An Uncertain Business:
Self-regulation by the British and Danish Nano Industries

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ABSTRACT The massive uncertainties about the potential risks, benefits, properties and future directions of nanotechnology applications is widely recognized as demanding a regulatory response, although the nature of that response is a matter of ongoing controversy. Given these uncertainties, most observers agree that in the short to medium term some form of self-governance of the nano-sector is the most appropriate and feasible response to the rapid advance and commercialization of nanotechnology. Through a pairwise comparison, this paper explores the conditions, which led the British, but not the Danish nano industry to engage in self-regulation. Differences in the degree of organization among private actors in Britain and Denmark are an important part of the explanation of self-regulation; but this variation does not explain it fully. Rather we must look to variations in the role of the state. Whereas regulatory authorities in Denmark have largely favored an arm's length relation with industry, HM Government's regulatory strategy has strongly emphasized collaboration with companies and their association: close government-industry cooperation in Britain created strong incentives for companies commercializing nanotechnologies to reassure stakeholders that they are adopting a responsible approach to doing so and are proactively and effectively mitigating any risks related to them. A code of responsible conduct was therefore an acceptable 'price' for the prospect of influencing and guiding the direction of nanotechnology policy in Britain. Unlike their UK competitors, Danish companies enjoyed fewer opportunities to shape regulatory decisions and research priorities; they were therefore faced with few urgent incentives to draft a code of conduct for Responsible Nanotechnology. The paper concludes that the catalyst of voluntary initiatives under the emerging governance regime for nanotechnology is likely public skepticism about the introduction of new technologies and the desire to convince public and market stakeholders of the ability of both government and industry to responsibly develop nanotechnologies.

Introduction

Spurred by concerns over the relatively unrestrained market entry of an increasing number of nano-enabled products and applications, awareness of nanotechnology has risen dramatically among governments, investors, environmental activists, and citizens groups alike. Nanomaterials are not of course in any sense unregulated, as they are covered – in principle – by existing legal frameworks on chemicals, consumer products, and the environment as well as product liability and occupational health and safety laws. These regulatory regimes were however "[…] enacted long before the prospect of nanotechnology was yet on the horizon. […] The issue is that the risk assessment criteria, regulatory oversight triggers, toxicity parameters, and threshold minimums outlined in health, safety and environmental regulations are no longer applicable (or less so, at least) in the context of nanotechnology-derived products" (Pelley & Saner 2009:6). While the need for government action is widely agreed (Sylvester *et al.* 2009), consensus on what would constitute an appropriate regulatory response has proven elusive. Given the enormous uncertainties about the future trajectory of the technology, most observers however agree that in the short to medium term some form of self-governance of the nano-sector is the most appropriate and feasible response to the rapid advance and commercialization of nanoscience and nanotechnology (see *e.g.* IRGC 2008; Bowman & Hodge 2007; Mantovani *et al.* 2010). In November 2006, a group of UK stakeholders came together to formulate a code of conduct for the responsible development, use and disposal of products incorporating nanotechnologies. The outcome of this process, the Responsible Nano Code, was – with some delay – launched in late 2008. The Nano Code[1] aims to establish consensus on good practice across the nano value-chain and to provide guidance on what companies commercializing nanoscience and nanotechnology can do to demonstrate responsible governance, while proactively and effectively mitigating any risks relating to them (RNCI 2008a). While the UK industry by endorsing the Responsible Nano Code, thus in effect has assumed responsibility for the opportunities and uncertainties presented by the rapid advance and commercialization of nanotechnologies, no comparable initiatives have been undertaken in Denmark. This paper explores the conditions, which led the British, but not the Danish nano industry to engage in self-regulation.

Industry self-regulation is often viewed as the outcome of powerful business interests, with the strength of organization to avoid or delay government intervention through traditional formal regulation (Traxler 2007:27). While there is certainly something to be said for this view, it nonetheless falls short for nanotechnology: first, the strength of interests ultimately concerns the degree of group organization (Schmitter & Streeck 1999); accordingly, increases in the strength of association will be characterized by a decline in the voluntary character of organization. At one extreme, this capacity may come close to zero, if an association must rely exclusively on spontaneous and voluntary member support. At the other extreme, we can think of associations with a degree of independence and control over members such that they approximate 'interest governments' (Streeck & Schmitter 1985; Traxler 2007). Even a cursory look at Britain and Denmark, however, clearly reveal that the organization of

[1] The Seven Principles of the Responsible Nano Code are Board Accountability; Stakeholder Involvement; Worker Health & Safety; Public Health, Safety & Environmental Risks; Wider Social, Environmental, Health and Ethical Implications and Impacts; Engaging with Business Partners; and Transparency and Disclosure. Additional information on the Nano Code is available at www.responsiblenanocode.org.

business interests does not confirm to such expectations: whereas the relevant British trade body, the Nanotechnology Industries Association (NIA), boasts neither the independence nor control over members to force upon them decisions and common interest definitions, associations in Denmark often do command such authority. The organization of business interests, if this is to imply 'private interest governments' (Streeck & Schmitter 1985), thus, clearly does not explain the outcome. Second, neither does the desire to forestall mandatory regulations however: while UK companies have indeed fended off statutory nano regulations, so have their Danish competitors. This is however largely an empty gesture; in fact, despite a decade of debate on the appropriate regulatory response to nanotechnologies, no government has to date introduced new nano-specific legislation. Britain and Denmark are no exceptions; nor have their governments seriously considered this alternative. If not originating with either the organization of business interests or a threat of legislation, why then did only UK companies engage in self-regulation? That is, what purpose does the Responsible Nano Code serve in Britain and what interests did British companies, but not their Danish competitors, believe they could achieve by agreeing to a code of responsible conduct?

To answer these questions, we must explore the underlying interest constellations for nanotechnology and how these related to self-regulation. While self-regulation may deflect government interference, in the current climate, where consensus on a regulatory response remains elusive, codes of responsible conduct are likely serve different purposes entirely. Specifically, this paper argues that close government-industry cooperation in Britain created strong incentives for companies commercializing nanotechnologies to reassure stakeholders that they are adopting a responsible approach to doing so. Governments and companies share strong and mutual interests in ensuring the safe and responsible commercialization of nanotechnologies. While these interests may intersect, progress on developing the necessary knowledge and instruments are nonetheless faced with industry concerns over confidentiality and intellectual property rights; and regulators' inability to address current information deficiencies without the cooperation of industry. Governments may induce companies to divulge information by creating mechanisms to reward such cooperation, specifically by allowing companies and industry representative access to key decision-making venues. Initiatives to support such a strategy might range from representation on policy-making bodies; over participation in the formulation and implementation of specific policy programs; joint research ventures, bringing together regulators, companies and representatives from their associations; to cooperation on standardization.

Yet close and ongoing collaboration risks provoking strong negative reactions from an increasingly skeptic public already lacking faith in governments' ability and motivation to ensure effective oversight of new technologies. The need to 'educate' the public on the benefits of nanotechnologies applies to all companies; but, the stakes significantly increase in the context of government-industry collaboration: the prospect of political influence on regulatory decisions and research priorities, thus, creates additional incentives for companies commercializing nanotechnologies to reassure stakeholders that they understand the technology and are proactively and effectively mitigating potential risks. A code of responsible conduct may thus be an acceptable 'price' for the opportunity to guide and shape the direction of nanotechnology policy. Whereas collaboration has been a stable of decision-making in Britain, Danish regulators have largely favored an arm's length relationship: authorities have encouraged neither representation nor participation in the formulation and implementation of specific policy programs nor joint research ventures, but have instead tended to rely on their own in-house capabilities to approach the regulatory challenges of nanotechnology. Unlike their UK competitors, Danish companies therefore enjoyed fewer opportunities to shape regulatory decisions and research priorities; and they were consequently faced with few urgent incentives to engage in self-regulation.

In exploring the preconditions for the development of self-regulation by the UK nanotechnology industry, the paper is structured as follows: the first section below opens by surveying the regulatory debate over nanotechnology as it has unfolded over the past decade. A second section explores the underlying interests of state actors and companies commercializing nanotechnology, while aiming to connect these interests to self-regulation. This is followed in a third section by a pairwise comparison of the role of industry in the British and Danish governments' environmental, health and safety strategies and research activities; the analysis explores how variations in government strategies for nanotechnology created different incentives for British and Danish nano companies: incentives which as discussed in section four in Britain were sufficiently strong to induced industry to engage in self-regulation. A fifth section concludes.

Regulating Nanotechnologies

Nanotechnology has been hailed as the next 'big thing' after the dot-com and biotechnology revolutions. The term nanotechnology is used broadly to refer to particles, materials, and products at the nanoscale (1 to 100 billionth of a meter[2]) as well as technologies used to manipulate, visualize, and characterize materials at this scale (Pelley & Saner 2009:2; Bowman & Hodge 2007). Compared to materials in their bulk form (macro and micro), the same materials at the nanoscale can exhibit significantly different chemical reactivity, electrical conductivity, strength, mobility, solubility, magnetic and optical properties (Bowman & Hodge 2007:3f.). Although arguably an extension of traditional techniques within the fields of engineering, biology, chemistry and physics, the purposeful and precise manipulation of atoms and molecules promises numerous benefits and applications as a means of enhancing or replacing existing conventional technologies with solutions that can provide improved price-performance ratios, manufacturing cost advantages and product differentiation (Bowman & Hodge 2007:3). Nanotechnologies (nanomaterials and processes) are expected to be one of the defining technologies of the 21st century and already find applications in almost every sector, from energy, manufacturing, chemicals and healthcare to textiles, the environment, construction, agriculture, and information and communication technologies.[3] In 2007, the global market for nano-enabled products was estimated at $147 billion. The market is projected to reach $1.6 trillion in 2013 and $3.1 trillion in 2015, and is expected to create 2 million jobs globally

2 For comparison, a single human hair is about 80,000 nm wide, a red blood cell is approximately 7,000 nm wide and a water molecule is almost 0.3nm across (RS&RAEng 2004b).

3 As an illustration of the rapid rate at which nanotechnology is being brought to the market, the Consumer Product Inventory (CPI) had grown by nearly 379 percent (from 212 to 1015 products) by August 2009, since it was first released in March 2006. See www.nanotechproject.org/inventories/consumer

(Mini-IGT 2010:21; OECD 2009c:21f.). Unsurprisingly, then, nanotechnology attracts large and rapidly increasing public and corporate investments, with global funding for nanotechnology research reaching $11.8 billion in 2006 – up by 13 percent from 2005 (Mini-IGT 2010:17).

Unfortunately, however, many of the same traits responsible for the potential benefits of nanomaterials – especially their small size and dynamic properties – also create potential environmental, health and safety hazards given their potential to penetrate and react with biological systems (Marchant *et al.* 2010:127; Swiss Re 2004). The promise of the technology itself – that materials at the nanoscale may exhibit novel and unpredictable physical-chemical properties – thus raises serious concerns over the adequacy of existing risk management systems. Although the body of knowledge is growing, the understanding of how the physical-chemical properties of nanomaterials (size, shape, composition, reactivity, surface area and/or chemistry) determine their biological effects remains unclear. Absent such an understanding, attempts to evaluate, model and predict the ecological and toxicological behavior of nanomaterials are faced with considerable obstacles. In addition, the establishment of toxicity protocols and standard procedures to describe, specify and measure nanomaterials and products are still at a very early stage (Mantovani *et al.* 2010:16). Consequently, regulators currently have neither the resources nor the (regulatory) instruments to effectively address these uncertainties and information gaps.

Although quick to embrace the economic potential of nanotechnology, government responses to the potential hazards arising from the rapid commercialization and increasing exposure to nanomaterials and applications have been somewhat more gradual. This is in part because nanotechnology displays all the characteristics of a classic policy dilemma with governments attempting to accomplish multiple, often conflicting goals at once: while on the one hand seeking to encourage economic development, governments must balance this desire against the need to ensure public safety, ethical standards and environmental integrity on the other (Hodge *et al.* 2007:6). Consequently, while the need for government action is widely agreed (Sylvester *et al.* 2009), consensus on what would constitute an appropriate regulatory response has proven elusive. The various regulatory proposals dominating the debate on nanotechnology can broadly be characterized as ranging from largely reactive approaches, urging regulatory restraint, to proactive calls for new nano-specific regulations and frameworks based on a strict application of the precautionary principle. The case for new or at least a stricter application of existing legislation is typically made based on the identification of a number of regulatory gaps, where common triggers and thresholds in existing frameworks may fail to set in (see Ludlow 2008); the existence of these regulatory 'fissures' therefore urges the need for a precautionary stance. Critics on the other hand claim that this risks imposing unfair and unacceptable costs on the nano-industry: if tougher regulations make it more difficult for products to enter the market, *e.g.* due to extended testing requirements or more comprehensive environmental impact assessments, the commercial potential of the industry will suffer, either delaying or reducing nanotechnology's claimed upside (Lin 2007:112; Sylvester *et al.* 2009).

While acknowledging the merits of a precautionary approach, no government has to date introduced new nano-specific legislation, although some jurisdictions, notably the EU, have recently begun to incorporate nano-specific requirements in revisions of existing legislation. Given the pervasive uncertainties and the limited availability of data on which to base appropriate regulatory standards, governments have – at least in the short to medium term – tended to favor a 'light touch' approach of amending and adapting existing frameworks with the potential risks of nanomaterials being evaluated on a case-by-case basis. The emerging governance regime for nanotechnology is thus characterized by an incremental adjustment of existing regulations, often combined with appeals for industry to assume responsibility for safely developing and handling manufactured nanomaterials during (either) production, processing and/or disposal. Looking across the field, the number of non- regulatory (voluntary) and complementary measures in the context of manufactured nanomaterials has indeed proliferated since 2006 (See Meili & Widmer 2010); the Responsible Nano Code can thus be seen as part of a broader trend, whereby companies commercializing nanoscience and technologies are attempting to demonstrate responsible business behavior, while proactively and effectively mitigating potential human health and environmental risks.

While the UK industry, by endorsing the Responsible Nano Code, thus in effect has assumed responsibility for the opportunities and uncertainties presented by the rapid advance and commercialization of nanotechnologies, no comparable initiative have been undertaken in Denmark. The organization of Danish nano companies is different than their UK competitors; a fact most clearly reflected in the absence of specialized trade body. Yet, the Danish political economy is densely populated with representative bodies, which have previously proven their capacity to accommodate and serve as channels of interest representation for new or emerging industries (Campbell *et al.* 2006); indeed, responsibility for representing and organizing the interests of the Danish nano industry has – quite naturally and as matter of routine, as one observer notes – fallen under the auspice of the Confederation of Danish Industries (DI). The interests of the emerging nano industry have thus been accommodated within established associational structures. Hence, if not a question of organization, we must ask: why did the British, but not the Danish industry engage in self-regulation? That is, what purpose does the Responsible Nano Code serve in Britain and what interest did British companies, but not their Danish competitors, believe they could achieve by agreeing to a code of responsible conduct? To answer these questions, the next section explores the underlying interest constellations for nanotechnology and how these may relate to self-regulation.

Self-Regulation and Business Interests

The rise of the Regulatory State has led to a surge in academic interest in what may broadly be referred to as *voluntary governance*. Just as mechanisms of self-regulation have proliferated in the shadow of the state, so has research focused on a broader spectrum of regulatory arrangements involving mixes of private and public elements scattered across the social sciences. Conceptual abundance unfortunately easily breeds confusion, forcing us to ask: *what is industry self-regulation?* Gunningham and Rees (1997:364) have advanced the following seminal definition of industry self-regulation as "[…] a regulatory process whereby an industry level (as opposed to a governmental or firm-level) organization sets rules and standards (codes of conduct) relating to the conduct of firms in the industry." While we can thus distinguish several analytic traditions (Porter & Ronit 2006:42;

Schaede 2000), this definition alerts us to the often central role of business associations in socioeconomic governance. Interest in *associational* governance grew out of the analysis of organized group behavior in politics.

The literature on neo-corporatism thus emphasized how representative groups were not only involved in preparing legislation; often their involvement in the policy process extended to the implementation of rules, in some cases backed by a statutory mandate – an institutional arrangement referred to as *regulated* self-regulation or 'private interest governments' (PIGs) (Streeck & Schmitter 1985). While industry self-regulation is clearly broader than the PIG concept,[4] it may nonetheless be instructive to briefly dwell at the incentive structure underlying the emergence of such governance arrangements. According to Streeck and Schmitter (1985:130f.), the process "[…] by which organized interests move into positions of incorporation and authority begins with disputes between interest groups and state agencies on the necessity, and the terms, of authoritative state intervention into group members' behavior. In many such cases, the mere presence of a state powerful enough, and willing, to establish direct control adds to the already defined interests of organized collectivities an additional and distinctive interest in preventing that control. This additional interest can be so strong that groups may be prepared to compromise on their substantive interests if this can save them from regulatory state interference." The underlying notion here is that of 'unburdening the state' (Staatsentlastung): for state agencies, the interests in (associational) self-governance stems from the promise of lower implementation costs cobbled with higher policy effectiveness, even if this implies a loss of direct control. For companies and their associations on the other hand, the incentive to accept self-governing responsibilities and authority flows exactly from the desire to prevent state intervention. Since group member normally command greater expertise and technical knowledge about the economic circumstances of the group, self-governance allows members to formulate less intrusive and more flexible rules and controls (Ogus 1995). Self-regulation therefore serves to minimize regulatory burdens on industry.

In this context, it is important to remember that the process leading to "[…] private interest governments would be impossible without the Damocles sword of threatened direct state intervention." (Streeck & Schmitter 1985:131) That is, if a negotiated agreement acceptable to government cannot be reached, or if the enforcement of such an agreement cannot be guaranteed, business must anticipate the unilateral imposition of (conceivably ill-informed and inefficient) statutory regulations (Scharpf 1997:202f.); to the extent that business values the flexibility and efficiency associated with formulating industry specific rules and controls higher than presumably more rigorous and intrusive public regulations, it is the (negative) incentives embodied in a credible threat of legislation, which ultimately acts as the driver of self-regulation (Halfteck 2006). The PIG concept – and indeed any explanation based on the 'shadow of hierarchy' – thus assumes that business will prefer no regulation to self-regulation and the latter to legislation (Héritier & Eckert 2008:3). This is undoubtedly a reasonable assumption: one, for which we can certainly find evidence in the debate over nanotechnology regulation. Indeed, corporate representatives and industry insiders have been quick to warn of the dire, if not catastrophic, consequences of ill-

[4] Specifically, the PIG concept restricts analysis to associational activities directly delegated or devolved by the state. Self-regulation, in contrast, implies that the private sector assumes regulatory functions and authority either through delegation of state powers, or – what is more common – by acting independently without authorization (Schaede 2000:23; Bartle & Vass 2007).

informed or premature regulations. Yet, beyond a few vocal opponents in the NGO community (*e.g.* ETC group and ICTA), few stakeholders appear to disagree with this position. In fact, while concerns over potential human health and environmental safety risks have shaped the regulatory agenda for the better part of a decade, no government has to date, as mentioned above, introduced new nano-specific legislation; Britain and Denmark are certainly no exception. And, where nano-specific regulatory requirements have in fact been incorporated in revisions of existing legislation, notably in France and the European Union, industry have not responded with appeals for self-regulation. So why, then, with no urgent incentives resulting from a pending threat of legislation, did the UK nano industry launch the Nano Code? To answer this question, we must dig deeper to explore the incentives – the opportunities and uncertainties, as it were – confronting companies and state regulators in the realm of nanotechnologies, and how these incentives may connect to codes of responsible conduct.

Business Interests and Nanotechnology

There are other incentives for responsible action by companies engaged in commercializing nanotechnology than a desire to forestall 'premature' statutory regulations. These include (but are not limited to) the risk of costly litigation and liability; the need to overcome public fears, stigmatization and backlash; and ultimately the entrenchment of uninformed or irrational public sentiments in official policy governing the technology (Marchant *et al.* 2008:53; Sylvester *et al.* 2009:169). The regulatory literature tends to assume that a company will seek to maximize its profits with reckless abandon. Although there may be some truth in this, it does not fully appreciate the inherent (financial) risks involved with placing a product on the market (Belinsky 2010:166). While overly zealous environmental, health and safety regulations probably do risk killing of the nanotechnology innovation boost, *e.g.* due to extended product testing cycles or more comprehensive environmental impact reports (Lin 2007:112), the current mix of scientific and regulatory uncertainty continues to act as barriers to successful commercialization (OECD 2010b). Mandatory regulations of course represent restrictions on the operational flexibility of companies; but they also serve as guidance on expected behavior. As Matsuura (2004:491) explain, when "[…] there is a clear legal framework associated with a technology, developers, users, and investors involved with that technology are better able to identify and quantify risk." Clear regulatory guidelines, based on risk data and with instructions for appropriate risk assessment methodologies, are therefore crucial to industry. Uncertainty of how nanotechnology will be treated under existing statutes and regulations, on the contrary, leaves companies potentially liable for damages in the event that manufacturing processes or products are eventually discovered to present safety or environmental problems (Sutcliffe & Hodgson 2006:12; Dana 2011). Broadly speaking, should workers, consumers or the environment suffer harm as a result of exposure to nanomaterials or nano-enabled products, companies may be liable for personal injuries and other damages under either a negligence standard or a strict liability standard.[5] Tort liability acts as a deterrent to

[5] Negligence occurs where a company fails to act with 'due care'; that is, the company did not meet the level of care one would expect from a reasonable person under the circumstances. Strict liability, on the other hand, does not directly depend upon the level of care exhibited by the manufacturer. Instead, it applies where a manufacturer produces a

companies introducing 'risky' products on the market: it makes companies bear the costs of damages to consumers or the environment and will therefore either force companies to raise prices, lose profits, or both; none of which is desirable (Belinsky 2010:171). Because the science is continuously evolving there is as Fink (2007:23) emphasize "[…] a possibility that, similar to the asbestos tort suits, issues arising out of nanotechnology will not become apparent until years or even decades after such nanoparticles have been dispersed. This could result in a flood of 'long tail' claims […]." Absent official guidance documents, however, companies remain uncertainty about their obligations, leaving them – as well as investors and insurers – guessing about their eventual degree of liability exposure. The experience with the asbestos litigation crisis, which as of 2002 had cost the industry $70 billion in defending lawsuits and compensating alleged injuries (Monica *et al.* 2006:55f.), naturally have businesses, insurers and regulators worried over the potential for a similar scenario for the nano-industry.[6] While much can be said for tort liability as an instrument to guard against human health and environmental hazards (see *e.g.* Dana 2011; Malloy 2011), offsetting potential claims by meeting the industry of standard of care nonetheless remains a key priority for companies commercializing nanotechnologies (Ware & Kelly 2009). Until a clear regulatory framework is established, however, companies will continue to struggle with effectively demonstrating the safety of production processes and products.

Consumers and business partners on the other hand obviously prefer to buy tested and safe product; but will tend to shy away from products with unknown effects or risks. And this only strengthens existing incentives for responsible action. Consumers – and perhaps more importantly the general public – are uncertain about the benefits of nanotechnology applications. Most observers agree that the success of nanotechnologies in large measure depends on public acceptance; the public therefore needs to be reassured that industry is working to minimize and mitigate any potential safety and health risks. Public opinion is crucial to the success and integration of new technologies: if the public turns against a technology, reactions may range from rejection of products and declining sales, over the erection of entry barriers, to the entrenchment of irrational or uninformed public sentiment in official policy. In this context, a single accident or incident involving nanomaterials in a consumer product or industrial process risks resulting in technology stigma and public backlash, which could threaten not only the company responsible, but ultimately the entire industry (Sylvester *et al.* 2009:169; Malloy 2011:7). The exposure of the industry to being misjudged based on a single misunderstanding is illustrated perfectly by the now infamous 2006 'MagicNano' debacle;[7] the reverberations of this first 'nano-scare' propelled nanotechnology into the world's media spotlight, leading NGOs, university researchers and politicians to question the ability of regulators and industry to adequately address human health and environmental concerns.

product that is unreasonably dangerous due either to a design or manufacturing defect or to inadequate warning of dangers associated with the product (Malloy 2011:11).

6 The widespread use of asbestos and its subsequent effect on human health has had a huge impact on industry: 6000 independent entities have been named as asbestos liability defendants, 61 companies have filed for bankruptcy due to asbestos claims and 1.1 million claims have been issued. It is estimated that the total cost of liability for asbestos-related losses could reach $200 to $275 billion (Sutcliffe & Hodgson 2006).

7 In April 2006, the German Federal Institute for Risk Assessment (BfR) issued an immediate recall of two nano-enhanced products, which had allegedly caused more than one hundred reported health incidents. Paradoxically, the BfR eventually concluded that MagicNano did not contain any nano-sized particles.

If nanotechnology is to avoid the fate of GMOs, stakeholders, *i.e.* customers, employees, governments, business partners, investors, insurance companies, the media, and especially the general public, need to be reassured that companies commercializing nanotechnologies are adopting a responsible approach to doing so and are proactively and effectively mitigating any risks related to them (Sutcliffe & Hodgson 2006:16).

Unfortunately, companies struggle to effectively demonstrate the safety of their products and processes; traditional risk management methodologies and instruments are as discussed above challenged by the enormous uncertainties about the risks, benefits, properties, and future direction of nanotechnology applications (Marchant *et al.* 2008:43). And this is not only a problem for regulators: while companies that produce and use nanomaterials ordinarily are in the best position to provide or obtain toxicity and exposure data on their products, companies lack testing protocols and standard procedures to describe, specify and measure nanomaterials and products (Mantovani *et al.* 2010:16). In the absence of such basic tools, defining and enforcing quality and safety controls aimed at proactively and effectively mitigating risk are difficult, if not outright impossible. And of course, companies are still looking for regulatory guidance in order to provide a predictable and stable business environment (Pelley & Saner 2009:14; OECD 2010b:89). Industry certainly has a role to play in developing the necessary risk management infrastructure (*e.g.* instrumentation, metrology, risk assessment methodologies, and guidance); ultimately, however, the market is unlikely to produce neither instruments nor guidance. Instead, the interests of companies are closely tied to the state's regulatory strategy for nanotechnologies; either expressed as direct (financial) support to demonstrate the safety of existing products or to provide the necessary risk management infrastructure.

State Interests and Nanotechnology

Having staked enormous financial and political resources on nanoscience and technology,[8] policy-makers and regulators share obvious – and similar – interests in ensuring the safe and responsible development of nanotechnologies. This ambition, and the more fundamental desire to minimize potential risks to human health and environmental integrity, is however currently frustrated by the inadequacy of traditional risk management principles and instruments (Marchant *et al.* 2008), resulting from information deficiencies in at least three key areas: the paucity of scientific data on the physical-chemical properties of nanomaterials, the speed of development within the field and its heterogeneous nature (Bowman & Hodge 2008:477). To redress these knowledge gaps, governments have devoted considerable resources to (eco)toxicological research, while intensifying cooperation on establishing common definitions and nomenclature, protocols for toxicity testing and reference materials, standards and instruments for measurements and characterization. Whereas government activities in these areas have gone some way in developing the necessary scientific knowledge and instruments, progress on identifying use patterns, exposure pathways and endpoints for manufactured nanomaterials has been more gradual and often problematic. Identifying use patterns, exposure pathways and endpoints – information

[8] In the US, for example, the accumulated investment under the Federal National Nanotechnology Initiative represents the biggest single investment in science and technology since the Space program.

necessary for conducting a comprehensive exposure assessment – requires extensive knowledge about manufacturing conditions, levels of production, industrial applications and uses, consumer products and behavior, environmental fate and distribution *et cetera* (Hansen 2009:46). In the absence of official statistical data on the use of manufactured nanomaterials in industry or consumer products (Meili & Widmer 2010:446), regulators however lack the most basic information to perform risk analyses of nanotechnology; and this problem is only exacerbated by the rapid pace of development within the field and its heterogeneous nature: collecting data on which materials are being produced, ascertaining how and for what applications these materials are being used, is difficult and costly, not least given the sheer number of facilities involved (Florini *et al.* 2006:45). Many nanomaterials are being developed in a decentralized fashion, with a significant percentage of production coming from small, dispersed facilities (university spin-offs and SMEs). Finally, absent mandatory reporting and notification requirements, companies often have little economic incentive to divulge information of an often commercially sensitive and proprietary nature to state regulators. It is thus, for example, hardly surprising that a conclusive database, listing all products containing manufactured nanomaterials in a given country or in a given sector of application, does not exist. In fact, compiling official statistical data and gathering sufficient knowledge to develop a systematic approach to risk management of nano-enabled products and applications already on the market is likely to overwhelm available risk management resources for most regulatory authorities; and by the time it is done, new generations of nanotechnology products will already be on the market, creating new risk uncertainties (Marchant *et al.* 2008:44).

Few observers question the need to address these information deficiencies. Mandatory instruments have been recommended by some stakeholders as an appropriate solution; unfortunately, mandatory instruments come with their own set of problems, and governments have generally tended to discard them as either politically undesirable, administratively impractical, or both. Instead, based on previous positive experiences, often combined with a lack of sufficient agency funding, regulators have increasingly turned to industry to gain access to information on market and technological conditions. By encouraging companies to share data that would otherwise not have been covered by existing reporting requirements, cooperation with industry may not only prove a sensible and feasible strategy to assist regulators in gauging the level of immediate risks to consumers and the environment; it may also support regulatory decisions and the design of appropriate controls. Absent mandatory disclosure and notification requirements, however, companies have few economic incentives to divulge information to state regulators; concerns over intellectual property, confidentiality issues and a desire to avoid adverse publicity should hazards be discovered at a later stage have been identified as important impediments (Hansen & Tickner 2007:355). This problem is of course not unique to nanotechnology; yet the speed of development within the field and the heterogeneous nature of the industrial bases certainly exacerbates such problems. Government regulators are usually poorly positioned to gather information about business operations or at least to gather it cheaply (Coglianese *et al.* 2004; Culpepper 2003). Often the best strategy for regulators seeking to penetrate a regulated industry's 'silence' is not through force, but the creation of positive incentives. Indeed, as Coglianese *et al.* (2004:279) emphasize, "[…] selective forms of what might be considered 'regulatory capture' by individual firms may well be desirable from the standpoint of the public interest in some cases, if in the process firms cede information that permits regulators to craft more effective and efficient regulatory policies." Governments cannot count on self-interested holders of information to reveal it fully and without bias; neither can government necessarily count on its power to compel the disclosure of information. Instead, a more efficient strategy, one which have been fielded across a range of industries, is to rely on cooperation (Coglianese *et al.* 2004:288f.): allowing companies and industry representative access to key decision-making venues can thus create incentives for companies to divulge information and encourage participation in risk management activities. Initiatives to support such a strategy might range from representation on policy-making bodies; over participation in the formulation and implementation of specific policy programs; joint research ventures, bringing together regulators, companies and representatives from their associations; to cooperation on standardization.

How companies respond to such a strategy depends in turn on the potential to influence the knowledge and perceptions of regulators so as to promote public decisions that either reduce their anticipated costs or increase their private benefits (Coglianese *et al.* 2004:290). For nanotechnologies, collaboration with government may be advantageous on two levels: tactically, access to the decision-making process may allow companies to lobby for government support in demonstrating the safety of existing products; such assistance could range from direct financial support for testing or coordinated research efforts for a particular group of products. Similarly, input on market and technological conditions could shape and expedite the drafting of regulatory guidance documents. Strategically, however, access to key decision-making venues also promises the prospect of influencing and guiding future regulatory decisions on policy and research intended on the one hand to develop appropriate risk assessment and management instruments, while promoting and supporting the commercialization of nanotechnology on the other. The prospect of political influence and participation in regulatory decision-making may thus be key to forging the strategic interest of business (Martin & Thelen 2008:4). Yet, while the desire to guarantee the safe and responsible development of nanotechnologies thus would appear to intersect, this 'marriage of convenience' is ironically unlikely to find favor with the audience it is ultimately meant to protect: the general public.

Public Confidence and Codes of Responsible Conduct

Although quick to embrace the economic potential of nanotechnology, government attempts to address the potential hazards arising from the rapid commercialization and increasing exposure to nanomaterials and applications, has as noted above, been somewhat more gradual. Indirect regulation of nanotechnologies through existing frameworks, however, readily feed into perceptions of government inaction in the face of unknown hazards. This is however dangerous terrain for regulators and industry alike. On the one hand, past safety issues with specific products, ranging from drugs to genetically engineered crops, have led to a widespread perception that industry pushes products to market without adequate safety testing, makes too many errors affecting people's health, and puts its own motives ahead of consumer safety (Macoubrie 2005:4). The absence of clear regulatory response to nanotechnologies thus risks enabling a perception of the "Wild West", with companies playing fast and loose with environmental, health and safety risks to frighten off potential customers and investors (Seear *et al.* 2009:75). On the other hand, bred by recent regulatory controversies over mad cow disease (BSE) and genetically modified organisms (GMOs), public confidence in regulatory agencies and their ability to act independently of the entities they are meant to control has eroded in recent years (Sylvester *et al.* 2009:168). With respect to the GMO experience, for example, government inaction and promotion of the technology resulted in declining trust in the agencies expected to regulate the industry, partly as "[…] the public viewed government and industry to be in cahoots."(Sylvester *et al.* 2009:172)

Presently, policy-makers and regulators struggle to convince an increasingly informed – and sometimes skeptical – public of their ability, indeed motivation to ensure effective oversight of nanotechnologies (Jaspers 2010:270). While public opinion still appears to be favorable to nanotechnologies, surveys have demonstrated that industry *and* government lack trust and credibility (Macoubrie 2005; Sylvester *et al.* 2009). For a skeptic public, close, ongoing cooperation between government and industry therefore may come to signify undue influence and bias, the risk of regulatory capture, and the creation of regulatory policy that systematically favors the interests of industry (Coglianese *et al.* 2004:333f.). If close government-industry collaboration is connected to perceptions of a lack of transparency in decision-making, a public generally suspicious of industry and lacking faith in government oversight of technologies, will remain distrusting, and ultimately unwilling to accept regulatory choices. In this situation, government guarantees of the ability to address potential human health and environmental concerns will inextricably be linked to industry's position; close government-industry collaboration on safety issues thus risks repeating the mistakes of the past, ultimately with the potential to create backlash and technology stigma.

Avoiding rampant notions of 'regulatory capture' among an increasingly skeptic and suspicious public is obviously in the mutual interests of government and industry. If regulators are to exploit the incentives created by granting companies access to the decision-making process, they must be able to reassure the public that collaboration does not compromise the commitment to guarantee human health and environmental safety. Similarly, the prospect of political influence creates incentives for companies to devise an instrument to reassure stakeholders (*i.e.* the general public, customers, employees, business partners, investors and insurance companies) that companies commercializing nanotechnologies are adopting a responsible approach to doing so – if not for other reasons, then simply to protect their privileged access to the decision-making process. And, this is where industry self-regulation may come in to play: voluntary measures in nanotechnology risk governance are generally attractive to companies, since they offer an opportunity to demonstrate responsible engagement, create public trust, ameliorate their reputations, and develop novel approaches to handle new risks (Meili & Widmer 2010:458). Although the public still knows little about nanotechnology, consumers are beginning to voice concerns. A code of responsible conduct may thus present an opportunity to address such fear before they escalate, by communicating a message that companies understand the technology and are taking a responsible and proactive approach to mitigating any potential risks (Bowman & Hodge 2009:148).

Specifically, a code of conduct can function as a 'market signal' which conveys important information about participating companies: a recurrent problem for consumers and the public is that they lack information about members of an industry; they are therefore likely to assume that all companies tend to perform similarly. Any industrial accident or incident involving a nano-enabled consumer product will therefore as illustrated by the 'MagicNano' incident tend to affect the entire industry. In this context, endorsing a code of responsible conduct can serve to credibly reveal information about desirable characteristics to stakeholders. Members of the code should thus as Barnet and King (2008:1156) argue "[…] be less at risk of spillover harm than nonmembers, as only members are believed to possess these superior characteristics." In other words, self-regulation may serve to shelter companies – and perhaps more importantly government – from criticism and hysteria in the wake of a future 'nanoscare' by allowing companies and regulators to distance themselves from potential culprits. To the extent that incidents or accidents can be written off as caused by a few 'bad apples', participating companies can garner public confidence that industry at large is taking a responsible approach to development. Finally, cultivating reputations as 'good citizens' or 'serious players' are a well-establish strategy of corporate influence (Hart 2004:50f.). A code of responsible conduct may therefore facilitate government's attempt to justify and legitimize cooperation with a segment of industry, which has demonstrated a commitment to responsible business behavior (Trumbull 2010:626f.); more so if this commitment has been formulated independently of government.

In short, governments and companies share strong and mutual interests in ensuring the safe and responsible commercialization of nanotechnologies. While these interests may intersect, progress on developing the necessary knowledge and instruments are nonetheless faced with industry concerns over confidentiality and intellectual property rights; and regulators' inability to address current information deficiencies without the cooperation of industry. Governments may induce companies to divulge information by creating mechanisms to reward such cooperation, specifically by pursuing a strategy of encouraging participation and access to regulatory decision-making; yet this strategy risks provoking strong negative reactions from an increasingly skeptic public already lacking faith in governments' ability and motivation to ensure effective oversight of new technologies. The need to 'educate' the public on the benefits of nanotechnologies of course applies to all companies; but, the stakes significantly increase in the context of government-industry collaboration: the prospect of political influence on regulatory decisions and research priorities, thus, creates additional incentives for companies commercializing nanotechnologies to reassure stakeholders that they are adopting a responsible approach to doing so and are proactively and effectively mitigating any risks related to them. A code of responsible conduct may thus be an acceptable 'price' for the opportunity to guide and shape the direction of nanotechnology policy.

Responsible Nanotechnology in Britain and Denmark

Empirically, this paper explores the incentives, which led the British, but not the Danish nano industry to engage in self-regulation, through a pairwise comparison of the role of industry in the British and Danish governments' environmental, health and safety strategies and research activities. The analysis employs the logic of a most similar systems design: Britain and Denmark were among the first countries to seriously engage with the potential human health and environmental risks of nanotechnologies; and both countries remain lead sponsors in the OECD's Working Party on Manufactured Nanomaterials, the main international platform for coordinating an efficient and effective response to the regulatory challenges of nanomaterials. In terms of legislative agendas, the scope of the British and Danish governments' engagement and strategies are nuanced only by slight differences: schematically summarized, these responses include formal strategies or policy statements on nanotechnology; followed by attempts to expand the knowledge base on potential risks; combined with the commission of regulatory gaps analyses; ultimately leading not to new regulations, but (indirect) regulation of nanotechnology through existing legislation (See also Pelley & Saner 2009:50). Although both governments may at first glance appear to have taken a proactive approach to nanotechnologies, their legislative strategies, while similar, have in fact however largely been re(tro)active. The prospect of new or at least a stricter application of existing regulations thus have had little direct impact on the incentives of companies in Britain and Denmark; and for one simple reason: in the short to medium run, mandatory regulation was in neither country perceived as a credible alternative to the path of incremental adjustment.

Why then, with no urgent incentives resulting from a pending threat of legislation, did the UK nano industry launch the Nano Code? To answer this question, the analysis varies the degree of government-industry collaboration in the regulatory decision-making process: The British regulatory strategy for nanotechnology was, as in Denmark, informed by a commitment to 'get it right', *i.e.* to ensure the safe and responsible development of nanotechnology. Making progress on this commitment was however from the onset frustrated by a number of information deficiencies: uncertainties regarding the number of nano-enabled products and applications on the market, the state of applied research and the likely future trajectory of the technology have in both countries created significant difficulties for government department and agencies to not only gauge the need for immediate action, but also to give strategic direction to research efforts intended on the one hand to develop appropriate risk assessment and management instruments, while promoting and supporting the commercialization of nanotechnology on the other. Gaining access to information on the market and technological conditions of industry has consequently been a key priority in both Britain and Denmark. However, whereas regulatory authorities in Denmark have largely favored an arm's length relation with industry, HM Government's regulatory strategy has strongly emphasized collaboration with industry; and this strategy has in return allowed UK companies and their association, the Nanotechnology Industries Association (NIA), unique access across a range of decision-making venues. Industry representatives have therefore been in a pivotal position to influence and guide HM Government's regulatory decisions and research priorities: an opportunity, moreover, unavailable to their Danish competitors.

Despite variations in the emphasis on encouraging collaboration with industry, government agencies in both Britain and Denmark have nonetheless favored largely similar instruments and initiatives to address existing knowledge gaps. Compared to Denmark, collaboration with industry has thus *not* greatly increased the policy options available to HM Government; it has however allowed HM Government to gain access to information from industry that has assisted regulators in setting priorities and developing technically and politically feasible solutions. The analysis first reviews these activities with a focus on the role of private (industry) actors in the formulation and implementation of research efforts, evidence gathering activities and stakeholder engagements; the analysis then seeks to evaluate the significance of this participation for the ability to realize regulatory ambitions in Britain and Denmark. In order to evaluate the argument advanced in the previous section, the analysis engages in a triangulation of methods: most of the data used in the empirical analysis derive from documents and other materials produced by public and private actors. Contextual information and information regarding the actors and their activities are drawn from a set of secondary sources and academic literature. Finally, in addition to the textual documentary sources, a significant amount of information is received through 14 in-depth interviews with representatives of private and public actors. The empirical analyses seek to triangulate these different sources to arrive at a more valid and reliable interpretation of each case.

Environmental, Health and Safety Strategies and Research Activities in Britain

The regulatory agenda for nanotechnology in Britain was set with the publication of a 2005 Government Action Plan (HM Government 2005); in the wake of its publication, several initiatives were undertaken, which in a relatively short time span set Britain on a regulatory path of ongoing stakeholder engagement and public dialogue; promotion of nanotechnology research and development; and active participation in international efforts to assist in a more informed response to the potential hazards, exposures and risks of nanotechnology. Guiding these activities was an ambition of 'getting it right' by ensuring that Britain "[…] reap[s] the benefits and avoid[s] the pitfalls." (HM Government 2005:1). In response to the 'exciting' opportunities and challenges of nanotechnology, HM Government devised a regulatory strategy strongly emphasizing coordination of efforts and collaboration with industry, civil society groups, the research community and the public; the door was thus opened for UK companies and their association to participate in and shape regulatory decision-making. And, as we shall see, HM Government's efforts to realize this regulatory ambition for nanotechnology has in many ways benefitted from the input and involvement of the NIA and its members. The NIA has, in fact, perhaps surprisingly for such a young organization, assumed a pivotal position in relation to many of HM Government's regulatory activities. Yet, this owes less to traditional lobbying activities. Rather, the ubiquitous uncertainties on how to realize HM Government's regulatory ambitions – how to 'get it right' – created powerful incentives for government departments and agencies to encourage private actors to contribute to and participate in the policy process. The range of NIA activities and partnerships is broad, covering individual and joint contributions to safety assessment, development of risk management methodologies, technological foresights, legal and technical assistance *et cetera*. These activities have of course been undertaken in support of members' interests; but many have also proven highly relevant to government regulators. Economics of space precludes a comprehensive analysis of all these activities; instead the analysis evaluates three areas which on the one hand are representative of the role of the NIA and its members. On the other hand, these areas also constitute central elements of HM Government's regulatory strategy: the program of scientific research into potential ecological and toxicological impacts of nanotechnologies, the Voluntary Reporting Scheme (VRS) run by the Department of Environment, Food and Rural Affairs (Defra) on a two year trial basis from 2006 to 2008, and the Nanotechnology Stakeholder Forum (NSF). Each of these activities were in different ways intended to provide the basis for future regulatory decisions; each in turn suffered under the information deficiencies identified above; and in all cases, the NIA assisted regulators in addressing these uncertainties.

Research Strategy and Activities

Under the Action Plan, HM Government launched a comprehensive research program to address uncertainties about the (eco)toxicological behavior and properties of nanomaterials as well as their likely human health and environmental impacts. To monitor progress and coordinate UK research efforts, the government established an inter-ministerial Nanotechnology Research Coordination Group (NRCG), chaired by the Defra. Under the auspice of the NRCG, 19 research objectives have been named and taken forward by five Task Forces focused on metrology, characterization and standardization (TF1); exposure sources, pathways and technologies (TF2); human health hazard and risk assessment (TF3); environmental hazard and risk assessment (TF4); and social and economic dimensions (TF5) (Defra 2007). With the NRCG acting as steering body, the UK research program constitutes a cross-government effort, which draws upon expertise from government departments and agencies, the UK Research Councils, academia and industry. As part of its remit, the NRCG also links to international partners, particularly the OECD and the International Standards Organization (ISO), with an aim to encourage knowledge exchange; to avoid unnecessary duplication of research efforts; and to ensure the development of common standards for nanotechnology. HM Government's research efforts have thus served two, often complementary, objectives: With a priority to increase the understanding of potential hazards and risks of manufactured nanomaterials, the NRCG has on the one hand supported and facilitated the collection of scientific evidence and experience required to guide future decisions on appropriate regulatory controls; on the other hand, to ensure that knowledge and ideas generated by fundamental research can be transferred to industry for commercial applications, government agencies have focused on establishing mechanisms to support collaborative research between industry, academia and other relevant bodies.

The UK research program has been able to draw on the extensive capacities of domestic research institutions and international networks; yet information deficiencies regarding use patterns, exposure pathways and endpoints have created significant obstacles to the NRCG's ability to give strategic direction to research into the ecological and toxicological behavior of nanomaterials. The fundamental research to underpin risk assessment and regulatory controls has successfully been pursued through the UK Research Councils; but completing an exposure assessment of manufactured nanomaterials required detailed information on current production phases, commercial applications and planned future product launches to which neither research institutions nor government agencies had access. As one Defra official explained, this not only created a problem of directing research efforts; it also urgently accentuated the need to gauge the levels of immediate hazards to human health and the environment. HM Government therefore recognized the need for regulatory authorities "[…] to develop links with industry to deliver the necessary research on the basis of need in the context of specific products and applications of nanotechnologies."(HM Government 2005:9). In an effort to promote knowledge exchange, representatives from industry were therefore encouraged to join the five NRCG task forces. In this capacity, the NIA has fed information drawn from its members on the state of applied research into the government research program and activities; information essential not only to identifying areas of immediate concern, but also of great assistance in guiding and informing research efforts and priorities. The extent of the association's integration in and the implications for HM Government's regulatory strategy can best be illustrated with examples drawn from one of the two research priority areas identified in the 2005 Action Plan: nanotoxicology.

With government committing to the safe and responsible development of nanotechnology, making progress in nanotoxicology naturally became a central priority. Government departments and agencies have consequently committed significant research funding to enable safety assessment of nanomaterials; in support of these efforts, government has moreover initiated a range of joint industry projects and surveys, many with the NIA as active partner. Most of those projects involving the NIA have focused on gathering the necessary evidence to support reliable exposure assessments, with the association typically supporting or facilitating the collection of information on the state of applied research in industry; that is, the NIA has augmented HM Government's evidence gathering capacities, acting either as intermediary between government and industry, processing and aggregating responses and information from members; or by identifying and facilitating contact and cooperation between regulators and individual companies with a particular interest in a given project. In one instance, the PROSPEcT project,[9] the NIA and its members are however making a more tangible and direct contribution to the development of risk management methodologies. Launched in 2009, as a 50:50 public-private-partnership, with the NIA acting as consortium manager, the PROSPEcT project brings together government agencies and research institutions, several university laboratories and industry as joint sponsors. Funded with £3.7 million, the PROSPEcT project represents one of the largest single contributions to the OECD WPMN *Sponsorship Program*, and aims to develop seminal ecotoxicological test methods and data on two agreed nanomaterials (cerium oxide and zinc oxide) that are of particular commercial relevance to the UK. The resulting scientific advancement is expected to provide crucial data on the physical-chemical and toxicological properties of these materials and increase the general reliability and feasibility of extrapolations of toxicological properties for novel nanomaterials.

Moreover, by engaging private companies, the PROSPEcT project serves as an important bridge to bringing research on these nanomaterials to the market thus promoting the ability of UK companies to compete internationally. While not itself engaging in any research activities, the NIA's administrative responsibility for the PROSPEcT project and the in-kind financial and technical contributions of its members are thus a good example of how cooperation according to one Defra official has allowed HM Government to share the burden of a 'massive' research agenda with industry. The project is however less interesting in this context as an example of industry's in-kind contributions to developing risk management methodologies for nanotechnology. Rather the

9 **Ec**otoxicology **T**est **P**rotocols for **R**epresentative Nanomaterials in Support of the **O**ECD **S**ponsorship **P**rogramme www.nanotechia-prospect.org

PROSPEcT project stands out as an example of how HM Government has successfully managed to engage the NIA as interlocutor between state and industry. What emerges from these examples is thus a clear pattern of how collaboration with the NIA has allowed HM Government to advance its regulatory ambitions. While not denying that the association and its members has provided tangible assistance in terms of financial resources and expertise, the NIA's primary contribution has nonetheless been indirect, but no less valuable for that: by joining with the NIA, government has gained access to information on the economic and technological circumstances of the nano industry; information which has assisted in guiding and informing strategic research priorities with an aim not only to encourage ongoing commercialization, but also essential to underpin efforts to advance reliable exposure assessments. And, this is a pattern we shall recognize in other areas of HM Government's regulatory activities.

Evidence Gathering Activities

Beyond the comprehensive government research program, a second strand of HM Government's evidence gathering approach has been directed at gaining access to existing data and experience from industry and research organizations. In September 2006, following extensive consultations with stakeholders, Defra introduced a two year trial Voluntary Reporting Scheme (VRS) for engineered nanoscale materials. Defra specifically sought information on the types and extent of nanomaterials being manufactured, applied, and marketed as well as information on current risk management practices in companies involved with nanotechnology. Information submitted under the VRS was intended to assist Defra in determining immediate levels of exposure and hazards to human health and the environment; additionally the scheme aimed to address concerns regarding existing regulatory controls, while enabling a more informed debate and ultimately decisions about the nature of appropriate controls (Defra 2006). As with similar initiatives in other countries, however, participation in the VRS has been limited: only 13 submissions were received at the end of the two year period, most of them from industry. Defra never appear to have set a clear baseline for how many submissions to expect, yet the low rate of participation in the VRS were openly called a disappointment. Officially, however, Defra' position is that the low quantity of submission seems to reflect 'the state of the industry'.

Whether a grave disappointment or reflecting 'commercial reality', Defra had been warned by stakeholders that the large amount of information requested, the resources needed to participate (especially with respect to SMEs) and particularly convincing companies to divulge information of commercially sensitive and proprietary nature on a voluntary basis might constitute significant obstacles to participation in the VRS. In response to these objections, Defra initially issued a guarantee that any information would be treated in confidence "[…] unless expressly given permission by the data owner to do otherwise" (Defra 2008:4). The credibility of this guarantee was however compromised insofar as Defra under the provisions of the Freedom of Information Act might be obliged to release information to third parties. To placate the concerns of companies, Defra consequently sought to engage the NIA as an intermediary to facilitate industry participation. With industry generally skeptical of the VRS, the NIA in return assumed an instrumental role in the design and fate of the

VRS. In fact, of the 13 submissions to the VRS, all industry submissions were made by NIA members, most of them through the NIA as an agent. That Defra provided no incentives for participation and equally important no disincentives for companies *not* participating in the VRS (Hansen & Trickner 2007:353f.), only accentuates the value of the NIA as a trusted interlocutor; this can best be illustrated with Defra's unsuccessful attempts to garner additional responses.

When Defra, disappointed with the initial nine submissions to the VRS in early 2007, commissioned the Nanotechnology Knowledge Transfer Network (KTN) to encourage another 1.100 companies to participate in the reporting scheme, the KTN succeeded in receiving only *one* additional submission. 13 submissions may not seem of much; however, as we shall see below, although quantitatively not impressive, the information received under the VRS did as a Defra official explained enable government to "[…] take a view on the quality of data that was being provided, on the quality of research that industry was doing, looking into the risks and benefits of particular nanomaterials. It enabled government to satisfy ourselves that particular nanomaterials were pretty much as safe as they could reasonably be expected to be. We were able to satisfy ourselves that there we no need to remove things from the market." Given the pervasive uncertainties regarding use and exposure patterns, gaining access to detailed and specific product information, data and experience from companies directly involved with commercial applications did assist government's efforts in relation to hazard identification and exposure mitigation; and in a broader sense the VRS thus served as an important enabler of HM Government's ambition of managing the potential human health and environmental risks of nanotechnology. In return for acting as interlocutor between government and industry, the NIA managed to secure significant concessions on the overall design of the VRS, particularly in relation to the issue of confidentiality – much to the frustration of other stakeholders.

Stakeholder Engagement

Among other initiatives undertaking to facilitate stakeholder engagement and public outreach, and with the aim of supporting and informing the activities of the NRCG, Defra set up a Nanotechnologies Stakeholder Forum (NSF) in 2005. The NSF brings together key stakeholders from industry, academia and civil society organizations to ensure that wider concerns and perspectives get built into early policy deliberations (NSF 2005). The NSF is chaired by Defra, but includes representatives from other departments and agencies, whose portfolio includes responsibility for nanotechnologies. Early meetings of the NSF were largely structured around the desire to discern the need for immediate action, while laying out government strategy and priorities. Much to the dismay of some stakeholders, the initial openness to stakeholder views appears to have worn out as the forum matured and the government's regulatory strategy began to coalesce. Whether the NSF have in fact directly influenced government policy and strategy in this area is debatable, with some stakeholders claiming disappointment in what the forum has not achieved. The NSF has nonetheless performed an important auxiliary function: on one hand, the forum has on an ongoing basis allowed government to engage stakeholders and communicate regulatory initiatives to a wider audience with feedback from these discussions subsequently being fed in to the development of policies and research priorities. Both the VRS and the 2010 UK Nanotechnology Strategy have for example been subject to stakeholder deliberations prior to their launch. On the other hand, the establishment of the NSF was driven by HM Government's desire to understand public aspirations about nanotechnology, industry drivers and the concerns of NGOs by pulling together the many diverging opinions of the stakeholder community. The NSF has thus functioned as an interface between government and the wider nanotechnology stakeholder community, with deliberations underpinning several of HM Government's regulatory activities.

That the NIA's role on the NSF has been somewhat less obvious than in the other areas of HM Government's regulatory activities, does not imply however that the association's participation has not been appreciated by government. Beyond the scientific and technical impediments discussed above, a separate obstacle quickly emerged from the fledgling nature of the industry. As one government official explained, the "[…] main problem has been identifying who they [industry] are in fact, because of course they are the ones who make the nanocovers and the nanoparticles and they are quite obviously nanomanufactures, but what about the people, who makes the paints with the nanotitaniumdioxide, what about the people who do micro and nanoelectronics? […] a lot of these people don't see themselves as nanomanufactures and it is difficult to talk to the entire industrial community […]." That is, the fragmented and heterogeneous nature of the industry challenges the capacity of government department and agencies to identify and canvass the views and needs of industry; and this in turn has created significant difficulties in formulating policies and measures to encourage the development and commercialization of nanotechnologies. The formation of the NSF represents one of the initiatives undertaking by HM Government to address this problem: the forum has allowed government to float ideas to stakeholders and in return receive feedback on initiatives best suited to the needs of industry. And, "as a valuable means of information exchange on developments in nanotechnologies […]" (HM Government 2009:8), the NSF has allowed government to engage the NIA in regular interactions on strategy deliberations.

Rather than constituting a platform for lobbying government policy, the NSF has allowed government and the NIA to engage in an exchange of information, valuable to both parties. As a forum open to the public, the NIA has thus obviously not monopolized representation in the NSF, with other stakeholders, including other industry associations, participating as well. However, established – and larger – industry associations often lack detailed technical insight on nanotechnology; the capacity to access the views of industry has therefore allowed the NIA to speak with a weight in policy deliberations beyond what the size of its membership might suggest. The NSF has thus underpinned the wider range of government activities to the extent that the forum has provided additional input and feedback on the design, formulation and implementation of regulatory measures; *i.e.* the NSF has facilitated HM Government's commitment to 'getting it right'. As one Defra official concluded, "[…] the forum has been a very useful group up until now. It has helped shape policy, has helped us understand better what public perceptions are in the world of nanotechnologies."

Summary

To briefly recapitulate, collaboration with industry in general and the NIA and its members in particular has shaped the effectiveness, indeed the outcomes, of several of HM Government's regulatory activities. By joining with the NIA, HM Government has gained access to information not only crucial to gauging the need for immediate action, but also allowing government to adopt a clear set of strategic priorities on the one hand intended to promote and support commercialization of nanotechnologies in the UK, while aimed at developing appropriate risk assessment and management instruments on the other. Information, moreover, which the UK regulatory authorities working through their tradition evidence gathering instruments would otherwise have found it difficult or impedingly costly to access. And in return for acting as interlocutor between government and industry, the NIA and its members has managed to secure significant concessions on the design policy and the direction of government regulatory strategies and research priorities. The close and collaborative pattern of interactions among regulators and industry has however on some occasions been met with skepticism and frustration from other stakeholders; a situation which created new challenges for government and industry in Britain. Before turning to these challenges below, the analysis however first reviews the role of industry in the Danish regulatory decision-making process.

Environmental, Health and Safety Strategies and Research Activities in Denmark

The Danish government has – albeit less by 'grand' design – undertaken and promoted much the same range of regulatory measures and activities as HM Government: like Britain, government agencies have focused on establishing institutional mechanisms and formulating policy measures to promote and support nanotechnology innovation and business applications; like Britain, Denmark has committed significant resources to address uncertainties about the ecological and toxicological behavior and properties of nanomaterials, including their likely human health and environmental impacts; like Britain, government has – although on a minor scale – sought to engage and canvass the views of stakeholders and the public to guide the development of policy and regulatory decisions; and like Britain, Denmark has prioritized active participation in international efforts to assist in a more informed response to the potential hazards, exposures and risks of nanotechnology. In contrast to Britain, however, the Danish government never (explicitly) committed to collaborating with industry; not because Danish authorities are more reluctant to consult and cooperate with industry than their UK counterparts. Quite the opposite: Denmark enjoys a well-established tradition of inclusive and extensive consultation, negotiation, and consensus with representatives of the main social and economic organizations. The close and cooperative nature of general government-business relations in Denmark therefore largely made an *explicit* commitment to collaboration redundant. Nonetheless, as one representative of the Danish EPA explained, the decision-making process for nanotechnology is different, not least "[…] since the associations of business have voiced few opinions [on these issues]." (*My translation*) And this as the official speculated "[…] might simply reflect that they are satisfied with our commitment to address these issues in the context of the EU or the OECD." (*My translation*) Perhaps – and Danish companies have certainly been very welcoming of government's regulatory strategy, despite this strategy largely being formulated and implemented without industry input or participation.

Rather than self-sufficiency or reluctance, however, the arm's length relation with business in the nano sector reflects a more fundamental difference between Britain and Denmark: the absence of a viable partnering organization, which could have assisted regulators with detailed information on the market and technological circumstances of the Danish nano industry. The absence of a specialized industry association, and with the established representative bodies either unable or unwilling to produce a progressive and explicit interest strategy for the Danish nano industry, has thus forced regulatory authorities to rely largely on their own in-house capabilities to approach the regulatory challenges of nanotechnology. The implications for the Danish government's regulatory strategy are again best illustrated in relation to research efforts, evidence gathering activities and stakeholder engagements – areas where Denmark has launched measures which largely mirrors HM Government's; while their design may differ, each of these activities were, like their UK equivalents, in different ways intended to inform future regulatory decisions; each in turn were confronted with – and sought to address – existing information deficiencies; each served their purpose individually; but, reflecting not least the absence of a (trusted) interlocutor between government and industry, neither allowed regulators to form a comprehensive understanding of the market and technological conditions of industry.

Research Strategy and Activities

Denmark never established an independent strategic research program on the risks of nanotechnology. The idea of a coordinated and comprehensive program was pitched to government on several occasions (*e.g.* Teknologirådet 2006), but never pursued. This then is the first difference between Denmark and Britain; only superficially so, however, as grant authorities, for example, following recommendations made in a 2004 Action Plan (Videnskabsministeriet 2004), have dedicated significant resources to research into toxicity, epidemiology and bioaccumulation of manufactured nanomaterials as well as funding to support the development of methodologies and instrumentation for monitoring. Grant-awarding bodies moreover tend in part to evaluate funding applications based on whether and how environmental, health and ethical aspects are integrated in project descriptions. Also, government research institutions and universities have established permanent research groups and centers, which link to international research programs under the auspice of the OECD, the EU and the ISO. The National Research Centre for the Working Environment (NFA) has for example since 2005 housed a research group focused on occupational health and safety risks associated with the fabrication and use of nanoparticles and nanoparticle products. Coordination across governmental agencies, research institutions and university centers is facilitated through an informal network of civil servants and experts established by the Danish EPA in 2006. Much like the British NRCG, the network aims to inform research priorities by collecting, interpreting and disseminating information and experiences with risk assessment and risk management of nanomaterials, while seeking to develop research guidelines in support of Denmark's contributions to ongoing efforts in the EU and the OECD. Yet, and this is the more evident difference between Britain and Denmark, industry has played little or no role in either of these activities.

Industry representatives were never invited to join the informal network; government regulators have therefore renounced an obvious opportunity to tap information on the state of applied research, which could have assisted in guiding and informing research efforts and priorities; neither have industry made direct research contributions to the development of risk management methodologies for nanotechnology. Unlike Britain, Danish authorities have not encouraged joint research ventures with industry similar to the PROSPEcT project, although in one instance the Danish Coating and Adhesives Association (Danmarks Farve- og Limindustri) is joint sponsor of a toxicity and exposure research project undertaken by the NFA. This is however rather the exception, with most research on hazard identification and exposure control undertaken exclusively by public research institutions. Where individual companies participate it tends to be as (passive) sponsors of research carried out by university experts and government research institutions. The implication as one industry representative explained is partly that government experts and university researchers are unable to keep abreast of the state of applied research; and partly, much to the representative's dismay that research findings are not allowed to flow back to commercial partners with a view to market and product applications, but are confined to government research institutions and university centers.

Gathering the necessary evidence to support reliable exposure assessments has of course been no less urgent in Denmark; yet research and evidence gathering activities in Denmark could not rely on the assistance of a (trusted) intermediary, which – like the NIA – might have supported or facilitated the collection of information from industry by processing and aggregating responses from members; or by identifying and facilitating contact and cooperation between regulators and individual companies with a particular interest in a given project. Could the main representative of Danish industry in this area, DI or one of its affiliate associations not have assumed this role? Hardly, as DI according to one representative has neither the financial nor technical resources to participate in active research; nor – and this is more to the point – does DI have the means to access information from members, which could have been fed in to research efforts with an eye to guide and influence government research priorities in support of members' needs and interests. The extensive capacities of domestic research institutions and links to international networks have allowed government research efforts to remain largely self-contained; deprived of the market and technological input, which the NIA and members have fed into the activities of the NRCG, research activities in Denmark have however assumed less of a strategic and more of an *ad hoc* nature according to the institutional interests of university researcher and government experts, although individual companies have on occasion agreed to (co-)sponsor toxicity studies and safety testing of specific nanomaterials of commercial interest.

This is not to diminish the value of government funded research in Denmark: indeed, university researcher and research institutions have made clear scientific advances, including valuable contributions to the global safety assessment of nanomaterials. What government research institutions and regulators only to a lesser extent have been able to achieve is to assess business related needs with respect to nanotechnology; nor has government's original ambition of formulating policy measures targeting particular application technologies or industry areas to promote and support nanotechnology innovation and business applications been realized (Videnskabsministeriet 2004; OECD 2009b:53). In short, unlike Britain, collaboration with industry has played only a minor role in supporting and facilitating the Danish government's research strategy. Government research institutions and regulators have occasionally engaged individual companies; yet the absence of an interlocutor between government and industry has prevented government from gaining access to representative and systematic information on the economic and technological circumstances of the entire nano industry; information, which could, as it did in Britain, otherwise have assisted in guiding and informing strategic research priorities. And, just as for Britain, this is a pattern we shall recognize for other of the Danish government's activities.

Evidence Gathering Activities

In the wake of the April 2006 MagicNano incident, the Danish EPA launched two evidence gathering exercises focused on identifying exposure patterns and potential hazards. The first of these projects, mapping the presence of nanomaterials in consumer products, was finalized in spring 2007 (Stuer-Lauridsen *et al.* 2007). The report identified 243 (alleged!) nano-enhanced articles and products on the Danish market. Nearly all products were imported with the majority only available through internet purchase. For most products, however, the report was unable to access information on characterization of nanomaterials; neither was the project team able to obtain documentation or verification of concentration levels (Stuer-Lauridsen *et al.* 2007:9). Parallel to the mapping exercise, the Danish Technological Institute (DTI) conducted a survey on the industrial production and use of nanomaterials (Tønning & Poulsen 2007). The survey, which ran from December 2006 to April 2007, sought information about the application and production of nanomaterials in the Danish industry, current risk management measures and waste disposal practices. A questionnaire was sent to 165 companies, which in different contexts had expressed interest in nanotechnology. Of 75 responses, 24 companies worked with nanomaterials. As the VRS, the two surveys were intended to assist the Danish EPA in determining the immediate levels of exposure and hazards as well as inform considerations on appropriate regulatory controls; moreover, by attempting to access existing technical data and experience from industry, the surveys represented cheap (DKK 300.000 each) instruments to quickly build the knowledge base (OECD 2009a).

Compared to the limited participation in the VRS – 13 submissions during its two year operation – the Danish survey(s) may thus appear to be a success: quantitatively, this is correct with the surveys identifying 243 products and generating 75 responses; qualitatively, however, the surveys yielded less evidence relevant to risk management than did the VRS. The mapping exercise was for example primarily focused on screening existing product databases, and therefore did not directly engage producers or retailers; the (unfortunate) effect of this approach was that for most products the project team was unable to access information on concentration levels or existing data on physico-chemical properties, categorization or measurement. While generating a market overview, the survey did thus not greatly increase the ability to identify exposure pathways or endpoints of specific nanomaterials. Similarly, the industry survey consisted 'merely' of a series of questions addressing mostly use patterns and occupational safety issues. Filling in the questionnaire was less demanding and time-consuming than meeting the submission criteria under the VRS and therefore goes a long way in explaining the higher response rate. In contrast to the VRS, which requested detailed information on properties, behavior measurement and detection techniques, the survey however only generated relatively basic and 'uncontroversial' information on use patterns and risk management practices. With the design and methodology of the two voluntary reporting instruments largely determined by the nature of information sought by the EPA, their 'success' was therefore to a lesser extent than the VRS dependent on input and support from industry. The surveys thus cannot be taken as testimony to the superior evidence gathering capabilities of Danish authorities. (In fact, the EPA commissioned both surveys with external consultants.)

The two surveys did nonetheless generate valuable, albeit basic information; yet what concern skeptics is that neither instruments allowed regulators to access detailed information on manufacturing conditions, production levels, industrial applications and consumer products, experience with detection techniques nor existing knowledge about physical-chemical and toxicological properties – information, critics maintain, essential to gauging not only the immediate levels of risks to human health and the environment, but also to enable an informed debate about the nature of appropriate controls. While the severity of such concerns is of course debatable, the nature of information requested does point to a second more important difference between the Danish surveys and the VRS: commercial confidentiality. Whereas neither of the Danish surveys explicitly mentioned how and for what purposes reported information might be used, the rights of data owners remained a contentious issue for the VRS. No such problems existed in Denmark; one the other hand, neither did the surveys (explicitly) seek to convince companies to divulge commercially sensitive or proprietary information on a voluntary basis. Again, the quantitative results cannot be taken as testimony to the superior evidence gathering capabilities of Danish authorities. Rather, the two voluntary reporting instruments were carefully designed to match anticipated problems of identifying and encouraging participation of relevant companies; in this sense they were a success. Yet, the quality rather than quantity of information submitted under voluntary reporting schemes is often a primary cause for concern (Hansen & Tickner 2007:353); and in this sense their effectiveness is more doubtful. Even though 13 submissions may not sound impressive, this should be contrasted with the still relatively limited number of nanomaterials in commercial application and/or in large volume production (OECD 2010a). Submissions to the VRS has yielded independent and detailed data inputs to hazard identification, dose-response assessment, and exposure quantification for a representative sample of nanomaterials; in contrast, the surveys only allowed Danish regulators to access basic information on use and exposure patterns, hardly sufficient for a comprehensive exposure assessment.

Why did Danish regulators not request detailed (and sensitive) information from industry? In fact, (informally) they did: yet absent a guarantee of commercial confidentiality neither survey managed to convince more than a few companies – fewer even than the VRS – to share such data. Defra as we have seen faced similar problems. But whereas Defra could turn to the NIA as a (trusted) intermediary to assist in convincing companies to participate, this option was not available to the Danish EPA. Industry associations did contribute to the

Danish reporting exercises; yet the nature of this contribution was largely passive. For example, although the list of recipients of the industry questionnaire were largely drawn up based on existing registers and input from university networks, the project team did engage DI and affiliates in an attempt to identify additional companies (Tønning & Poulsen 2007:26f.). The questionnaire itself was however designed by the project team in close cooperation with research institutions, but without consulting industry. This in contrast to the VRS, which was launched following extensive consultation with stakeholders especially the NIA. The mapping exercise on the other hand noted the absence of an intermediary as a clear obstacle to identifying and convincing producers and retailers of nano-enabled products to divulge sensitive product information (Stuer-Lauridsen *et al.* 2007:69). The scope and ambition of the UK and Danish voluntary reporting schemes thus reflect variations in policy options available to regulators: with no interlocutor capable of indentifying and convincing members to participate, the Danish EPA was effectively limited to request information, which would not be confidential or sensitive; nor as valuable to guide regulatory decisions and exposure mitigation efforts as the detailed data inputs to the VRS.

Stakeholder Engagement

Finally, the Danish government's regulatory ambitions have equally embraced the promotion and encouragement of nanotechnology innovation and business applications. With the aim of formulating supportive policy measures, Danish regulators have therefore on several occasions emphasized the importance of knowledge exchange and cooperation with industry. Yet the fledgling nature of the nano-industry has created equal problems of identifying and canvassing the views and needs of industry. Nonetheless, a stakeholder forum comparable to the NSF was never established in Denmark. Instead, Danish authorities have engaged industry through three alternative mechanisms: first, the industry survey explicitly encouraged responses on the need for guidelines and regulation of nanotechnology. Second, authorities have maintained a continuous and informal dialogue with stakeholders on the development of policy. Rather than with an interlocutor, however, the basis of this dialogue has as one government official explained been individual companies approaching regulators to voice their concerns and views; regulators themselves have rarely sought to initiate such exchanges. Finally, in November 2007, the Danish EPA together with the Danish Chamber of Commerce, the Confederation of Danish Industry (DI) and their affiliate sub-associations hosted a public workshop for industry, NGOs and other stakeholders concerning responsible development of nanotechnology (Miljøstyrelsen 2007).[10] According to an EPA official, the purpose of the workshop – much like the NSF – was to foster dialogue with stakeholders; the official however went on to emphasize that the workshop has not impacted on government policy or research priorities. The minimal impact is hardly surprising since the workshop was held subsequent to the finalization of the majority of government's regulatory measure. In contrast to the NSF, the workshop was thus primarily a vehicle to communicate regulatory initiatives to a wider audience

[10] The workshop was held under the auspice of 'Kemikaliedag', a yearly reoccurring environmental policy stakeholder event.

In Britain, the NSF has served as an interface between government and the wider nanotechnology stakeholder community, with deliberations underpinning and informing several of HM Government's regulatory activities and priorities. HM Government has therefore been able to access information on the research needs of companies situated across the nano value chain, the nature of industry drivers and market conditions as well as the state of applied research. While the absence of a stakeholder forum in Denmark has not as such restricted the range of policy options available to government, it has limited the input of current and representative information from industry. Danish regulators are clearly no less capable of addressing the entire industrial community than their UK counterparts; consequently absent a stakeholder forum or an association which could have fed the views of industry into the formulation of policy, guiding and directing regulatory measures and research priorities to support the needs of Danish nano companies have certainly been more difficult; the implications as an industry insider regretfully explained is that Denmark is no longer of commercial interest; among other reason identified where the absence of mechanisms to bring knowledge from universities to the market. Neither a stakeholder forum nor an interlocutor would probably have changed this assessment; but they would have assisted regulators in identifying and canvassing the views and needs of industry, and could thus have facilitated the formulation of policies and measures to encourage the development and commercialization of nanotechnologies.

Summary

Summing up, the Danish government has undertaken and promoted much the same range of regulatory measures and activities as HM Government. In contrast to Britain, however, the Danish government never (explicitly) committed to collaboration with industry. The emerging governance regime for nanotechnology in Denmark is thus largely defined by an arm's length relation among regulators and industry. This in part reflects the absence of a viable partnering organization, which could have assisted regulators with detailed information on the market and technological circumstances of the Danish nano industry. As one government official explained: "The Confederation Danish Industries is who you approach to access the views of industry. Beyond Kemikaliedag [the stakeholder workshop], however, I search my memory for an occasion where they had an opinion [on nanotechnology]. If we were talking about endocrine disruptors or chemicals in general, then they would certainly have a position, but I simply cannot recall an occasion where they had a position on nanotechnology […]." (*My translation*) This may seem strange behavior from an *industry* association: even if DI was satisfied with the Danish regulatory approach to nanotechnology, government regulatory initiatives and research activities should nonetheless have created ample opportunities to shape regulatory decision-making and research priorities to the benefit of members. Of course, government's regulatory strategy did not, as we have seen, encourage collaboration with industry, and therefore has created few incentives for DI or the Danish nano industry to establish an organizational platform to influence and participate in government's regulatory activities. On the other hand, the absence of a viable partnering organization only reinforced the need for regulators to rely on their own in-house capabilities.

Government-Industry Collaboration and the Responsible Nano Code

Danish companies never experienced the pivotal role in decision-making enjoyed by their UK competitors. In Britain, on the contrary, the privileged access to the policy-making process created powerful incentives for nano companies to join with their association in an attempt to influence policy and research priorities. The dependence of HM Government's regulatory strategy on the ability to establish and maintain collaborative relationships with industry, thus testifies to the significant, albeit largely subtle, influence companies and their association have had in shaping and guiding regulatory decisions and priorities in Britain. Yet this situation created new problems. As Coglianese *et al.* (2004:335) emphasize: "For at least the past half-century, social scientists and legal scholars have viewed closeness between regulators and industry as a matter of concern […] Closeness has implied influence and bias, the risk of regulatory capture, and the creation of regulatory policy that systematically favors the interests of industry." In the short to medium term, the absence of clear regulatory response to nanotechnologies may enable a perception of the "Wild West", with companies playing fast and loose with environmental health and safety risks to frighten off potential customers and investors (Seear *et al.* 2009:75). On the other hand, bred in large measure by recent regulatory controversies over mad cow disease and genetically modified organisms, public confidence in regulatory agencies and their ability to act independently of the entities they are meant to control are at an all time low (Sylvester *et al.* 2009:168). The privileged position of industry under HM Government's regulatory strategy, resulting from close, ongoing engagement among regulators, companies and their association, could easily feed into criticism of a perceived lack of transparency; that is, potential notions of 'locker-room discussion' or 'old boys clubs' in regulatory decision-making obviously risk alienating a public generally suspicious of industry and lacking faith in government oversight of technologies. With the experience of GMOs in fresh memory (see RS&RAEng 2004), avoiding rampant notions of 'regulatory capture' among an increasingly skeptic public was obviously in the mutual interests of government and industry. They therefore needed an instrument to legitimize their partnership by reassuring stakeholders that companies commercializing nanotechnologies are adopting a responsible approach. And, this instrument was the Responsible Nano Code.

Developed by a process of multi-stakeholder engagement, the Nano Code aims to establish consensus on good practice in the research, production, retail and disposal of products using nanotechnologies and to provide guidance on responsible business behavior (RNCI 2008a:3). Specifically, the Code seeks to "[…] help promote transparency and accountability and so help build confidence in the technology to that ensure its potential is fulfilled." (RNCI 2008a:5) In this way, the Nano Code allows participating companies to communicate that they understand the technology and are committed to taking a responsible and proactive approach to mitigating any potential risks. The Code may assist consumers in distinguishing among 'responsible' companies and those playing fast and loose with potential hazards; in the future, companies subscribing to the Code may thus be able to shelter their operations from criticism and hysteria in the wake of a 'nanoscare' by allowing companies to distance themselves from potential culprits. If anything, the GMO experience however "[…] teaches that the public is unlikely to trust information coming from industry." (Sylvester *et al.* 2009:171) And, since at least the advent of the chemical industry's Responsible Care program, the image of unilaterally enacted codes of responsible conduct have been tarnished as largely empty gestures, intended either as marketing ploys or as instruments to fend off much needed regulation. While such concerns are certainly reasonable for many voluntary initiatives, several elements of the Code can however be understood as attempts to raise the legitimacy and credibility of the Code: first, rather than a unilateral industry initiative, the Nano Code was as mentioned above developed through a multistakeholder consensus process: the involvement of businesses, governments, NGOs and/or trade unions in code developments tend to lend legitimacy and credibility in the eyes of external audiences beyond what pure industry initiatives can hope for (Vogel 2008:269f.; Berstein & Cashore 2007). Hence, the participation of the Royal Society, the UK consumer organization, Which?, the trade union Amicus as well as several independent experts and academics may deflect some potential criticisms of the Code as a simple marketing ploy.

Second, the accompanying documents to the Code clearly emphasize that it is not envisaged as, in any way, supplanting, displacing, or otherwise subverting the evolving regulatory process, but is merely designed to provide guidance during the transitional period in which appropriate national and international regulatory frameworks are being evaluated and developed (RNCI 2008a). In other words, the stated aim of the Nano Code is *complementary* rather than *preemptive*. Such statements may of course be a mere façade. But the sign-off on the Code by non-business stakeholders does nonetheless lend some credibility to such claims. Third, from the onset, a balance of funding was sought, which would ensure independence from businesses and other specific influences. It was therefore agreed that the Royal Society, Insight Investment and the Nanotechnology Knowledge Transfer Network – but not the NIA nor its members – would fund the initiative, as organizations not involved or representing those involved in the development or commercialization of nanotechnologies (RNCI 2007). Similar considerations led to agreement that a projected benchmarking process would be undertaken by an independent group, which – so as to avoid conflicts of interest – would not include company representatives (RNCI 2008b). These elements of the Code thus address some of the criticisms levied against other voluntary initiatives, *e.g.* the DuPont-Environmental Defense Nano Risk Framework, particularly their lack of transparency and inclusion. Finally, early in the process, HM Government was invited to join in the development of the Code, but declined the invitation. The UK government thus has no (direct) competencies in relation to the Code, which fall entirely within the scope of private (business) actors' responsibilities. As one government official explained "[…] we were quite keen that government shouldn't be seen to endorse the Nano Code as such; it shouldn't come with a government stamp […] we felt it was really industry's role to lead the way on this […]." The official however also emphasized: "It's certainly something we are happy to stand behind, happy to see a Code developed." And, although not willing to join in the initiative, HM Government has indeed generally been welcoming of the Nano Code (*e.g.* HM Government 2008). The refusal to join can thus be seen as a measure to distance HM Government from industry, allowing participating companies to independently cultivate reputations as 'good citizens', while communicating a message of responsibility to garner public confidence. The Nano Code may therefore facilitate government's attempt to justify and legitimize cooperation with a segment of industry, which has demonstrated a commitment to responsible business behavior; more so as this commitment has been formulated independently of government.

In short, the Responsible Nano Code originates with the need to reassure stakeholders (*i.e.* the general public, customers, employees, business partners, investors and insurance companies) that companies commercializing nanotechnologies are adopting a responsible approach to doing so and are proactively and effectively mitigating any risks related to them. While the desire to avoid technology sigma and public backlash applies (equally) to all nano companies, it is interesting to note that surveys on the eve of the initiative's launch demonstrate similar awareness and knowledge about nanotechnology in Britain and Denmark (RS&RAEng 2004a; Informationscenter for Miljø og Sundhed 2007); neither has the degree and tone of media coverage been markedly different (Anderson *et al.* 2005; Kjærgaard 2010). Yet, unlike Denmark, HM Government's strategy of close collaboration with industry significantly increased the stakes for British companies: the need to protect their influence on regulatory decisions and research priorities by avoiding rampant notions of regulatory capture created strong incentives for UK companies. And a code of responsible conduct was thus viewed as an acceptable 'price' for an opportunity to guide the direction of nanotechnology policy. The explanation for self-regulation in Britain and Denmark thus owes little to variations in government legislative ambitions. Rather the explanation lies with the incentives created by HM Government's regulatory strategy for the emerging nanotechnology governance regime.

Conclusion

Upon assuming the regulatory challenge of nanotechnology, the governments of Britain and Denmark confronted a number of immediate problems arising from the uncertain and ill-understood nature of the technology. Guided by a commitment to 'get it right', both governments set off on a regulatory path of ongoing stakeholder engagement and public dialogue; promotion of nanotechnology research and development; and active participation in international efforts to assist in a more informed response to the potential hazards, exposures and risks of nanotechnology. The scope of engagement and regulatory strategies are nuanced only by slight differences; it is thus the commonalities of government responses, which stand out from the analysis. Government agencies in both countries have focused on formulating policy measures and establishing institutional mechanisms to promote and support nanotechnology innovation and business applications; both countries have committed significant resources to address uncertainties about the (eco)toxicological behavior and properties of nanomaterials; and both countries have sought to engage and canvass the views of stakeholders and the public to guide the development of policy and regulatory decisions. Where Britain and Denmark diverge however is in the role and reliance on private actors in the policy process. Whereas regulatory authorities in Denmark has largely favored an arm's length relation with industry, HM Government's regulatory strategy has strongly emphasized coordination of efforts and collaboration with industry; and this has in turn facilitated the integration of the NIA and its members in the emerging governance regime for nanotechnology. Table 1 summarizes the different role of private (industry) actors in Britain and Denmark.

TABLE 1 Government-Industry Cooperation in Britain and Denmark Compared

	NIA	DI
Access to Decision-Making	**High**	**Low**
Policy-Making Body	NRCG	Informal network
Participates	Yes	No
Significance	High	-
R&D programs	PROSPEcT	NANOKEM
Participates	Yes	Yes[a]
Significance	High	Medium
Evidence Gathering Initiatives	VRS	Surveys
Participates	Yes	Yes
Significance	High	Low
Stakeholder Engagement	NSF	Kemikaliedag
Participates	Yes	Yes
Significance	Medium	Low

[a] Danmarks Farve- og Limindustri

Confronted with a set of complex market and technological contingencies, HM Government 'best' response was to engage industry to gain access to information that could assist in setting priorities and developing technically and politically feasible solutions. Given its intimate knowledge of members and their activities, the NIA has been admirably well placed to supply this information. Why did Danish regulators not adopt the same strategy? They did not, partly because the traditionally close and cooperative nature of government-business relations in Denmark made an *explicit* commitment to such a strategy redundant; partly, because they did not have the option: the Danish nano industry has taken no organizational steps to ensure that the industry's special needs and interests are granted an independent and institutionalized expression within the overall organizational context of the representational system. The absence in Denmark of a viable partnering organization therefore only reinforced the need for regulators to rely on their own in-house capabilities. And this in turn only reduced the incentives for the Danish nano industry to establish common organizational structures to support and guide the operations of companies. While in a position to fend off mandatory regulation – largely an empty gesture as government strategy never embraced this alternative – Danish nano companies have thus been unable to collectively engage regulators with a view to shape government strategies and activities. Danish companies therefore never experienced the pivotal role in decision-making enjoyed by their UK competitors. In Britain, on the contrary, the privileged access to the policy-making process created powerful incentives for nano companies to join with their association in an attempt to influence policy and research priorities. The dependence of HM Government's regulatory strategy on the ability to establish and maintain a collaborative relationship with industry, thus testifies to the significant, albeit largely subtle, influence companies and their association have had in shaping and guiding regulatory decisions and priorities in Britain.

Differences in the degree of organization among private actors in Britain and Denmark are thus an important part of the explanation of self-regulation; yet not if this is to imply 'private interest governments': while the NIA boasts neither the independence nor control over members to force upon them decisions and common interest definitions, DI has previously demonstrated such capabilities in areas as diverse as industrial relations and waste management. For all its autonomy and clout with members, however, DI has produced little or nothing in terms of a progressive and explicit interest strategy for the Danish nano industry. As it were, DI lacks the structures to access and channel the interests of the Danish nano-industry in to regulatory decision-making: DI has taken no organizational steps to ensure that the industry's special needs and interests are granted an independent and institutionalized expression within the overall organizational context of the association. Information on the number of nano-enabled products and applications on the market, the state of applied research and the likely future trajectory of the technology is therefore no less accessible to DI than to Danish regulators. DI has thus been unable to proactively engaging regulators with a view to shape government strategies and activities. The NIA management on the other hand professes intimate knowledge of the activities of members; and although the membership of the NIA is relatively small, the association nonetheless does boast some claims to legitimately expressing the views of the industry by representing some of the most prominent companies involved in the development and commercialization of nanotechnology, such as *e.g.* BASF, Unilever, and Johnson Matthey. And, the capacity to tap detailed information on the market and technological circumstances of a wide variety of companies, combined with the ability to promote information circulation among members, has greatly increased the attractiveness to HM Government of partnering with the association.

The Responsible Nano Code thus originates with the need to reassure stakeholders (*i.e.* the general public, customers, employees, business partners, investors and insurance companies) that companies commercializing nanotechnologies are adopting a responsible approach to doing so and are proactively and effectively mitigating any risks related to them. The desire to avoid technology sigma and public backlash obviously applies (equally) to all nano companies. Yet, unlike Denmark, HM Government's strategy of close collaboration with industry significantly increased the stakes for British companies: the need to protect their influence on regulatory decisions and research priorities by avoiding rampant notions of regulatory capture created strong incentives for UK companies. And a code of responsible conduct was thus viewed as an acceptable price for an opportunity to guide the direction of nanotechnology policy. The explanation for self-regulation in Britain and Denmark thus owes little to variations in government legislative ambitions. Rather the explanation lies with the incentives created by HM Government's regulatory strategy for the emerging nanotechnology governance regime. Should we let this shake our general confidence in arguments, which rests on the shadow of hierarchy? Hardly. But it does remind us to stay alert of the importance of actors and their interests when investigating the emergence of voluntary governance mechanisms. Indeed, nanotechnology indicates that industry self-regulation may emerge for other reasons entirely than the desire to preempt statutory regulations. The current regulatory climate dictates a largely reactive approach; in this context, codes of responsible conduct – as well as voluntary initiatives more generally – are likely to serve different purposes, resulting from the broader public skepticism about the introduction of new technologies and the desire to convince the public and the market in the ability of both government and industry to responsibly develop nanotechnologies.

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