8

The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology

Levi-Faur, D. and H. Comaneshter (2007), 'The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology', in Graeme Hodge, Diana Bowman, and Karinne Ludlow (Eds), New Global Regulatory Frontiers in Regulation: The Age of Nanotechnology, Cheltenham: Edward Elgar, pp. 149-165.

Dr. David Levi-Faur and Hanna Comaneshter

This chapter discusses and explores the menu of strategies that are feasible, effective and desirable for the regulation of a new and powerful set of technologies, commonly known as 'nanotechnology'. Nanotechnology refers to 'the development and application of materials, devices and systems with fundamentally new properties and functions because of their structures in the range of about 1–100 nanometers' **(xxx, xxx, pp.).** Nanotechnology is the result of the growing ability of scientists to manipulate the basic building blocks of nature, and represents an interdisciplinary cooperation between physics, chemistry, biotechnology, material sciences and engineering toward studying assemblies of atoms and molecules (Renn and Roco, 2006). The applications range from the design of new materials, new instruments and new weapons to the development of new medicines and a range of therapies for some of the most serious human illness. The benefits, alas, are not without some safety risks that might demand a costly solution. Some of the serious safety concerns revolve at the moment around the basic building blocks of the nanotechnologies (particles smaller than one billionth of a meter) that may pose a new class of ecological and human hazards. Risks are, however, difficult to assess, and little is known about the parameters that should guide the regulatory response. Civil society groups and state regulators are calling for a cautious and prudent approach, as are businesses and international organizations. For example, Allianz (2005: 3), one of the world's biggest insurers, in a recent working paper published jointly with the OECD, calls for 'a precautionary approach based on risk research and good risk management to minimize the likelihood of nanoparticles bringing a new dimension to personal injury and property damage losses or posing third

party liability and product-recall risks'. At the same time, there is a widespread recognition that the global nature and global effects of nanotechnology require a regulatory response which has both global and national dimensions.

We therefore ask to what extent the growing attention to risk and to political and economic efforts to develop systems of risk management can coexist with new and innovative methods of regulation that rely to a significant degree on voluntarism, rewards and accountability to third parties, rather than hierarchical controls, legal sanctions and prescriptive regulation. We pose this question fully aware that there are no tailor-made comprehensive frameworks for the regulation of nanotechnology. Nanotechnology legislation and regulation will most probably fall at first under current frameworks such as the toxic substances control acts, clean air acts, food safety regulation and the like. The issue is likely to be on the agenda for years to come and, if our experience with older 'risk' technology is any guide, any solution that is proposed or formulated is likely to be contested. What we might usefully do at this stage is to focus the discussion on the basic tenets that should enlighten our decisions. Accordingly, this chapter sets out the intellectual and practical challenges associated with the emergence of nanotechnology in two theoretical frameworks, namely, those of the 'risk society' and 'responsive regulation'. This chapter points to the uncertainties and ambiguities that are inherent in each of these frameworks, and suggests how the discussion of future trajectories of nanotechnology regulation may benefit from both frameworks and from the understanding that the open questions that they pose are systematic, inherent features of modernity that we have to learn to live with.

We start our discussion with the theoretical framework of the 'risk society' and the application of techniques of 'risk analysis' to the study of regulation. We find that more and more issues are framed and analysed through the notion of risk, and many authors suggest that we are living on a high-tech frontier whose consequences no one completely understands, and which generates a diversity of possible futures and outcomes (Giddens, 1998:25). The regulation of nanotechnologies, the topic of this volume, deals with one of the most important sets of technologies that exemplify the concerns associated with the 'risk society' and the dilemmas it raises. Indeed, there are not many examples that fit so well with, or speak so clearly to, the notion of the 'risk society' as the challenges of nanotechnology. Moreover, unlike other cases where the

discussion of the associated risks has *followed* the development of new technologies, the discussion on the proper regulatory framework for the governance of nanotechnology risks is *accompanying* the development of the technology and the associated products themselves. Probably for the first time ever, the attempt to develop a regulatory framework for a new technology is emerging on the public agenda hand in hand with the development of the technology itself. Indeed, it may well be that the end result of discussions at the national and the global level on the regulation of nanotechnologies will be a regulatory framework that *precedes* the discovery and development of several of these technologies.

For some, the very fact that regulatory issues are being raised so early in the life-cycle of the new technologies is a measure and evidence of the severity of the problems these technologies create. It might even be argued that the severity of the problems requires strict command and control regulation backed by the systematic and comprehensive authority by the state, with the application of its baggage of legal and criminal sanctions. Strong state regulation at the national level and strong intergovernmental regimes at the global level are the only solution for the issues raised by the concerns of the 'risk society'. Yet, for others, the very nature of the challenge, most of all its being open-ended and complex, calls for a more open approach to regulation, one which responds to the demands of the *regulatees* and which builds on their regulatory capacities and their intimate familiarity with the risks involved. Moreover, the necessity to regulate nanotechnology research, production and marketing at both global and national levels makes the recourse to some 'responsive' forms of regulation, which mobilize civic regulatory activity, all the more useful.

The history of regulation and the history of technology suggest that the manner and degree of the regulation of new technologies always reflect the specific context and era in which they first emerged. Stakeholders in nanotechnology regulation will need to deal with a number of issues that are central to the frameworks of risk society and responsive regulation. In what follows, we first present each of these frameworks. We then explore their common implications and internal contradictions as they deal with issues of nanotechnology regulation. We conclude with some insights into how policymakers should perceive the challenges and design the regulatory regimes to deal with them. Probably the most important of these is the suggestion that 'civil regulation',

‘state regulation’ and ‘hybrid regulation’ are not competing alternatives for the regulation of nanotechnology, and that the ‘responsive regulation’ approach is even more relevant to risk regulation than to non-risk issues.

Nanotechnologies and the risk society

A risk society, argues Anthony Giddens, is a society that increasingly lives on a high-tech frontier, with consequences which no one completely understands, and which generates a diversity of possible futures and outcomes (Giddens, 1998: 25). Giddens touches here on a relatively well-elaborated theme in the discussion of the politics of regulation: humanity’s interaction with nature. At a certain point, he tells us, sometime in the past 50 years or so we stopped worrying so much about what nature can do to us and started worrying much more about what we have done to nature (Giddens, 1998). New types of risks emerged following these developments. Unlike the risks of the industrial age, Beck argues, contemporary nuclear, chemical, ecological and biological threats are: ‘(1) not limitable, socially or temporally; (2) not accountable according to the prevailing rules of causality, guilty and liability; and (3) neither compensable nor insurable’ (Beck, 1999: 2). Technologies that are produced with a view to empowering humankind (or at least some parts of it) are also said to result in new, man-made, far-reaching risks.

The literature distinguishes between four major risks: ecological, health, safety and moral. *Ecological risks* are risks that may harm non-human organisms and their supporting physical conditions (Wiener et al., 2005: 1218). Examples include pollution and other environmental hazards that affect the ozone layer or other natural resources (e.g. water, air). *Health risks* are risks that may cause latent impairment of human health as a result of acute or chronic exposure to elements such as pesticides in food or radiation. *Safety risks* are risks that may cause injury or fatality to humans as an immediate result of acute (i.e., short-term) exposure to hazards (Hammitt et al., 2005: 1219). They include workplace accidents, automobile crashes, airplane crashes, and terrorism. Finally, *moral risks* are risks that represent deviance from, or threat to the moral values of communities. Examples of moral risks include child pornography, tolerance of violence and racial, ethnic and gender discrimination. These four ‘end

categories' of risks may be subdivided into a few thousand 'sources' of risk. These sources are not exclusive; alcohol, for example, can be categorized as both a health and a moral risk. Categorization, especially when moral risks are considered, may vary between countries as well as over time. Nanotechnology, for that matter, can create various risks, among them ecological, health and safety risks, in the manufacturing process. The prospect of nanotechnology being applied with even more disastrous effects than nuclear bombs (e.g., miniaturized robotic weapons, and intelligent target-seeking ammunition that can destroy army personnel but not equipment) may exemplify the moral aspects of risk regulation (Clarke, 2005).

The abundance of risks and – perhaps more important – the growing intolerance of the costs of risks (or more precisely, certain risks) on the part of society led to the invention, promotion and institutionalization of social, economic and political instruments that are meant to tame risks so as to maximize the efficiency of production and the allocation of resources. Risk management is increasingly becoming professionalized and a salient feature of complex organizations – from corporations to states – so as to allow the implementation of a cost-effective approach to human hazards. This is reflected in the intellectual attempt to define risk and to develop analytical tools that will allow society to deal with risk in a rational manner. Risk has thus been defined as 'the probability that a particular adverse event will occur during a stated period of time, or result from a particular challenge' (Baldwin, 1997: 2). Risk regulation seeks to reduce personal and environmental injuries before they occur by addressing the potential causes of such injuries, that is, the risk of such injuries (Shapiro and Glicksman, 2003: 1). Risk regulation is said to represent a 'systematic way of dealing with hazards and insecurities induced and introduced by modernization itself' (Beck, 1992: 21). The right way to deal with risk is via risk assessment that includes three components: the probability of harm resulting from the activity or product; the amount of harm which occurs if the risk materializes; and the cost of taking measures sufficient to avert the risk (Ogus, 1994: 142). Risk assessment should be followed by risk management and risk communication. There are three types of risks allowing for three main assessment categories: 'risks that society will not be willing to tolerate, risks that society will tolerate due to the small-scale danger they pose, and risks between these two extremes that need to be controlled and managed' (Ogus, 1997: 142).

A risk paradigm is therefore emerging with its own particular ways and conceptual procedures to deal with social, economic and technological issues. This new paradigm is expected to shape the way nanotechnology issues will be discussed, the policy arenas and the communities that will take part in the process – all are expected to shape the solutions that will be offered. This new risk paradigm is intimately entwined with regulatory analysis. Not only are both 'regulation' and 'risk' said to be important characteristics of modern capitalism, but the regulatory state may find a new mission, confronting today's risks. Indeed, it is reasonable to define a new role for the capitalist state, one which goes beyond Adam Smith's classic agenda. In this new role the capitalist state has a duty and the capacity to minimize the risks for its citizens, and regulation is a major instrument that empowers citizens in this role. Risks – rather than property rights or egalitarian concerns – become therefore one major rationale for state interventionism.

Yet there are at least five difficulties that should be considered when thinking about the regulatory state as a risk-management state. First, risks seem to be growing and becoming more complicated to explain, predict and assess. The costs of risk-management failures are expected to increase exponentially rather than proportionally. What is the empirical and theoretical basis that assures us that anyone, including states, can provide these safety regulation services effectively? Second, there is no such thing as 'real risk' or 'objective risk' (Slovic, 1999). Any risk assessment includes the perspective, interests and perception of the assessor. Public, non-expert views add another source of bias, and so do cultural and regional differences. Together these 'subjective' sources of risk assessment present a challenge to the legitimacy of the modern capitalist order in general, and of technological and economic innovation in particular. Third, internal paradox may create a legitimacy crisis. While we increasingly need to turn to experts in order to assess risks, Baldwin and Cave (1999: 80) argue that within the 'risk society' the case for trusting experts may grow ever weaker. After all, the experts, or some kinds of expert, create the risks. 'Experience accordingly tells us more and more often that we cannot rely on experts to guide us in our choices but must insist on a new political dialogue built on the death of deference to those claiming special expertise' (Baldwin and Cave, 1990). Fourth, even if we are to trust our elected officials and our national regulatory regimes, how should the transnational and global

nature of these risks be dealt with? The transnational nature of the technology makes it essential that effective controls are harmonized across national borders, but problems of collective action make effective governance regimes difficult to achieve. Finally, a backlash against the themes raised by the 'risk society' appears, along with an alternative approach which points to the political and social foundation of 'fear' and its role in public life. This 'fear society' approach argues that the politics of fear dominates public life in Western societies and has captured the public imagination. Being scared and scaring one another has become a common feature of public life. The defining feature of this new situation is the belief that humanity is confronted by powerful destructive forces that threaten our everyday existence (Furedi, 1997; Glassener, 1999). Terrorist attacks, climate change, asteroid collisions, nuclear war, bird flu pandemics and, yes, even nanotechnology risks are examples of the cultivation of fear in public life. However, the lines that distinguish the 'real' from the 'imagined', or 'science fiction' from 'science', are hard to draw (Furedi, 1997). The culture of fear resonates powerfully with the political and social distrust not only in politicians but in others more generally. Through one mechanism or another, this culture of fear is expected to create a regulatory response which will impede and control the development, production and marketing of nanotechnology.

Nanotechnologies and responsive regulation

If the risk society is one major framework which is expected to shape the discussion around the governance of nanotechnology, the theoretical framework of responsive regulation, as formulated by Braithwaite and the Australian School of Regulation, should be expected to act as the second (Grabosky and Braithwaite, 1986; Ayres and Braithwaite, 1992; Braithwaite, 2002; Gunningham & Grabosky, 1998; Parker, 2002). The responsive regulation approach suggests that government should be responsive to the conduct of those they seek to regulate, in deciding whether a more or less interventionist response is needed (Ayres and Braithwaite, 1992). Governments and regulators should be responsive to the effectiveness of the regulatory structures of the *regulatees* in designing their regulatory regimes, before they turn to hierarchical regulatory strategies and punitive means of enforcement (Braithwaite, 2002: 29). Responsive regulation asserts that at the core of policy regimes is a compliance decision

by the regulated entities. The cooperation of the regulated can be better achieved through the development of a range of self-regulatory mechanisms and through system-based and performance-based regulation rather than prescriptive regulation. These suggestions are based on observations about how regulators and regulatory regimes function in reality (Grabosky and Braithwaite, 1986) as well as major studies that suggest why they collapse or fail (Rees, 1994). The role of civil regulators – private actors, third-party and advocacy groups – in maintaining and nurturing the regulatory regime and encouraging sustained compliance, is a central tenet of the 'responsive regulation' approach (Gunningham and Grabosky, 1998).

Regulatory formalism, with its hierarchical, Commad & Control approach and its prescriptive rules is the alternative approach to responsive regulation (see figure 8.1). Here the designers of the regulatory regimes know and define the problems and the solutions in advance, and design the rules to mandate those responses (Braithwaite, 2002: 29). Much of the creation, expansion and current restructuring of the modern administrative state is grounded in the assumption that the problems and their solutions are known, that they are relatively stable, and that they can be tackled by a long-standing legal framework. In short, the early administrative state of the 20th century, as well as the process of reform since the 1980s, reflect the assumptions of the 'regulatory formalism' approach. Given the dominance of regulatory formalism and the constraints on the length of this chapter, it is our strategic decision to devote much of this section of the present chapter to the clarification of the range of strategies and instruments that are part and parcel of the responsive regulation approach.

[Insert Figure 8.1 about here]

Let us present the major concepts that are intimately connected with the notion of 'responsive regulation' as suggested above. First is the notion of civil regulation that institutionalizes voluntary global and national forms of regulation, by creating private (non-state) forms of regulation to govern markets and firms (Vogel, 2006). Civil

regulations attempt to embed international markets and firms in a normative order that specifies responsible business conduct. While mostly compatible with state regulation and with intergovernmental norms, civil regulation by its very definition goes beyond state regulation. ‘What distinguishes the legitimacy, governance and implementation of civil regulation’, Vogel tells us, ‘is that it is not rooted in public authority. Operating beside or around the state rather than through it, civil regulations are based on ‘soft law’ rather than legally binding standards: violators are subject to market rather than legal penalties’ (Vogel, 2006: 2-3). Market penalties should be understood here not only as direct and immediate economic outcomes but also as penalties that are connected with the standing, reputation and shaming of the corporation and its managers and employees. Because penalties can be high even if they are not based on legal norms and state enforcement, it might be useful to distinguish between ‘voluntary regulation’ and ‘civil regulation’. The latter should be conceived as broader than the former.

This leads us to define voluntary regulation as a broad category of social and human behavior in which regulatory compliance is not imposed on the individual or the organization but is partly or wholly based on the choice and the institutional design of the *regulatees*. The motivations for voluntary regulation may differ and so do the results; yet there is one constant feature that characterizes it, and that serves as an umbrella for a broad range of regulatory strategies. This feature is the consistent commitment, which is not required by law, to control behavior in such a way as to minimize the *regulatee's* freedom of action. Voluntary regulation is a historical phenomenon that precedes modernity and is recognized in wide areas of business and social activity. The scholarly and public interest in voluntary regulation is derived from a recognition of the shortcoming of ‘regulatory formalism’ including: (a) expensive and cost-ineffective regulatory strategies (Breyer, 1993); (b) inflexible regulatory strategies that encourage adversarial enforcement (Bardach and Kagan, 1982); (c) legal constraints on the subject matter, procedure and scope of regulatory discretion; (d) *regulatee's* resentment that leads to non-compliance or ‘creative compliance’ (McBarnet and Whelan, 1997). The turn to voluntary regulation is partly a response to the failures of formal regulation, but that does not mean that it is a problem-free or costless form of regulation. The basic puzzle of why firms and other social and

economic organizations would take upon themselves responsibilities that are not mandated by law is still in need of more scholarly attention, and its scope and implications need to be more clearly determined (Arora and Cason, 1996; Prakash, 2001).

Self-regulation is a basic and common form of civil regulation and is often but not always voluntary. Self-regulation is the activity that takes place when social and business actors exert control over private action via collective action (Baldwin and Cave, 1999: 125). The self-regulatory regime is based on a certain level of agreement and will to cooperate between various stakeholders, including professional and business competitors. Self-regulation may include a wide variety of techniques and instruments covering various facets of collective action. It may be defined with one or all of the following aspects: entry regulation (e.g., licence to operate a service); exit regulation (e.g., withdrawal of licence to operate a service); cost regulation (e.g., price of professional services); service regulation (e.g., the level of service expected from the provider); content regulation (e.g., degree of violence); and standard regulation (e.g., degree of acceptable noise).

Third-party regulation is yet another form of civil regulation which is often voluntary. Here processes of accreditation by third parties is a central enforcement strategy and 'a voluntary contractual relationship between firm [and more generally, the regulatee] and the party auditing the facility in place of relying solely on the regulatory agency as enforcer' (Kunreuther, McNulty and Kang, 2002: 309). Third-party regulation is a prevalent feature of modern life. One of its popular forms is 'auditing'. Indeed, the notion of audit is now used in a variety of contexts to refer to growing pressures for verification requirements (Power, 1997). Third-party regulators are sometimes called 'gatekeepers' (Kraakman, 1986). These include senior executives, independent directors, large auditing firms, outside lawyers, securities analysts, the financial media, underwriters, and debt-rating agencies (Ribstein, 2005: 5-6). Volunteerism is a measure and characteristic, however, of the *regulatee* and not necessarily the third party. The incentives facing the third party to enter into these relations might be economic, and

indeed often are, but they can also be enforced by the legal regime (either by the state or by the civil organization that shapes the regulatory regime). An example of a third-party regulation that is motivated by market considerations is the SGS Corporation. It does inspection, verification, testing and certification; it has been listed on the Swiss Stock Exchange since 1985 and has more than 46,000 employees, in over 1,000 sites around the world. Another is EurepGAP, a private sector body that sets voluntary standards for the certification of agricultural products around the globe. It brings together agricultural producers and retailers that want to establish certification standards and procedures for Good Agricultural Practices (GAP). Certification covers the production process of the certified product from before the seed is planted until it leaves the farm. EurepGAP is a business-to-business label and is therefore not directly visible to consumers. A form of third-party regulation that is socially motivated is the 'green' or 'social' labels that are offered and promoted by non-governmental, non-profit organizations (Courville, 2003). A more coercive form of third-party regulation is criminal or civil liabilities of the 'third party' in the event that it fails to perform its duties. Indeed, much of the new expansion of regulation in the field of corporate governance is about the expansion of responsibility and demand for accountability from stakeholders who are not necessarily the offending persons but still are in a position to prevent non-compliance.

We can now move on to the introduction of four hybrid forms of regulation (see figure 8.2). Legal penalties, whether criminal or civil, are not a substitute for persuasion, warning and shaming, but can be conceived as escalating steps of enforcement in a range of strategies that are available to the regulators (Ayres and Braithwaite, 1992: 35). Similarly, civil regulation and state regulation can be thought of as a range of strategies that are available to the designers of regulatory regimes and are employed in different manners and at different intensities depending on the life-cycle of the problem. Four forms of hybrid regulation can and should be distinguished here. First is co-regulation**,** where responsibility for regulatory design or regulatory enforcement is shared by the state and civil actors. The particular scope of cooperation may vary as long as the regulatory arrangements are grounded in cooperative techniques and the legitimacy of the regime rests at least partly on public–private cooperation.

[Insert Figure 8.2 about here]

A second form of hybrid regulation is enforced self-regulation**,** where 'the government would compel each company to write a set of rules tailored to the unique set of contingencies facing that firm. A regulatory agency would either approve these rules or send them back for revision if they were insufficiently stringent' (Ayres and Braithwaite, 1992: 106). Rather than having the government enforce the rules, most enforcement duties and costs would be internalized by the *regulatee*, who would be required to establish its own independent compliance administration. The primary function of government inspectors would be to ensure the integrity and transparency of the work of the compliance group of the regulatees. State involvement would not stop at monitoring. Violations of the privately written and publicly ratified rules would be punishable at law (Ayres and Braithwaite, 1992).

A third form of hybrid regulation is meta-regulation. The notion of meta-regulation is closely related to the notion of enforced self-regulation as formulated above, yet, unlike enforced self-regulation, it allows the *regulatee* to determine its own rules. The regulatory role is confined to the institutionalization and monitoring of the integrity of the work of the compliance group of the regulatees. In this sense, it is about meta-monitoring (Grabosky, 1995). In Christine Parker's formulation, the notion of meta-regulation has been used as a descriptive or explanatory term within the literature on the 'new governance' to refer to the way in which the state's role in governance and regulation is changing (Parker, 2002). 'Meta-regulation' 'entails any form of regulation (whether by tools of state law or other mechanisms) that regulates any other form of regulation' (Parker, forthcoming). Thus, it might include legal regulation of self-regulation (e.g. putting an oversight board above a self-regulatory professional association), non-legal methods of 'regulating' internal corporate self-regulation or management (e.g. voluntary accreditation to codes of good conduct) or the regulation of

national law-making by transnational bodies (such as the EU) (Parker, forthcoming). In Bronwen Morgan's formulation, it captures a desire or tendency 'to think reflexively about regulation, such that rather than regulating social and individual action directly, the process of regulation itself becomes regulated' (Morgan, 2003: 2).

Finally, there is a fourth form of hybrid regulation, often known as 'multi-level regulation'. Here regulatory authority is allocated to different levels of territorial tiers – supranational (global and regional), national, regional (domestic) and local (Marks and Hooghe, 2001). There are various forms of multi-level regulation depending on the number of tiers that are involved and the particular form of allocation. Regulatory authority can be allocated on a functional basis (whereby regulatory authority is allocated to different tiers according to their capacity to deal with the problem) or on a hierarchical basis (where supreme authority is defined in one of the regulatory tiers), or simply be a product of incremental, path-trajectory processes (where the regime is the result of the amalgamation of patches, each designed to solve a particular aspect as it occurred on the regulatory agenda).While much of the discussion on multi-level governance (which is a broader term than multi-level regulation) focuses on the transfer of authority between one tier and another, one should also note that the overall impact of multi-level regulation can be that of accretion.

Regulation for the age of risks

Issues of nanotechnology regulation are therefore most likely to be discussed within two different frameworks. The framework of the risk society suggests that nanotechnology should be considered as a potential hazard, and therefore should be subject to techniques of risk assessment, risk management and risk communications. A debate about the extent, scope and nature of risks that are peculiar to nanotechnology would reaffirm the dividing line between, on the one hand, those who perceive risk analysis and risk management to be the solution to the challenges of nanotechnology and, on the other hand, those who are likely to doubt it. The inherent tensions and ambiguities concerning the techniques, instruments and actors who can draw the line between risks that are worth taking and those that are not promise to make any decision controversial. The

framework of responsive regulation suggests that nanotechnology should be subject to a mixture of civil, state and hybrid forms of regulation. The problem is, however, that what we know about the optimal mixture and about the political and technical limits of different forms of regulation is very limited.

What we are therefore experiencing is a degree of uncertainty about the risk and about the regulatory response to risks. This uncertainty is inherent in the regulatory process, and we are unlikely to eliminate it. The real issue is how to live with it and how to decide the right regulatory response given the ambiguities involved in nanotechnology risks. One way to frame the issue, and to live with this uncertainty and ambiguity, is to call for either deregulation or strict regulation of nanotechnology. This will be – in one form or another – a rehearsal of the deregulation debate and consequently will reinforce the issue as a debate between the political Left (anti-business, pro-regulation) and the political Right (pro-business, anti-regulation). Although nanotechnology can create a global risk, the nanotechnology discourse is mainly a Western one. We think this is a mistake that stems from a failure to understand the nature of the global and national regulatory order as an order grounded in multiple regulatory networks which are only partly state-centered, which only rarely rest on one form of regulation, and which enable organizations to exercise power at minimal economic cost, with minimal visibility and in a manner which is likely to provoke minimal resistance (Grabosky, Smith and Dempsey, 2001: 184). We therefore suggest that we do not choose between civil, state and hybrid forms of regulation but instead apply some combination of them. Figure 8.3 presents the options for nanotechnology regulation as we see them. The intersection of tendencies toward more or less civil regulation (axis Y) and more or less state regulation (axis X) allow us to distinguish four regulatory responses to the uncertainties and ambiguities that are involved with the new nanotechnology:

The deregulatory response (bottom-left corner) advocates less regulation of both the civil and state types. The civilization response (upper-left corner) advocates more civil regulation and less state regulation. The prescriptive regulation response (bottom-right corner) advocates reliance on state regulation rather than on civil regulation. Finally, the responsive regulation approach suggests reliance on both civil and state regulation and mainly on the combination of the two that we titled 'hybrid regulation'. Hybrid regulation shares responsibility between those who possess the professional and

scientific information about nanotechnology risks (business and researchers) and those who have the ultimate legal monopoly to enforce rules via criminal sanctions (the state). This approach may reduce the cost of some aspects of the regulation since compliance costs may be lower and more effective when established under those who have the most information about the risks, and are also likely to result in less resistance from the regulatees (Ayres and Braithwaite, 1992).

[Insert Figure 8.3 about here]

Hybrid regulation has many institutional forms, and each has its strengths and weakness, benefits and shortcomings. The reliance on a network of regulatory strategies, however, may extend our security net vis-à-vis nanotechnology hazards and may also provide more security than the application of either state or civil regulation on its own. This positive-sum game for regulatory strategies of risk reduction is not without costs. It may well result in excessive regulation without eliminating completely the risk of regulatory failure. These costs are, however, unavoidable if we recognize the inevitability of a degree of uncertainty and ambiguity as a systematic feature of modernity itself.

Concluding remarks

Regulation and risk are said to be defining characteristics of modern society, and it should not be surprising that both are expected to have an important impact on the governance of nanotechnology. We are told, however, that the relations between regulation and risk should be explored rather than assumed (Hutter, 2001: 8). The authors therefore offer, within this chapter, an elaborated discussion of the relations between the two notions. The chapter begins with a discussion of the notion of the risk society and its relation to regulation, before moving to the issue of regulatory reform, clarifying the notion of 'responsive regulation' as an alternative to command and control and legalistic, prescriptive regulation. The authors raised the question of the extent to which the growing attention to risks and the political and economic efforts to

develop systems for risk management can coexist with new and innovative methods of regulation which rely on significant degrees of voluntarism, rewards, transparency and accountability rather than on hierarchical controls and sanctions.

The answers offered are derivative of the early (probably too early) phase in the development of nanotechnology, and of the brief experience with the health and safety hazards that are connected with it. They are also derivative of a constrained ability to define the 'real' risk on the one hand and to create consensus around this definition on the other. Under these circumstances the authors' recommendations emphasize the importance of public attention on the issue and at the same time the need for more research and deliberation in policy communities around the world. In addition, we feel confident that the voices of the 'risk society' and the countervailing forces of the 'fear society' are adding important dimensions to debate on and research into these issues. In a similar vein, we embrace hybrid forces and forms of regulation and reject the zero-sum view that perceives state and civil regulation or national and global regulation as inherently competing forms of regulation. Debate on whether public needs and concerns should be met by civil or state forms of regulation is misconceived. What is needed is debate about what institutional forms, or, even more appropriately, what blends of institutional form, are best suited to the given task. The design of hybrid regulatory regimes is our challenge, whether with regard to Internet governance or to genetic engineering. Nanotechnology, therefore, requires us not only to come up with technological solutions but also to change our perceptions as to what governance is, and especially what regulatory governance is. It therefore represents a welcome contribution to human welfare on yet another dimension.

References

Allianz and the OECD (2005), *Small sizes that matter: Opportunities and risks of Nanotechnologies*, www.allianz.com/azcom/dp/cda/0,,796454-44,00.html, 25 November 2006.

Arora, S. and T.N. Cason (1996), 'Why Do Firms Volunteer to Exceed Environmental Regulations?', *Land Economics*, 72 (4), 413-432.

Ayres, I. and J. Braithwaite (1992), *Responsive Regulation: Transcending the Deregulation Debate*, Oxford: Oxford University Press.

Baldwin, R. (1997), *Law and Uncertainty – Risks and the Legal Process*, UK: Kluwer Law International.

Baldwin, R. and M. Cave (1999), *Understanding Regulation*, Oxford: Oxford University Press.

Bardach, E. and R.A. Kagan (1982), *Going by the Book: The Problem of Regulatory Unreasonableness*, Philadelphia: Temple University Press.
Beck, U. (1999), *World Risk Society*, UK: Polity.
Beck, U. (1992), *Risk Society: Towards a New Modernity*, London: Sage Publications.
Braithwaite, J. (2002), *Restorative Justice and Responsive Regulation*, Oxford: Oxford University Press.
Breyer, S. (1993), *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Cambridge, Mass: Harvard University Press.
Clarke, S. (2005), 'Future Technologies, Dystopic Futures and the Precautionary Principle', *Ethics and Information Technology*, 7, 121.
Courville, S. (2003), 'Social Accountability Audits: Challenging or Defending Democratic Governance', *Law and Policy*, 25 (3), 269-297.
Furedi, F. (1997), *Culture of fear: risk-taking and the morality of low expectation*, London: Cassell.
Giddens, A. (1998), *The Third Way*, Cambridge: Polity.
Glassner, B. (1999) *The Culture of Fear: Why Americans are Afraid of the Wrong Things*, New York: Basic Books.
Grabosky, P. (1995), 'Using Non-Governmental Resources to Foster Regulatory Compliance' *Governance*, 8, 527-50.
Grabosky, P. and J. Braithwaite (1986), *Of Manners Gentle: Enforcement Strategies of Australian Regulatory Agencies*, Oxford: Oxford University Press.
Grabosky, P., R.G. Smith and G. Dempsey (2001), *Electronic Theft: Unlawful Acquisition in Cyberspace*, Cambridge: Cambridge University Press.
Gunningham, N., and P. Grabosky (1998), *Smart Regulation: Designing Environmental Policy*, Oxford: Clarendon Press.
Hutter, M.B. (2001), *Regulation and Risk, Occupational Health and Safety on the Railways*, Oxford: Oxford University Press.
Kunreuther, H.C., P.J. McNulty and Y. Kang (2002), 'Third-Party Inspection as an Alternative to Command and Control Regulation', *Risk Analysis*, 22 (2), 309-318.
Kraakman R. (1986), 'Gatekeepers: The Anatomy of a Third-Party Enforcement Strategy', *Journal of Law, Economics and Organization*, 2, 53-104.
McBarnet, D. and C. Whelan (1997), 'Creative compliance and the defeat of legal Control: the magic of the orphan subsidiary', in: Hawkins, K. (Ed.), *The Human Face of law*, Oxford: Oxford University Press, pp. 177–198
Morgan, B. (2003), *Social Citizenship in the Shadow of Competition: The Bureaucratic Politics of Regulatory Justification, Law, justice, and Power*. Burlington, Vermont: Ashgate Dartmouth.
Marks Gary and Lisbet Hooghe (2001), *Multi-level Governance and European Integration*, New York: Rowman and Littlefield Publishers, Inc.
Ogus, A. (1994), *Regulation – Legal Form and Economic Theory,* Oxford: Clarendon Press.
Ogus, A. (1997), 'Risk Management and "Rational" Social Regulation', in R. Baldwin, (ed.) *Law and Uncertainty – Risks and the Legal Process*, UK: Kluwer Law International.
Parker, C. (2002), *The Open Corporation: Effective Self-Regulation and Democracy*, New York: Cambridge University Press.
Parker, C. (Forthcoming), 'Meta-Regulation: Legal Accountability for Corporate Social Responsibility?', In: Doreen McBarnet, Aurora Voiculescu and Tom Campbell,

eds (eds), *The New Corporate Accountability: Corporate Social Responsibility and the Law*, Cambridge: Cambridge University Press.

Power, M. (1997), *The Audit Society: Rituals of Verification*, Oxford: Oxford University Press.

Prakash, A. (2001), ‘Why do firms adopt “beyond-compliance” environmental policies?’ *Business Strategy and the Environment*, 10 (5), 286-299.

Rees, J.V. (1994), *Hostages of Each Other: The Transformation of Nuclear Safety Since Three Mile Island*, Chicago: Chicago University Press.

Renn O. and M.C. Roco (2006), ‘Nanotechnology and the Need for Risk Governance’, *Journal of Nanoparticle Research*, 8 (2), 153-191.

Ribstein, E.L. (2005), *Sarbanes-Oxley After Three Years*, Illinois Law and Economics Working Papers Series, No. LE05-016.

Shapiro, S. and R. Glicksman (2003), *Risk Regulation at Risk*, California: Stanford University Press.

Siegel R.W., E. Hu and M.C. Roco (eds.) (1999), *Nanostructure Science and Technology*, Dordrecht, Netherlands: Springer (former Kluwer Academic Publishers).

Slovic, P. (1999), ‘Trust, Emotion, Sex, Politics, and Science: Surveying the Risk-Assessment Battlefield’, *Risk Analysis*, 19 (4), 689-701.

Vogel, D. (2006) ‘The Role of Civil Regulation in Global Economic Governance’, A paper prepared for the annual meeting of the American political Science Association, Philadelphia, September.

Wiener, J.B., Hammitt, J.K., Swedlow, B., Kall, D. and Zhou, Z. (2005), Precautionary Regulation in Europe and the United States: A Quantitative Comparison’, *Risk Analysis*, 25 (5), 1215-1228

Responsive Regulation		Regulatory formalism
Civil regulation		State regulation
Voluntary compliance		Coercive compliance
System-based and Performance-based regulation	*vs.*	Perspective regulation
Self-regulation		Public regulation
Third-party regulation		Second-party regulation
Gatekeepers		Keepers
Hybrid regulation		Monolithic regulation

Figure 8.1: Approaches for Regulatory Analysis and Regulatory Design

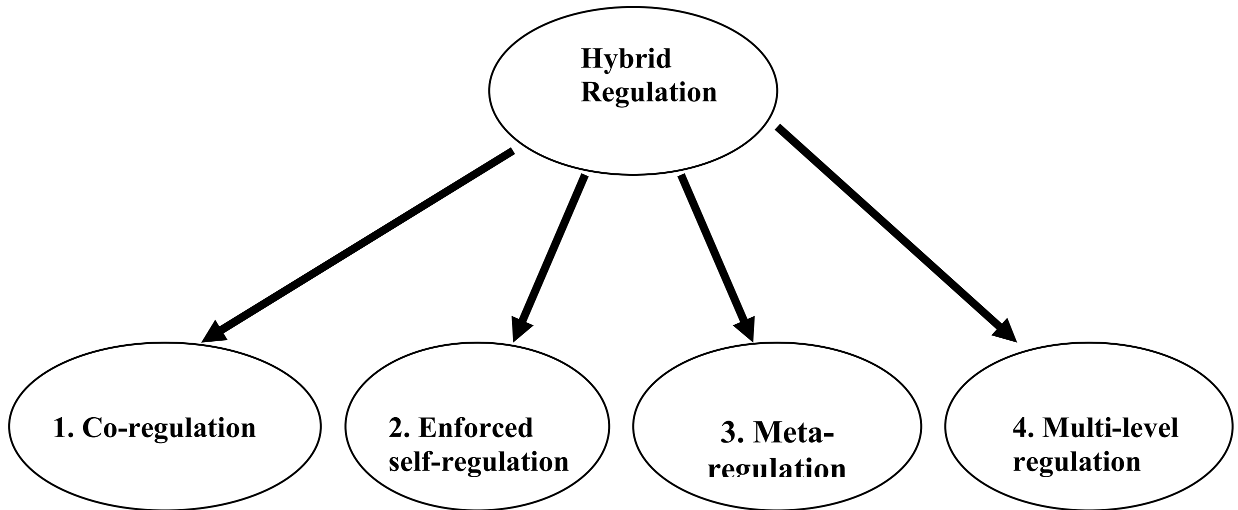

Figure 8.2: Four Forms of Hybrid Regulation

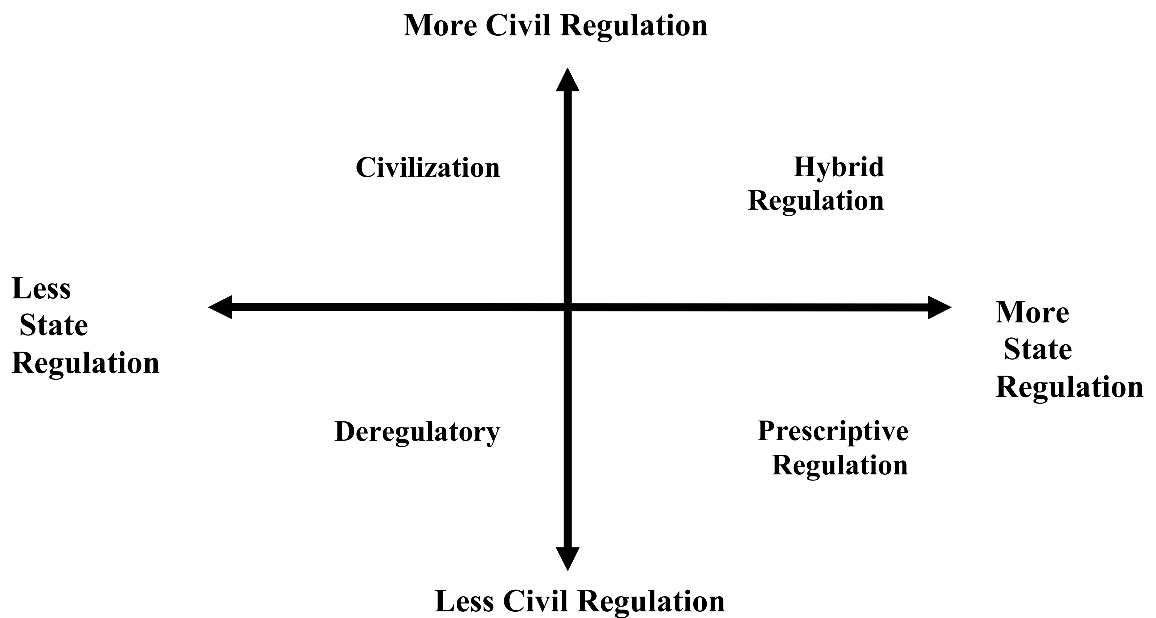

Figure 8.3: Regulatory Responses for the Risk Society