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ORIGINAL PAPER

What can Prudent Public Regulators Learn from the United Kingdom Government's Nanotechnological Regulatory Activities?

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Abstract This contribution discusses the United Kingdom (UK) government's regulatory activities related to nanotechnological development. The central question is what other prudent public regulation can learn from the UK government's regulatory strategy, its regulatory attitude and its large variety of regulatory measures. Other public regulators can learn from the interactive and integrative UK regulatory approach. They can also draw lessons from the critique on the UK government's regulatory attitude and its problems to cope with specific nanotechnological challenges. These lessons are based on an evaluation of the UK government's regulatory activities from the viewpoint of prudent regulation. The notion of responsive regulation, which provides basic ideas for the evaluation methodology, refers to a view on prudence that focuses on moral constitutional values. Interestingly, a similar view on prudence has been discussed in nanoethics.

Keywords Nanotechnological regulation · Governance · Governability · Legitimacy · Prudent regulation · Responsive regulation

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Introduction

Regulators[1] and academics who are interested in regulatory issues of modern technologies are having exciting times. The emergence of nanotechnologies[2] seems to pose particular challenges to social and economic regulation. One question is whether the current regulatory toolkit is able to cope with nanotechno-

[1] Following Black, we regard regulation as "intentional attempts to control or order people or states of affairs (albeit mindful of the unintended consequences of those intentions)" [5]. Public regulation refers to sustained and focused control exercised by a public agency, on the basis of a legislative mandate, over activities that are generally regarded as desirable to society ([42]: 363). By private regulation we understand sustained and focused control of social conduct and states of affairs exercised by a private organisation, on the basis of its statutory mandate.

[2] Nanotechnology is described as an emerging engineering discipline that applies methods from nanoscience to create products. Nanotechnologies refer to technologies of the very small, with dimensions in the range of nanometers. See the report of the British Royal Society and the Royal Academy of Engineering (2004), available at: http://www.nanotec.org.uk. A clear and consistent definition of 'nano' still is missing. Nanotechnology is an interesting example of the converging technologies, which connect diverse disciplines of science. In the case of nanotechnology physics, chemistry, genetics, information and communication technologies and cognitive sciences are connected.

logical risk problems, which have been characterised by increasing uncertainty, complexity, and ambiguity [25]. In light of the huge promises of profit-making, governmental ambitions and potential benefits to society it is expected that applications of nanotechnologies will penetrate and permeate through nearly all sectors and spheres of life, and will be accompanied by immense changes in the social, economic, ethical and ecological spheres [30, 39]. At present there is much speculation, but hardly any certainty about nanotechnological risks and technological evolution paths. Does this mean that current regulatory action is deemed to a *laissez faire* approach, which means to do nothing until there is more certainty about nanotechnological development and its risks? Must regulators stick to a reactive strategy or can they develop an anticipatory regulatory approach by which conflicting interests and undesirable lock-in of technological evolution can be accommodated in an early stage?

This contribution explores a prudent approach to nanotechnological regulation. Regarding regulating as a reflective learning process it is presuppose that public regulators can benefit from examples of emerging foreign nanotechnological regulation and the successes and failures of other technological regulation. To explore the opportunities of prudent nanotechnological regulation I evaluate the United Kingdom (UK) government's regulatory activities. In this regulatory field, the UK is one of the pioneers and key players. It has developed an interesting regulatory strategy that responds to the regulatory challenges of nanotechnological development. Although the UK nanotech regulation has been introduced only recently, some preliminary observations can be made regarding its achievements and deficiencies. The central research question of this paper reads: *What can prudent public regulators learn from the regulatory activities of the UK government related to nanotechnologies*?

To answer this question I will first discuss the regulatory challenges of nanotechnological development that call for prudent regulation. Second, I will underpin the approach of prudent public regulation I am advocating. The paper then focuses on its case study, in which the UK's nanotechnological regulatory activities will be described and evaluated. Finally, I will draw conclusions regarding the lessons other public regulators could learn from of the UK regulatory activities.

Regulatory Challenges

Tensions Between Public Interests

The main task of public regulation is to safeguard recognised public interests.[3] According to socio-legal thought, public safeguards imply the protection of constitutional rights as well as the facilitation of desirable social, scientific and technological development and innovation [20, 24, 49]. With regard to technological development, the protective function of public regulation serves to reduce risks and uncertainty, to determine the acceptability of risks and to create trust, while the facilitating function deals with the support of technological innovation. Risk management, which includes decisions about the tolerability or acceptability of risks, is the main task of protective regulation [2]. Facilitating technological development also includes a contribution to the acceptance of technological products and outcomes. Public resistance to nanotechnologies could be a significant barrier to its development [4, 39]. Nanotechnological regulation can learn from experiences with genetically modified (GM) food [41] and the broad approaches to risk governance, which regard risk communication as an important stage of regulation [25]. Hence, public regulators must be prepared to cope with potential public resistance to nanoproducts.

Another challenge refers to conflicting public interests. In nanotechnological development the public interests related to health, environment, employment, occupational safety, privacy, equality, property, national security, scientific research and technological development are involved [15, 17]. Regulatory problems arise, for example, in the manufacturing process of potentially highly beneficial nano-products, where em-

[3] Basically, public regulation is regarded as a means to correct perceived deficiencies in the market system in meeting certain collective interests ([34]: 2). According to economic theory, the many types of public regulation (i.e. legislation, incentives, communication) can be assigned to the categories of economic or social regulation [45]. The public interest justification for *social regulation*, which refers to such matters as health and safety, environmental protection, and consumer protection, tends to centre on two types of market failures. These are information asymmetries and spill-over effects (or externalities), which adversely affect individuals who are not involved in the transactions. The primary rationale for *economic regulation* refers to the fact that monopolies of industries are in general regarded as undesirable.

ployees are exposed to nanoparticles which may be harmful to their health. In this example, society's and industry's interests of technological innovation may be conflicting with the employee's interest in occupational health and safety. As this example indicates tensions may exist between the facilitating function and the protective function of public regulation. In the above example, support for nanotechnological development ('facilitating function') can conflict with protective measures ('protective function') that require waiting with the production of free and deliberately engineered nanoscale materials until there is evidence about health hazards related to the manufacturing process.[4] Hence, nanotechnological regulation is confronted with the problems of balancing potentially contradictory interests. Tensions between publicly recognised interests are also indicating problems of governability, which will be discussed in the next section.

Problems of Governability

Regulatory challenges are induced by particular and general problems of governability. From the very beginning of technological development public regulation has been confronted with particular problems of governability [29, 44]. In the case of nanotechnological regulation these problems arise from the specific characteristics of risk, problems and path dependencies of technological development, as well as from general governance constraints.

Governability of Nanotechnology—Risk Problems

At present there is much speculation, but hardly any certainty about nanotchnological risks. The assessment of the social, ethical and legal consequences relies more on hypothetical assumptions than on rigorous scientific analysis.[5] Speculation concerns include, for example, the emergence of self-replicating nanobots described by Eric Drexler [12], but also the occurrence of epidemics caused by nanotechnological applications. Although there is little evidence about risks, several early studies have shown that there is a number of potential human health risks associated with engineered nanoparticles. It has been shown, for instance, that large doses of nano-particles can cause cells and organs to demonstrate a toxic response ([19, 25]: 15, 41), and that the higher surface reactivity and surface-area-to-volume ratio of nanopowders may increase the risk of dusk explosion. It is expected that the impact of nanostructures on the environment will be significant because of the potential for bioaccumulation and persistence. There is some evidence that the downsized material structures will lead to surprising and unpredicted, or unpredictable, effects. Referring to similar cases (i.e. the asbestos case and drug disasters) many social scientists expect that nanotechnologies will have far-reaching effects on our health, environment, safety and constitutional freedoms [15].

Nanotechnologies are still in an early stage of development. Applications of nanotechnologies already exist in, for example, paints, food additives and cosmetics.[6] In its refined approach to risk governance, the Swiss-based International Risk Governance Council (IRGC) [25] have identified four generations of nanotechnological development, which are characterized by increasing complexity, increasing uncertainty and ambiguity of risks.[7] When technologies are emerging,

[4] This refers to a certain interpretation of the precautionary principles that is often mentioned in nano-debates [19, 23, 28, 37].

[5] However, recently scientific instruments to assess exposure to engineered nanomaterials in air and water, to evaluate their toxicity and to predict their impact on the environment and human health have been discussed [30].

[6] In literature, the numbers of existing nanoproducts vary from 300 to 500 (Woodrow Wilson International Center 2006, available at http://www.nanotechproject.org; Information Society 2006, available at http://www.innovationsociety.ch; [26, 27, 30].

[7] In this approach, nanotechnological risk problems are categorized according to the *knowledge* about the behaviour of nanostructures and about human responses to appraised hazards properties of nanotechnological development. This categorization is refined by relating the general categories to the generations of nanotechnological development. Regarding the knowledge about the impact of nanoproducts the study distinguishes between *simple, complex, uncertain and ambiguous* risk problems. According to the IRGC classification ([25]: 24), there is uncertainty and increasing complexity in the *first generation* (stable behaviour of nanostructures; after 2000). In the *second generation* (after 2005) the nanostructures' properties are designed to change during operation, so behaviour is variable and potentially unstable. The integration of passive and active nanostructures in the *third generation* (after 2010) is expected to lead to unpredictable behaviour because of the complexity of systems with many components and types of interactions. Unpredictable behaviour is as well expected from the *fourth generation* applications (after 2015), in which fundamentally new functions and processes emerge from engineered nanosystems and architectures that are created from individual molecules or supramolecular components.

potential hazards cannot be determined exactly. Complex technological development increases the uncertainty of risks. Due to the complexity and speed of nanotechnological development, there is little certainty about the nature of the particular evolution paths [25]. As a consequence, unexpected effects may occur and risk assessment can be quickly out-of-date. This is why some governance models are rejecting the traditional approach which focuses only on a clear cause-and-effect connection between the behaviour of nanomaterials and their implications [25, 28].

In the context of technological risk governance, the notion of ambiguity includes two aspects. It denotes the variability of (reasonable) interpretations based on identical observations and the assessments of risks. For example, the ability of some nanoparticles to penetrate human brain tissue may be interpreted as an adverse effect, but also as just a bodily response without any health implications. Ambiguity refers also to the variability of normative evaluation with respect to the tolerability of observed effects on a given value or norm. In the context of pluralistic values and norms the importance of the values and norms involved is controversial. Stakeholders can diverge about whether assumed impacts of technology violate or meet predefined values. Regulatory challenges, thus, concern risk evidence, risk interpretation and the tolerability of risks.

Undesirable Paths of Nanotechnological Development

Regulatory problems may also arise from undesirable path dependencies of technological development. This is the case when technological development is getting locked-in in a way that other desirable options are excluded [38]. In this case, technological development becomes more or less irreversible and other desirable development paths may be cut off. Regarding the promise of huge profit-making that is ascribed to nano-products, it is likely that paths which strongly and primarily support nanotechnological development will be taken [31, 50]. Then public regulation can be confronted with difficulties or impossibilities to bring protective measures into the design and application of technology, particularly when safeguards imply large implementation and compliance costs, and when they delay technological development. In this situation we are facing the difficulty that an enormous effort is required to break through locked-in technology and to open alternative paths of development. Openness of technological development is also required to reduce the dependence on technology. As our reliance on computers and computer-assisted systems shows, technological ubiquity makes human intervention difficult [40, 50].

Governability—General Constraints

Nanotechnological regulation is also confronted with general governability constraints, amongst which limited public budgets, generate biases in regulatory measures, and give rise to problems in relation to effectiveness, efficiency and acceptance of public regulation.

Public budgets are generally too limited to fund all possible safeguarding measures. Funding depends on priority setting in public policy, and priority setting depends on the power of the stakeholders involved. Influential stakeholders can succeed in realising their interests at the disadvantage of other parties involved. Regulatory measures can be biased where governance focuses on the support of research and development of nanotechnologies and where there is hardly any budget for protective measures.

Limited resources of public budgets and the necessity of building trust amongst the 'regulated' require effective and efficient regulation, as well as the acceptance of technologies. Nanotechnological regulation can learn from the general problems with regulatory effectiveness and efficiency that have been discussed as major constraints to the governability of public regulation. In the current debate on public governance, critical remarks have been made about implementation and compliance deficiencies of public regulation.[8] In this discussion it is said that certain modes of governance foster the acceptance and effectiveness of regulation, while others are rather detrimental to trust building [8, 36]. Voluntary accords between public and private actors ('negotiated rule-making'), for example, are regarded as more effective than 'command and control' legislation [3,

[8] The current public governance debate is about shifts in coordination and steering methods, and about shifts in approaches and instruments of collective action ([35]: 58). It is a reaction on the critique on the functioning of governments (i.e. to provide remedies for problems of effectiveness and efficiency of collective action) and an attempt to link the contemporary state to the contemporary society.

7, 21, 22]. Soft law mechanisms[9] are said to be more effective than hard law, since it is assumed to be able to cope with the uncertainty of regulatory situations and the dynamics of social development [47]. Conversely, potential drawbacks of soft law include its unpredictability, unreliability, as well as poor due process and accountability facilities [10]. A regulatory challenge is, thus, to combine the most advantageous aspects of public and private regulation, non-hierarchic and hierarchic regulation, soft law and hard law in order to enhance regulatory compliance and break through undesirable lock-ins of nanotechnological development.

Methodology of Prudent Public Regulation of Technology

What is Prudent Regulation About?

In the previous section we saw that regulatory action related to nanotechnologies has to cope with conflicting interests and potentially biased power relations, as well as with problems of technological acceptance, particular risk problems, difficulties of technology locked-in, limited budgets for safeguarding measures and problems of regulatory effectiveness. The method we are seeking for should therefore provide facilities for accommodation conflicting interests and potential rejection of nano-products. It should be able to respond to changing insights into nanotechnological development and risk problems, as well as to learn from earlier failures and successes of technological regulation. Furthermore, it should provide for acceptable hybridisation of governance modes and instruments, as well as for beneficial collaboration of public and private actors.

In my conceptualisation, I build on Philip Selznick's concept of responsive regulation [9, 32, 43]. Responsive regulation seeks to respond to social needs and problems. It assumes that regulatory structures emerge in interactive co-evolutionary processes.[10] Co-regulation is a key method of responsive regulation. Responsive regulation refers to Aristotle's ideas on prudence ('phronesis'). It presupposes a responsibility for the quality of the lives of future generations. In Selznick's theory, 'prudence' inspires a particular regulatory attitude. Prudence encompasses practical wisdom that is concerned with the making of appropriate moral judgments in concrete regulatory situations [43]. 'Practical wisdom' is based on empirical insights into successes and failures of (technological) regulation, as well as on experience with building bridges between conflicting normative requirements.

Interestingly, the notion of prudence has also been discussed in nanoethics [13, 14]. Like Selznick, Dupuy emphasises that 'prudence' must not be reduced to economic calculation ([13]: 238). Like Dupuy and Grinbaum, Selznick [43] stresses that practical wisdom is more than cunning intelligence. According to these views, a regulator would, for example, act prudently only if he supports public engagement in nanotechnological development because she/he is driven by the requirements of legitimacy and good governance. This would not be the case, when our regulator supports public engagement due to the fear that he might lose his reputation and may not be re-elected at the next election. Prudent regulation, thus, encompasses a critical assessment of regulatory attitudes and performances. In the next section we deal with the normative criteria of this evaluation.

Requirements of Legitimacy and Good Governance

In the Western tradition of the democratic and legal state, public regulation is bound to certain principles of legitimacy. These principles are: legality (rule of law), constitutional rights, democratic decision making and control, checks and balances of power, and judicial review [11]. They are regarded as requirements for the realisation of the basic values of freedom, equality,

[9] By soft law we understand rules of conduct which in principle have no legally binding force, but which nevertheless have effects in legal practice [46]. Examples of soft law are: public and private action plans related to nanotechnology, codes of conduct and standards.

[10] By co-evolution we understand co-development and mutual shaping of governance structures. Institutional structures are modulated by all governance actors who are part of the coordination process related to social action [38]. In our case actors are: regulators, scientists, technologists, entrepreneurs, and citizens. Co-evolution implies mutual dependencies, but also partly autonomy of regulatory actors. Established structures, rules, methods, and policies are seen as undergoing a continuous process of revision.

legal certainty, democracy, and effectiveness. In the different jurisdictions of the Western states these values and principles have been interpreted in various ways. However, internationalisation and globalisation challenge those views of national legitimacy. They raise the question, for example, whether it makes sense to focus on the rule of law in a situation where national nanotechnological regulation is largely influenced by international standardisation activities that are not based on legal competences. The same question arises with regard to soft law regulation of public and private actors, which has not been laid down by democratically elected actors.

However, legitimacy questions of multi-level and multi-actor regulation should not be confined to the legitimacy models of the nation states. In multi-level regulation, legitimacy is provided through a 'surrogate' political process with certain additional measures. Such additional measures imply stronger participation of citizens in the regulation process, increased transparency of regulation, as well as increased accountability and control of the impartiality and objectivity of regulators.[11] Participation is regarded as a general prerequisite of democracy. More specifically, the participation of consumers and other stakeholders requires representation in the bodies that are laying down regulation. Participation of consumers will only be effective if their representatives can rely on the relevant expertise and financial sources. Transparency of regulation requires information about the regulation process concerned and its outcomes. Transparency is effective only when the information is accessible, intelligible, all-embracing and objective. Accountability calls for clear formulation and adequate distribution of the responsibilities of the regulators. Control requires the independence of regulators. Independence is safeguarded through excluding financial or other interests in the nanotechnological industry that could affect impartiality.

Evaluation Questions

This paper seeks to examine and provide answer to the following question: what can prudent public regulators learn from an evaluation of the existing UK regulatory activities related to nanotechnology? Referring to the process of policy-making and implementation, this article evaluates the regulatory strategy (including regulatory approach, modes, measures, instruments and attitude), the regulatory process and regulatory outcomes. The evaluation is guided by the paradigm that public regulation should effectively and legitimately respond to the challenges of nanotechnological development. According to the features of (prudent) responsive regulation discussed in the previous sections, the following questions will be answered:

1. *Regulatory strategy*

How can the regulatory approach be characterised (active/passive, interactive/not interactive, integrative/piecemeal, anticipatory/reactive)?

Is the regulatory strategy based on reflective experimentation with governance modes and instruments, or is this not the case?

Is the regulatory strategy primarily driven by moral constitutional values or rather by economic or other rationales?

Does the regulatory strategy focus on the protection of constitutional rights, as well as on the support of nanotechnological development?

Is the regulatory strategy based on reflective revision of regulation structures?

Is the selection of modes of regulation based on an analysis of their strength and weakness in terms of effectiveness, efficiency and legitimacy (including empirical insights into successes and failures of other technological regulation)?

Does the regulatory strategy include measures to cope with the specific governability problems of nanotechnological development ('particular risk problems and undesirable development'), or is this not the case?

2. *Regulatory process*

Are the relevant interests balanced and accommodated? Is regulation drawn and implemented in interaction/collaboration with the relevant stakeholders or is this not the case?

Are the requirements of good governance taken into account in the regulation process (i.e. the requirements of participation, transparency, democratic control and independence of regulators)?

3. *Regulatory outcomes*

Are the objectives of regulation reached with appropriate means or is this not the case ('cost-effectiveness')?

[11] According to the White Paper on European Governance, crucial principles of good governance are openness, participation and accountability [18].

Can the regulation be regarded as legitimate or are there legitimacy deficiencies?

Is the regulation accepted in practice or is there public resistance?

In the next section the UK government's regulatory activities will be evaluated. To be able to answer the evaluation questions, the article will first explore the role of the UK government within UK regulatory action, as well as its policy goals and regulatory strategy.

United Kingdom Regulatory Activities Related to Nanotechnologies[12]

UK Government's Role

The emerging UK regulation related to nanotechnologies has been influenced by certain events that took place in the UK, the EU and other jurisdictions. The willingness of the British Government to engage with nanotechnological regulation was triggered by the publication of Prince Charles' alleged nanotech views and fears in British newspapers in April 2003.[13] When earlier in 2003 the Better Regulation Taskforce recommended the British Government to create nanotechnological regulatory controls, in line with the precautionary principle, the government failed to follow-up this recommendation. However, taking up the publication of the Prince of Wales concerns, a debate on nanotechnological risks and regulation emerged in British newspapers and other societal spheres, resulting in calls for appropriate regulation [48]. The UK Government initially responded with 'risk denial', and noted once more that existing regulation were sufficed to protect the public from possible risks of nanotechnologies. Nevertheless, following ongoing debates on nanotechnological risks [1], the British Government commissioned the Royal Society and the Royal Academy of Engineering (RS-RAEng) to investigate the opportunities and uncertainties of nanoscience and nanotechnologies.

Regulatory institutions emerged in reaction to the conclusions and recommendations of the RS-RAEng report, which was published in 2004.[14] The RS-RAEng concluded that nanotechnologies, in particular nanoparticles, could represent considerable risks. In the Report's recommendations potential health and environment risks of free engineered nanoscale materials were identified. A key conclusion of the report was that lack of data pertaining to health, safety and environmental hazards arising from free nanoparticles. In their recommendations, the RS-RAEng set out a series of research priorities and pointed to the need of stronger public 'upstream engagement'. In its Response, the UK government launched an action plan, which included a range of regulatory measures (2005).[15] This plan can also be regarded as a response to the EC's Action Plan related to nanosciences and nanotechnologies, which was published in the same year [16]. In 2005, the Nanotechnology Industries Association (NIA) was established, which has been active in standardisation, best practices and other regulatory guidance, and which is supported through governmental funding. Early 2006 the Royal Society, Insight Investment and the NIA founded the Nanotech Governance Code Initiative. Two years after the implementation of UK Government's Response, the Council for Science and Technology is in the process of reviewing the Government's progress in relation to its Response, and assessing the implications of any new developments.[16]

Policy Goals and Regulatory Strategy

Policy Goals

According to the consulted policy documents, the main objectives of the UK Government's regulatory measures are to safeguard responsible nanotechnological development and to shape international global development in the context of the benefits of nanotechnology. The UK Government considers that it is essential for the emerging regulatory regimes to

[12] The case study is based on policy documents and literature.

[13] Prince Charles was alleged by the Mail on Sunday (27th of April) as having serious concerns over nanotechnologies, because of 'Grey Goo fears', a scenario whereby self-replicating nano-machines consume the entire biosphere (see, [12]). Greenpeace UK expressed similar concerns.

[14] Available online at http://www.nanotec.org.uk/finalReport.htm.

[15] Available online at http://www.dti.gov.uk/science/.

[16] The Council for Science and Technology is the UK Government's top-level advisory body on science and policy issues.

be internationally agreed and harmonised to realise the benefits of nanotechnologies more quickly and cost effectively. Health, safety, environmental and (more general) consumer rights, as well as property rights and scientific freedom, are the crucial legal values at stake. The UK Government expressed its willingness to take public concern about the benefits and risks of nanotechnologies seriously into account. In this regard, the UK Government is inclined to learn from the BSE-crisis and the regulation process related to biotechnology [33]. According to the UK Government's Response to the Council for Science and Technology's Call for Evidence, the overall objective of its policy is that the UK remains at the forefront of the development of nanotechnologies.[17]

Regulatory Strategy

In line with the recommendations of the RS-RAEng (2004), a main focus of the UK Government's regulatory strategy is to gather the necessary evidence to enable appropriate controls to be determined. Other regulatory cornerstones are: the promotion of nanotechnological development and research, a support of stakeholder and public engagement, the review of the existing regulatory framework, international engagement, national co-ordination and the support of standardisation and other activities of self-regulation (amongst which codes of conduct and best practices). In line with the EU policy the UK government's regulatory approach focuses on the self-control of researchers and industry, as well on incremental adaptation and harmonisation of existing regulatory frameworks. The regulatory focus does not lie on the establishment of specific nanotechnological legislation. In the regulatory activities, instruments of soft law are used rather than instruments of hard law [10].

Regulatory Measures

Evidence Gathering The voluntary reporting scheme for industry and research organisations is an important measure to provide the UK Government with information on potential risks of nanotechnologies. In September 2006 the Department for Environment, Food and Rural Affairs (Defra) introduced a Voluntary Reporting Scheme (VRS) for engineered nanoscale materials. The scheme's purpose is to develop a better understanding of the properties and characteristics of 'free' engineered nanoscale materials, in order to enable informed consideration of potential hazards and risks and enable decisions to be made in relation to the necessary controls to protect human health and the environment. More specifically, the scheme is expected to deliver information through which the applicability of existing legislation can be tested. It is being run by Defra and will operate to September 2008. From March 2006 to June 2006 the proposed scheme was under consultation. In this process 120 relevant stakeholders were addressed[18] and a workshop was held. Following some new input Defra modified the proposal. The scheme refers to free and deliberately engineered nanoscale materials (dimensions to 200 nm). It is targeted at any company or organisation involved in manufacturing, using, importing or managing wastes consisting of those nanoscale materials. Data submission follows a certain format that has been set out in the Annex of the scheme. The format is not, however, mandatory. Data can also be submitted through third parties, including, for example, trade chambers, which will be important in cases were organisations wish to remain confidential. The scheme is subject to six monthly reviews. Guidance is expected to change as the scheme is developed and refined. Quarterly updates will be made public, and a six-monthly summary report has been published in Spring 2007.

According to the quarterly reports covering the period 22/09/2006 to 22/06/2007, nine submissions were received (seven of these were received from industry and two from academia). In the first review of the scheme the Advisory Committee for Hazardous substances (ACHS) felt that the current low level of response to the scheme, and the variable quality and relevance of data submitted was due, in part at least, to shortcomings in the scheme guidance, particularly in defining how the data submitted will be used and what data might be relevant. The Committee has recommended some changes to aid clarity in the data reporting form. In its response, Defra stressed that these recommendations will be taken forward. It will continue to monitor the situation and provide support in the completion of the data submissions where this

[17] See note 15.

[18] Only 37 stakeholders replied.

is requested. It is in regular contact with the UK's nanotechnologies industries and the research community to raise the profile of the scheme and to resolve areas of uncertainty regarding its scope and objectives. Interestingly, the European Nanotechnology Trade Alliance (ENTA) has offered to act as a 'broker' through whom submissions to the scheme may be made. According to Defra, this may afford anonymity to anyone wishing not to disclose company, personal or other details in their submission.

Promotion of Nanotechnological Development and Research The UK Research Councils are funding ongoing fundamental research (for example, the Economic and Social Research Council (ESRC) invests about £40 million per annum in research grants and supports 40 new PhD studentships per annum). In addition, the Department of Trade and Industry is spending £90 million over 6 years on research and infrastructure that promotes the commercialisation of nanotechnologies with a focus on collaborative research and technology transfer. ESRC and Defra are funding several projects on social and economic aspects of nanotechnologies, including the adequacy of current risk governance frameworks, scenario workshops, potential barriers to nanotechnological development and the role of non-scientific expert advice. Moreover, Defra has commissioned a project to examine the nature and magnitude of the potential environmental benefits, including the implications for government policy.

Support of Stakeholder and Public Engagement In 2005, the UK Government published its programme for public engagement on nanotechnologies. The programme is centred on three Government funded projects: Nanodialogues, the Nanotechnology Engagement Group (NEG), and Small Talk. Nanodialogues examine the practicalities of the concept of 'upstream' public engagement through a series of case studies. The NEG is charged with mapping out and analysing the current practices of public engagement on nanotechnologies with the aim to provide information about the conditions under which early public engagement can influence policy and decision-making. The Group also functions as a forum for deliberation on the implications of ongoing public engagement activities. According to UK Government, "Government needs to learn from the activities taking place under this programme, as well as those funded by other organisations, to maximise the benefits of any new public dialogue initiatives".[19] To ensure that this learning takes place, the chair of the specific Government Task Force is involved in the three funded projects.

In addition to these projects, Defra has set up a Nanotechnologies Stakeholder Forum, which enables key stakeholders from industry, academia and civil society organisations to learn about and discuss each other's views, as well as Government activities, on appropriate research and control. The purpose is to create more informed and thus stronger policy outcomes through interaction of these stakeholders, in which they constructively address their concerns.

As concerns the dialogue with industry and academia, Defra and Health and the Safety Executive (HSE)[20] have organising a series of debates over the responsible development of nanotechnologies. These discussions have included the issue of good practice guidance for the manufacture, use and disposal of nanomaterials. In this dialogue government organisations encourage researchers and businesses to adopt a precautionary approach. To ensure transparency, information is widely disseminated through web pages, infolines, and a HSE helpdesk.

Review of Existing Regulation In the implementation of the UK Government's Response to the RS-RAEng (2004) report, each government department was commissioned to analyse and document how current regulations for which they have responsibility accommodate nanoparticles. The departments' reviews have been analysed by HSE with regard to its responsibilities in the field of health and safety regulation concerning industrial chemicals and the risks they pose in the workplace. In addition to the specific reviews by the relevant departments and agencies, the Office of Science and Innovation (OSI) within the Department of Technology (DTI) were asked to commission a short study to provide an overview of the potential regulatory implications for the UK of developments in nanomaterials across all product and activity types and regulatory areas. This study was published in December 2006.[21]

[19] See note 15, Government Response to Call for Evidence by the CST, chapter 2 (11).

[20] HSE is a UK regulatory authority which is responsible for the negotiation, agreement and enforcement of implemented EU regulation and other UK regulation concerning chemicals, workplace exposure, control of accident hazards etc.

[21] Available at http://www.dti.gov.uk/science.

In all these reviews, the main question was whether existing regulation is adequate to deal with potential hazards from engineered nanoscale materials. The aims of the studies were to identify any significant existing or future likely regulatory gaps, as well as inadequacies or inconsistencies of regulation. Subjects of the reviews were the regulations related to the development, manufacture, supply, use and end of life of free engineered nanoparticles. In the reviews regulations concerning marketing controls, health and safety, consumer and environmental protection and waste regulation (amongst which food safety, chemicals, medical devices, pharmaceuticals, cosmetics and waste disposal regulations) were screened. 86 examples of current legislation were identified. According to the reviews, the existing regulations are not tailored to free engineered nanoparticles. More specifically, the DTI study identified nano-specific regulatory problems with regard to thresholds, definitions, scopes and interpretations of current regulations. The study recommended adaptations to the existing regulatory framework to accommodate the properties and implications of nanomaterials. It also recommended the use of an integrated regulatory approach, especially since current regulation was not designed with nanotechnology in mind and is inevitably piecemeal, being contained in various statutory provisions spread over different areas of regulatory activity.

According to the UK Government, all reviews of the existing regulatory framework have concluded that the current legislative approach is capable of regulating current and emerging risks posed by engineered nanoscale materials.[22] In its view, no significant gaps have been detected. It admits, however, that there is not enough understanding of the potential risks and thus of the adequacy of the risk assessment models on which existing regulatory frameworks are based. This is why it emphasises the need of standardised risk assessment and the review of European regulations on chemicals and cosmetics.

International Engagement The UK has developed a wide network of international contacts in the field of nanotechnology. With regard to regulatory activities it is strongly co-operating with the United States (US). The UK is playing a prominent role in the regional and international discussion. For example, in October 2006 the UK hosted a meeting of the OECD Extended Steering Group on Manufactured Nanomaterials. It is holding the Chairs and the Secretariat for the newly created Technical Committees for Nanotechnology Standards both in the EU and the International Standards Organisation (ISO). The UK Government is closely co-operating with the EC and other European Union (EU) Member States to encourage co-operation on the responsible development. For example, UK Government is working with the EC to reach agreement on the interpretation of nanomaterials in the context of the new Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation.[23]

Cross-national collaboration is being supported by the UK Overseas Science & Innovation Network. This Network has been very active in promoting UK nanotechnologies and co-operation through meetings with representatives of Japan, Germany, Taiwan, Malaysia and Singapore. International engagement also means to bring together scientists from across the UK and beyond, to build research capacity, encourage knowledge transfer and forge links with international researchers and policy makers. This is one of the tasks of the UK Environmental Nanoscience Initiative (ENI), which provides exploratory grants and acts as a bridge between fundamental science and policy development.

National Co-ordination The UK Government has established a large network of regulatory co-ordination. The government's implementation of its Response to the RS-RAEng (2004) report is co-ordinated through the Nanotechnology Issues Dialogue Group (NIDG), which is chaired by the Office of Science and Innovation (OSI). Other co-ordination groups are: the Nanotechnology Research Co-ordination Group (NRCG), the Committee of the Research Councils UK (RCUK) and the NanoSafeNet. The NRCG is chaired by Defra. It is responsible for developing a cross-government research programme into the potential human health and environment risks posed by the products of nanotechnologies and overseeing the programme of public dialogue and socials research. NIDG ensures that the Work of the NRCG is integrated with other parts of the programme of work set out in the Government's Response. The RCUK is a strategic partnership through which the UK's eight Research Councils work together to champion the research, training and innovation they support.

[22] See Government Response to Call for Evidence by the CST, chapter 2.

[23] See [6].

Support of Standardisation and Other Activities of Self-regulation According to the consulted policy documents, the DTI is supporting the British Standards Institute and the National Physical Laboratory activities to place the UK in a leading position for the development of international standards for nanotechnologies. The DTI supports also the Institute's work on the Good Practice Guide on handling and disposal of free engineered nanomaterials, the Guide to specifying nanomaterials, and the Good Practice Guide for labelling of nanoparticles. Furthermore, the UK Government is funding the regulatory activities of the NIA.

In the next section the UK Government's regulatory activities will be evaluated. In this evaluation we seek answers to the questions that were formulated in "Evaluation Questions". Since the UK nanotechnological regulation has been introduced only recently, our evaluation focuses mainly on the regulatory strategy.

Evaluation

The UK Government's regulatory strategy seems to be active, interactive and integrative, but also strongly reactive. It is built on a pioneering attitude aimed at taking the lead in regulatory action related to nanotechnologies. Regulatory leadership is based on gaining key positions in international standardisation organisations, pioneering with good practice guides and terminology documents, bringing them into the relevant EU bodies, hosting important meetings and conferences and funding research and public dialogue. By funding regulatory activities of science and industry, the UK Government is speeding up national nanotechnological development. Comparing the UK to other EU Member States, the size of UK Government subsidies is remarkable. Regarding the dialogue the UK Government is conducting with industry, citizens, other governments and international organisations and the consultation on regulatory action it has initiated the regulatory approach occurs to be strongly interactive and integrative. Integration of various UK regulatory activities is taking place in the co-ordination network the UK government has established.

One reason why I tend to regard the UK regulatory strategy as reactive is due to the way in which the UK Government is dealing with legislation. The voluntary self-reporting schemes and the reviews of existing legislation show that the UK Government is ready to wait with legislative action until there is evidence about the properties and risks of nano-products, which could indicate regulatory gaps. Another reason for characterising the UK approach as reactive is that governmental action was primarily taken under pressure of other actors (amongst which the RS-RAEng is one). As discussed above, the UK government initially responded to the Prince of Wales and the Better Regulation Taskforce's calls for controls over nanotechnologies by denying the necessity of creating regulation. In sum, the UK Government's regulatory approach can be characterised as an interactive and integrative reaction on growing insights into regulatory needs and concerns.

Regarding the emphasis the UK Government is placing on the promotion of the benefits of nanotechnological applications economic rationales appear to be the primary motives underlying its regulatory strategy. We saw that this strategy is being driven by considerations of cost-effectiveness and the ambition to remain at the forefront of the development of nanotechnologies. In the light of this focus it is questionable whether the ideas on responsible development, which are mentioned in the policy documents, will be put into practice. By now, the constitutional values involved in nanotechnological development have not been studied in depth. The studies the UK Government has undertaken and commissioned focus on 'technical' regulatory gaps rather than on 'moral' gaps.

According to the consulted policy documents, the UK Governments regulatory strategy focuses on reflective learning. In its response to the Call for Evidence of the Council of Science and Technology, the UK Government has repeatedly stressed that it needs to learn from public concern, stakeholder engagement and experience with other technologies. In the consulting process, which it has initiated with regard to the voluntary self-reporting scheme, one aim was to learn from nanoscience and nano-industry. To learn from the (lack of) submissions of academia and industry is still an important issue in the reviews and governmental discussions related to this scheme. Furthermore, according to the intentions of the UK Government, insights into the current low level of submission will guide further action with regard to the scheme. In this context the question arises, however, whether the UK Government seriously analysed the potential weakness of the

voluntary reporting scheme before it laid down its regulatory guidance. Otherwise it could have learnt from critical remarks on effectiveness problems that were made during the consultation process, and which seem to be corroborated by the few data submissions. If the UK Government had seriously taken into account the critical remarks on the strong interests of commercial confidentiality and intellectual property, as well on the reliability problem of open data submission formats, it possibly would have taken more mandatory action to enhance the enforcement level.

Regarding the specific governability problems the UK Government's monitoring of the nanotechnological development is an import regulatory measure which has been designed to assist it with dealing with the specific regulatory challenges of increasing uncertainty and complexity of risk problems and locked-in technologies. With regard to risk problems, the UK focus is relying on the traditional model of evidence gathering. By primarily focusing on soft law instruments, the UK government appears to have learnt from general governability critique on 'command and control' legislation.

In this early stage of regulatory development it is not yet possible to adequately answer the question of whether the relevant interests have been balanced and accommodated. What we can see is that there is a process of ongoing evaluation. Regulation is drawn and implemented in interaction and collaboration with the stakeholder involved. In this stage of emerging regulation, only some preliminary remarks can be made on the requirements of good governance. Participation in regulatory decision-making has been supported by measures of public engagement and stakeholder consultation. In the case study presented here, we saw that transparency on governmental decision-making is provided by the disclosure of policy documents. With regard to the requirements of accountability, independence of regulators and democratic control further empirical study must be undertaken. These and other requirements of good governance must be explored more deeply in the future stages of nanotechnological development.

Conclusion

To answer the central question of this paper ('what can prudent public regulators learn from the regulatory activities of the UK government related to nanotechnology') the first step is to explore whether we can regard UK Government as a prudent regulator. Considering the answers to the evaluation questions discussed in "Evaluation", it is possible to conclude that some aspects of the UK Government's regulatory strategy corresponds to the characteristics of prudent regulation. This is certainly the case with the UK Government's strategy of ongoing monitoring and reflective review of the regulatory frame, as well as with its interactive and integrative regulatory approach. As a prudent regulator, the UK Government has made a start to experiment with governance modes and instruments. However, the focus on primarily voluntary modes of soft law seems to be insufficient in the case of strong commercial and confidentiality interests. It remains to be seen whether the UK Government will take a prudent stance of 'smart' hybridisation and combine the advantages of voluntary regulation with the advantages of mandatory legislation. Other public regulators can learn from the prudent UK regulatory approach and from the challenges of 'smart' hybridisation the UK Government's regulatory strategy is indicating.

Other public regulators can also learn from the potential 'failures' of UK regulatory activities. If it turns out that the self-reporting scheme and other regulatory measures are not effective, other countries can try to avoid these problems. Considering the focus on the promotion of nanotechnological development ('economic rationales') and the initial resistance to take regulatory action we doubt that the UK Government can be regarded as a prudent regulator. According to our methodology, prudent regulation is driven by moral constitutional values and not primarily by economic rationales. A similar conclusion can be drawn with regard the UK Government's focus on evidence gathering (amongst which the regulatory activities of the self-reporting scheme and many funding activities). In this context the question arises whether the evidence related measures will be appropriate to cope with the specific nanotechnological risk problems. According to influential risk governance studies we discussed in the second section, the traditional evidence gathering approach, which is based on clear cause-and-effect relations, seems not to be adequate to cope with the increasing uncertainty and complexity of nanotechnological risk problems. The reviews of current relevant UK legislation show how problematic the focus on risk probability is. With this focus a regulator could end up in a vicious spiral and being unable to take regulatory

action because evidence of hazard or risk cannot be provided. Hence, other regulators could also learn to avoid locked-in regulation and to learn form new methods of risk assessment.

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