

In 2009, Europe moved further toward product labeling. The EU's new cosmetic products regulation,[172] food information to

166. VCI, GUIDANCE FOR THE PASSING ON OF INFORMATION ALONG THE SUPPLY CHAIN IN THE HANDLING OF NANOMATERIALS VIA SAFETY DATA SHEETS (2008).

167. SWISS STATE SECRETARIAT FOR ECON. AFFAIRS (SECO), SAFETY DATA SHEET (SDS): GUIDELINES FOR SYNTHETIC NANOMATERIALS (version 2.0) (2012), *available at* http://www.bag.admin.ch/nanotechnologie/12171/12176/index.html?lang=en.

168. SAFE WORK AUSTRALIA, PREPARATION OF SAFETY DATA SHEETS FOR HAZARDOUS CHEMICALS: CODE OF PRACTICE (2011), *available at* http://www.safeworkaustralia.gov.au/sites/SWA/about/Publications/Documents/642/COP_Preparation_of_Safety_Data_Sheet_for_Hazardous_Chemicals.pdf.

169. WORKPLACE HEALTH & SAFETY QUEENSLAND (WHSQ), LABELING OF WORKPLACE HAZARDOUS CHEMICALS (2011).

170. ISO, *Nanotechnologies*, ISO/TC 229 (2005).

171. Including size distribution, shape and aspect ratio, crystallinity, dustiness, surface area, degree of aggregation or agglomeration, ionization (redox potential), biodurability or biopersistence, and surface coating.

172. Regulation 1223/2009, art. 16, of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products (recast), 2009 O.J. (L342) 59, 70 (EC).

consumers regulation,[173] and biocidal products regulation[174] 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 products marketed within the EU containing nanoparticles with the word "nano" in brackets. Following Europe's lead, New Zealand amended its Cosmetic Products Group Standard 2006 to include additional labeling, aligning it with the EU Cosmetics Regulation, Article 19 (Labeling) and Article 6 (Obligations of Distributors).

Still, as the author discussed previously,[175] the effectiveness of these regulations is in doubt due to scientific and technical limitations related to the measurement of nanomaterials. To show regulatory compliance, manufacturers have to distinguish between nanomaterials and non-nanomaterials by implementing the EC recommendation on the definition of nanomaterials.[176] However, it is not always clear whether a material fulfills the criteria of the definition. A recent report by the EC's Joint Research Centre (JRC) concluded that: "[N]one of the currently available methods can determine whether all kinds of potential nanomaterials meet the regulatory definition or not."[177]

b. Product Control

In the last few years, more governments have taken their first steps towards product and market control. These mechanisms impose great burdens and expenses on companies wishing to sell certain nanomaterials. However, as mentioned above, the EU and North America have taken different approaches to this type of regulation. While the EU attempts to cover a broader range of nanomaterials under its regulatory screening, countries in North America choose to focus on "hot-spot" areas where they believe there is a higher likelihood for risk.[178] At this time, it is too early to judge which approach is more effective at protecting the public and changing industry behavior towards more socially responsible development.

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173. Regulation 1169/2011 on Food Information to Consumers, 2011 O.J. (L304/18) (EU).

174. Regulation 528/2012, Concerning the Making Available on the Market and Use of Biocidal Products, 2012 O.J. (L167/1) (EU).

175. Snir, *supra* note 58, at 84–85.

176. *Commission Recommendation of 18 October 2011 on the Definition of Nanomaterial*, 2011/696/EU OJ (L 275/38).

177. THOMAS LINSINGER ET AL., EUROPEAN COMM'N JOINT RESEARCH CTR. (JRC), REQUIREMENTS ON MEASUREMENTS FOR THE IMPLEMENTATION OF THE EUROPEAN COMMISSION DEFINITION OF THE TERM 'NANOMATERIAL' 9 (2012), *available at* http://publications.jrc.ec.europa.eu/repository/handle/JRC73260.

178. *See supra* Part V.B.1.

In the EU, for example, the EU regulation on Plastic Materials and Articles Intended for Coming into Contact with Food demands that nanomaterials should be used for this purpose only after being authorized on a case-by-case basis.[179] Similarly, the Biocidal Regulation sets the conditions for an authorization of biocidal products containing nanomaterials, which include: the approval of an active nanoscale substance should be explicitly mentioned (Article 4(4)); where nanomaterials are used in a biocidal product, the risk to the environment and to health should be assessed separately (Article 19(1)(f)); and biocidal products containing nanomaterials are not eligible for "simplified authorization procedure" (Article 25).[180]

Additionally, at the national level, several countries issued notifications in the Rapid Alert System for Food and Feed (RAFF) restricting the commerce of some novel food products enhanced by nanotechnology.[181] A somewhat similar product control effort was undertaken by the Canadian government in 2010 to ban the use of nanomaterials in organic products under the Organic Product Regulation.[182] Organic food standards forbidding the use of nanomaterials exist in other countries as well (such as the UK and Australia), but these were initiated by private organizations and are not incorporated into the national legislation.

In North America, the US EPA has been the most active regulatory agency regarding nanomaterials, and it has mainly focused on a case-by-case application of its authorities under Section 5(e) Pre-manufacture Notice (PMN) Consent Order, and Section 5(a)(2) SNURs of TSCA.[183] Since 2008, US EPA has reviewed over 150 PMNs

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179. Regulation 10/2011 on Plastic Materials and Articles Intended to Come into Contact with Food, art. 9, 2011 O.J. (L12/1) (EU).

180. Regulation 528/2012, Concerning the Making Available on the Market and Use of Biocidal Products, 2012 O.J. (L167/1) (EU).

181. For example, in 2008, Finland issued a notification of unauthorized novel food (use of nanotechnology for increased metabolic usability stated on the label) regarding a food supplement imported from the United States; in 2009, Slovenia issued a notification of an unauthorized novel food ingredient obtained through nanotechnology (creatine monohydrate) in food intended for athletes, which came to Europe from the United States, via Poland; and in 2010, Austria issued a notification of an unauthorized novel food ingredient (clinoptilolite) obtained through nanotechnology in a food supplement from Germany. *See Rapid Alert System for Food and Feed (RASFF) Portal*, EUROPEAN COMM'N, https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=searchResultList.

182. Gov't of Canada, Canadian Gen. Standards Bd., *Organic Production Systems General Principles and Management Standards*, CAN/CGSB-32.310-2006, *amended* June 2011.

183. Another area in which the US EPA has been somewhat active in using its authority to grant companies conditional registrations under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). However, in the case of HeiQ Materials' AGS-20 product (nanosilver powder) the EPA had to face a Natural Resources Defense Council (NRDC) petition to court because of lack of substantive evidence that the product will not cause unreasonable adverse effects on human health. The court concluded that under EPA's own criteria the product

for nanomaterials and entered into TSCA PMN consent orders with several companies (including Thomas Swan & Co. Ltd., CNano Technology Ltd., Arkema Inc., Pyrograf Products Ltd., and SouthWest NanoTechnologies, Inc.) regarding the manufacture of their CNT products. The consent order includes requirements for submission of product samples and MSDS, specific inhalation tests, and material characterization information. As mentioned above, it also requires the company to follow specific personal exposure control measures. The company is prohibited from manufacturing, importing, processing, distributing in commerce, using, or disposing of these products in the US for any nonexempt commercial purpose, pending the development of information and the completion of the EPA's review of, and regulatory action based on, that information.[184]

In addition, US EPA issued SNURs for several nanosubstances such as silica and alumina,[185] multi/single wall carbon nanotubes (M/SWCNT),[186] infused CNT generics,[187] and potassium titanium oxide.[188] These SNURs aim to provide the EPA with a basic set of information on the nanosubstances, to help evaluate the intended uses of the nanoscale materials, and to take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment. The SNURs require:

> [A]ny person who began commercial manufacture, import, or processing of [the nanosubstance subject to the SNUR] . . . after the date of publication of the proposed SNUR must stop that activity before the effective date of this final rule. Persons who ceased those activities will have to meet all SNUR notice requirements and wait until the end of the notification review period, including all extensions, before engaging in any activities designated as significant new uses.[189]

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posed an unacceptably high health risk to toddlers and to that extent granted the petition. *See Natural Res. Def. Council v. EPA*, 735 F.3d 873, 886–87 (9th Cir. 2013).

184. U.S. EPA, OFFICE OF POLLUTION PREVENTION & TOXICS, *Regulation of a New Chemical Substance Pending Development of Information; Consent Order and Determinations Supporting Consent Order*, P-08-0177, *available at* http://www.nanolawreport.com/EPA%20Premanufacture%20Notice%20Number%20P-08-0177.pdf.

185. Significant New Use Rules on Certain Chemical Substances, 73 Fed. Reg. 65743, 65751–52 (Nov. 5, 2008).

186. Multi-Walled Carbon Nanotubes and Single-Walled Carbon Nanotubes; Significant New Use Rules, 75. Fed. Reg. 56880, 56880–89 (Sept. 17, 2010) (to be codified at 40 C.F.R. pts. 9, 721); Multi-Walled Carbon Nanotubes; Significant New Use Rule, 76. Fed. Reg. 26186-92 (May 6, 2011) (to be codified at 40 C.F.R. pts. 9, 721).

187. Significant New Use Rules on Certain Chemical Substances, 77 Fed. Reg. 20296, 20299–300 (Apr. 4, 2012) (to be codified at 40 C.F.R. pts. 9, 721).

188. Significant New Use Rules on Certain Chemical Substances, 77 Fed. Reg. 61124 (Oct. 5, 2012).

189. Multi-Walled Carbon Nanotubes; Significant New Use Rule, 76 Fed. Reg. 26,186 (May 6, 2011) (to be codified at 40 C.F.R. pts. 9, 721).

So far, the EPA issued SNURs mainly to require additional testing as a pre-condition for manufacturing and importing permits rather than to impose specific market controls. Indeed, as mentioned above, it also requires the company to follow specific personal exposure control measures and, in some cases, adds a "no-release-to-water restriction," but these requirements are relatively marginal.[190]

In response to the EPA testing requirements, the NanoSafety Consortium for Carbon (NCC), a US-based association of carbon nanomaterial producers, was established primarily to submit a proposed testing consent agreement to the EPA. To reduce testing costs while still providing the EPA with sufficient data to make informed decisions, NCC proposed a testing program for a representative set of carbon nanomaterials. Testing would be conducted based on protocols developed by independent scientists.[191] If approved by the EPA, member companies would be granted comprehensive permission to commercialize their CNT products based on the collective testing they conducted on selected materials.[192] By establishing such a voluntary program, the involved businesses are granted recognition and greater credibility for their activities, which may lead to more flexible regulatory compliance requirements that save the business time and resources. In this case, the public regulation drove the private innovative approach that resulted in an informal tacit collaboration.

5. The Transnational Debate: Regulatory Coordination

Despite the lessons learned from the commercialization of GMOs, the urgency to take actions to avoid similar regulatory divergence, and international trade barriers to nanobased applications, there has been little coordination of national regulations transnationally. The first and only regulatory initiative to be

190. In this context, it is worth noting Environment Canada's activities under Section 85 of the Canadian Environmental Protection Act (CEPA). Since 2007 Environment Canada issued more than twenty Significant New Activity (SNAc) Notices requiring pre-manufacturing information regarding the nominated nanosubstances. *See, e.g.*, Significant New Activity Notice no. 15007, 141 C. Gaz. 52, 2007 (Can.). While the Canadian CEPA SNAcs are very similar in nature to US EPA TSCA SNURs, in all notices related to nanomaterials they only required information submission with no additional exposure control requirements. The author therefore classified them in the GNRI database as mandatory data collection initiatives.

191. Letter from John C. Monica, NCC's counsel to James Alwood, U.S. EPA Chemical Control Division (Apr. 6, 2011), http://www.nanolawreport.com/AlwoodLetterandProposal20110406.pdf (regarding NanoSafety consortium for carbon and proposed testing agreement).

192. J. C. Monica, *An Industry-Driven Approach to EHS Issues: The NanoSafety Consortium for Carbon*, 7 NANOTECHNOLOGY LAW & BUS. 254, 254 (2010).

introduced so far in that direction is the Canada-US Regulatory Cooperation Council Nanotechnology Initiative (RCC). Following the 2011 announcement of Prime Minister Stephen Harper and President Barack Obama on the creation of the RCC to increase regulatory transparency and coordination between the two countries in twenty-nine areas, including nanotechnology, a Joint Action Plan has been developed.[193]

Under the command of the Joint Action Plan, the Nanotechnology Work Plan was developed to "share information and develop joint approaches on regulatory aspects of nanomaterials—including terminology and nomenclature, as well as risk assessment and management."[194] The Work Plan contains five work elements: (1) identification of common principles for the regulation of nanomaterials; (2) identification of common criteria for determining priority setting; (3) the sharing of best practices for assessing and managing the risks of nanomaterials; (4) identification of gaps and priorities for future information gathering; and (5) development of a model framework for regulating products and applications of emerging technologies with respect to potential impacts on the environment, human health, food or agriculture.[195] As of September 2013, efforts are still underway to implement the Work Plan, and it is too early to comment on the effectiveness of this initiative.

VI. CONCLUSION

The trends presented in this Article indicate a self-organizing structure of global nanotechnology regulation. Rather than showing a pure risk-based legal logic for a governmental strategic approach to regulation, they suggest that a combination of economic, political and social factors (such as public pressure and market competitiveness) drove the development of GNRIs. GNRIs involve powerful private actors that have created original norms that stimulate national and transnational policies. These norms are in no way more fuzzy or less specialized than the equivalent ones developed under public standard-setting process, but they are more adaptive to change. In addition, private GNRIs also help diffuse public policies around the

193. *Joint Statement by President Obama and Prime Minister Harper of Canada on Regulatory Cooperation*, WHITEHOUSE.GOV (Feb. 4, 2011), http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf.

194. David Morin et al., *Canada-US Regulatory Cooperation Council Nanotechnology Initiative: Introduction & Background*, slide 13 (2013), http://nanotech.lawbc.com/uploads/file/00105620.PDF.

195. *Id.* at slide 14.

world, hence taking a prominent part in shaping supranational regulatory norms.

As the nanotechnology industry has moved forward, the GNRI landscape has become more dense and globalized. Since 2008, we have seen an increase in public regulatory activities, which have gradually moved toward more mandatory market controls and risk management requirements. Still, taking into consideration current conditions of scientific uncertainty, the risk-based approach to regulation that is largely adopted by governments might not be sufficient (or even desirable) to oversee the development of emerging technologies.

To date, the focus has mostly been devoted to workplace exposure. This was the most logical first step—as historically, workers have been first to be exposed to new environmental risks. However, as technology evolves, regulation is likely to penetrate other environmental media such as air, water and soil. Furthermore, more attention is likely to be given to the entire life cycle of the product, including its disposal as well as the manufacturing and processing stages. The historical path of regulatory development in other emerging technologies, such as the Internet, shows that formal regulation eventually catches up with practical needs. As the field grows and matures, formal regulation becomes more dense and detailed. However, it is possible that due to unique aspects of nanotechnology, its development will still be motivated primarily by self-regulation and other soft law mechanisms that allow greater flexibility (supplemented by professional judgment) when implemented.

Despite the relative success of the few established public-private partnerships, few such initiatives have been developed over the years. Several explanations can be offered for this state of affairs: first, governments like to stay independent; second, governments are slow to respond, whereas businesses stay ahead of important developments; and third, there is a lack of trust between governments and businesses resulting in the other side not taking advantage of the partnership arrangements and output. Whatever the reason, partnership in the field of nanotechnology seems to focus on issues underlying regulation, such as developing test methods for risk assessments and validation of control measures, rather than on directly shaping the regulatory approach. Such collaborations are likely to continue in the future as this field continues to grow and new methods for risk assessment and management of the emerging materials are developed. Nevertheless, it is the author's view that institutionalized hybrid forms of governance are unlikely to emerge in this field.

Any theory attempting to explain the GNRI landscape should focus on the constant dialogue between public and private regulation. In order to understand these dynamics, it is not enough to look at each of the initiatives as an autonomous and isolated unit. It is important to analyze how information has moved around the globe and how public and private actors have interacted in shaping supranational norms. This area of study requires additional investigation.

Regulatory Tool	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Risk Management Process			1			1	3	11	12	13	12	6	11	70
Private			1			1	2	9	7	7	8	4	4	43
Public							1	1	5	6	4	2	3	22
Hybrid								1					4	5
Data Collection						1	5	3	11	12	7	2	15	57
Public							4	2	11	12	6	2	15	52
Hybrid						1	1	1				1		4
Private											1			1
General Guidelines	1			1	1			4	6	3	7	4	8	35
Public									3	3	2	3	7	18
Private	1			1	1			4	3		5		1	16
Hybrid												1		1
Product Control									4	1	4	3	4	16
Public									3	1	3	3	4	14
Private									1		1			2
Labeling & Disclosure					1	1		1	1	2	2	4	4	16
Public					1					2	1	4	2	10
Private						1		1	1		1		2	6
Emission Standards										2	2	3		7
Public										1	2	2		5
Private										1		1		2
Regulatory Coordination													1	1
Public													1	1
Total	1		1	1	2	3	8	19	34	34	34	23	43	203

Table 2—Descriptive statistics for the annual distribution of total GNRIs during 2000–2012 by the regulatory tool (Risk Management Process, Data Collection, General Guidelines, Product Control, Labeling & Disclosure, Emission Standards, and Regulatory Coordination) and separated by actor type (public, private, or hybrid).

Regulatory Scope	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Occupational Health			**1**	**1**		**2**	**3**	**10**	**9**	**11**	**16**	**11**	**11**	**75**
Hybrid						1	1	1				2	3	8
Private			1	1		1	1	8	6	4	9	4	4	39
Public							1	1	3	7	7	5	4	28
General	**1**						**2**	**7**	**9**	**6**	**4**	**4**	**6**	**39**
Hybrid													1	1
Private	1						1	6	3	1	1	1	2	16
Public							1	1	6	5	3	3	3	22
Industrial Chemicals					**1**		**2**	**2**	**10**	**11**	**9**	**3**	**16**	**54**
Hybrid								1						1
Private					1			1	1	3	3			8
Public							2		9	8	6	3	16	45
Food, Drug, Cosmetic									**4**	**4**	**1**	**4**	**5**	**18**
Private									1					1
Public									3	4	1	4	5	17
Agriculture, Pesticides, Veterinary									**1**			**1**	**3**	**5**
Public									1			1	3	5
Textile, Paint, Electronics						**1**				**1**	**2**			**4**
Private						1					2			3
Public										1				1
Consumer Products					**1**		**1**						**2**	**4**
Private													1	1
Public					1		1						1	3
Organic Products									**1**		**2**			**3**
Private									1		1			2
Public											1			1
Total	**1**		**1**	**1**	**2**	**3**	**8**	**19**	**34**	**34**	**34**	**23**	**43**	**203**

Table 3—Descriptive statistics for the annual distribution of total GNRIs during 2000–2012 by the regulatory scope (General, Occupational Health, Industrial Chemicals, Food Drug &Cosmetics, Agriculture Pesticides & Veterinary, Textile Paint & Electronics, Consumer Products and Organic Products) and separated by actor type (public, private, or hybrid).

Region / Tool	Europe	North America	Global	Australia	Asia	Middle East	Total
Risk Management Process	**33**	**21**	**4**	**3**	**6**	**3**	**70**
Hybrid	3				2		5
Private	21	17	4			1	43
Public	9	4		3	4	2	22
Data Collection	**19**	**30**	**2**	**5**	**1**		**57**
Hybrid	2		2				4
Private		1					1
Public	17	29		5	1		52
General Guidelines	**18**	**3**	**12**	**1**	**1**		**35**
Hybrid	1						1
Private	9	2	5				16
Public	8	1	7	1	1		18
Product Control	**6**	**9**		**1**			**16**
Private	1			1			2
Public	5	9					14
Labeling & Disclosure	**9**		**1**	**3**	**2**	**1**	**16**
Private	5		1				6
Public	4			3	2	1	10
Emission Standards	**5**	**2**					**7**
Private	2						2
Public	3	2					5
Regulatory Coordination		**1**					**1**
Public		1					1
Total	**90**	**67**	**19**	**13**	**10**	**4**	**203**

Table 4—Descriptive statistics (as generalized in Figure 6) for the distribution of total GNRIs during 2000–2012 by the geographic region (Global, Europe, North America, Australia, Asia, and Middle East), the focus of the regulation (Risk Management Process, Data Collection, General Guidelines, Product Control, Labeling &Disclosure, Emission Standards, and Regulatory Coordination), separated by actors type (public, private, or hybrid).

Region / Scope	Europe	North America	Global	Australia	Asia	Middle East	Total
Occupational Health	**33**	**23**	**9**	**5**	**4**	**1**	**75**
Hybrid	6		1		1		8
Private	17	15	7				39
Public	10	8	1	5	3	1	28
General	**18**	**7**	**7**		**5**	**2**	**39**
Hybrid					1		1
Private	8	4	3			1	16
Public	10	3	4		4	1	22
Industrial Chemicals	**16**	**31**	**3**	**4**			**54**
Hybrid			1				1
Private	7	1					8
Public	9	30	2	4			45
Food, Drug, Cosmetic	**14**	**1**		**2**		**1**	**18**
Private	1						1
Public	13	1		2		1	17
Agriculture, Pesticides, Veterinary	**2**	**2**		**1**			**5**
Public	2	2		1			5
Textile, Paint, Electronics	**4**						**4**
Private	3						3
Public	1						1
Consumer Products	**2**	**1**			**1**		**4**
Private	1						1
Public	1	1			1		3
Organic Products	**1**	**1**		**1**			**3**
Private	1			1			2
Public		1					1
Total	**90**	**67**	**19**	**13**	**10**	**4**	**203**

Table 5—Descriptive statistics (as generalized in Figure 7) for the distribution of total GNRIs during 2000–2012 by geographic region (Global, Europe, North America, Australia, Asia, and Middle East), the scope of regulation (General, Occupational Health, Industrial Chemicals, Food Drug &Cosmetics, Agriculture Pesticides & Veterinary, Textile Paint & Electronics, Consumer Products and Organic Products), separated by actors type (public, private, and hybrid).

Tools \ Scope	Occupational Health	General	Industrial Chemicals	Food, Drug, Cosmetic	Agriculture, Pesticides, Veterinary	Textile, Paint, Electronics	Consumer Products	Organic Products	Total
Risk Management Process	**50**	**14**	**5**	**1**		**1**			**71**
Voluntary	50	14	5	1		1			71
Data Collection	**6**	**5**	**35**	**6**	**3**		**2**		**54**
Voluntary	5	2	9	2	1		2		21
Mandatory	1	3	26	4	2				36
General Guidelines	**9**	**15**	**7**	**3**		**1**			**35**
Voluntary	9	14	6	3		1			33
Mandatory		1	1						2
Product Control			**7**	**4**	**2**			**3**	**16**
Mandatory			7	4	2			1	14
Voluntary								2	2
Labeling & Disclosure	**4**	**4**		**4**		**2**	**2**		**16**
Voluntary	4	4				2	2		12
Mandatory				4					4
Emission Standards	**7**								**7**
Voluntary	7								7
Regulatory Coordination		**1**							**1**
Voluntary		1							1
Total	**76**	**53**	**40**	**18**	**5**	**4**	**4**	**3**	**203**

Table 6—Descriptive statistics for the distribution of total GNRIs during 2000–2012 by the regulatory tool (Risk Management Process, Data Collection, General Guidelines, Product Control, Labeling & Disclosure, Emission Standards, and Regulatory Coordination) and the scope of regulation (General, Occupational Health, Industrial Chemicals, Food, Drug & Cosmetics, Agriculture Pesticides & Veterinary, Textile Paint & Electronics, Consumer Products and Organic Products), separated by the regulatory obligation (mandatory or voluntary).