Coping with the complexity, uncertainty and ambiguity of risk problems related to nanotechnologies development – how can public regulation be developed in a process of reflective learning?

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Work in progress, do not quote![1]

1. Introduction

Quite recently regional and national regulators became aware of the huge governance challenges of the emerging nanotechnologies.[2] In the past six years governments, NGO's and industries have set up national, regional and international networks, in which the benefits, risks, ethical, legal and social aspects of nanotechnological development are being discussed.[3] Though there is much concern about the risks of these new technologies, no specific legal action has been taken by now to anticipate potential damage to health, safety, the environment, and consumer protection. One of the few pioneering regulatory initiatives is the United Kingdom's proposal of a voluntary reporting scheme for industry on engineered nanoscale materials which includes a partial regulatory impact assessment.[4] Another initiative is the US 21st Century Nanotechnology Research and Development Act of 2003, which authorises the funding for nanotechnology

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[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 (The Royal Academy, 2004, see: www.nanotec.org.uk). 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.

[3] Amongst which in Europe: Nanoforum (www. nanoforum.org); reports of the European Commission on nanotechnolgies, 2004 (Community Health and Consumer Protection); The US National Nanotechnology Initiative (Kalil, 2004); in the UK the report of the Royal Society and Royal Academy of Engineering (www.nanotec.org.uk) and the DEMOS-report (www.demos.co.uk); in Switzerland the White Papers of the International Risk Governance Council (www.irgc.org).

[4] See, www.defra.gov.uk/corporate/consult/nanotech-vrsl/index.htm.

research and development over four years.[5] By this Act a National Nanotechnology Advisory Panel has been established. In the EU, the focus lies on responsible development of nanosciences and nanotechnologies.[6] With regard to public regulation, the EU advocates an incremental approach. It opts or using existing legislative structures (e.g. dangerous substances legislation, cosmetic legislation, patent law) to the maximum, revisiting them, and, when appropriate only, amending them. In addition to the review and modification of existing legislation, the EU is making an effort to intensify international cooperation with a view to adopting a declaration or a 'code of good conduct' for the responsible development and use of nanotechnologies.[7] Apart from national and regional initiatives a more general approach to technological governance can be derived from the Precautionary Principle, which has been highly debated in international politics (Ashford 2002; Haum et.al, 2004; Krämer, 2003; Majone, 2002; Rip, 2006a). Though there is no general rule in the application of this Principle in different states, there is a common understanding that precautionary action should not be postponed if there is a lack of full scientific certainty in cases where there are serious risks and potential irreversible damages for health and the environment. By now, however, it has been difficult to limit the vagueness of this Principle. Another relevant principle is the As-Low- as- Reasonably Possible- Principle, which is applied to determine the tolerability of risks.

Regarding the risk problems of nanotechnologies all these regulatory efforts seem too piece-meal and partisan. Public risk regulation still is mainly based on the assumption of a hierarchic, homogeneous and linear technological evolution (Ladeur, 2003). As Renn and Roco put it (IRGC, 2006:28): "The current regulatory measures generally deal with a single event and its cause-and-effect, and do not consider the life cycle of products, secondary effects of interactions with other events. Regulatory organization and measures are fragmented by the area of jurisdiction, type of regulation (product, process, etc.), intervention levels and national and international harmonization of assessment and management procedures (or the lack thereof)." Obviously, current regulatory measures cannot cope with the new uncertainties, complexity and ambiguity of risk problems that are induced by the emerging nanotechnologies. The implications of nanotechnological development call for a trans-boundary and global governance approach, in which reactive and proactive, anticipatory regulatory measures are integrated.

[5] On December 3, 2003 the President of the United States signed this Act into law (see, Public Law No: 108-153), see also Honda, 2004; Fisher and Mahajan, 2006.
[6] Communication from the Commission, Nanosciences and nanotechnologies: An action plan for Europe 2005-2009 COM (2005) 243 final.
[7] See note 3, p. 11 (7.1).

In this paper I seek answers to the question which strategy of public regulation can cope with the risk problems of nanotechnological development. Which regulatory approach do public regulators need to manage risks and to anticipate damages to freedom, health, the environment, as well as to facilitate nanotechnological development? Which institutional structure can satisfy the need for international harmonisation of regulatory standards? To answer these questions we first must know what the particular risk problems of nanotechnological development are about. In the next section these risk problems will be characterized. The third section deals with a theoretical framework that can underpin an anticipatory regulatory approach which integrates corrective regulatory measures. My proposition is that a responsive regulatory approach based on interactive and reflective social learning can cope more effectively and legitimately ('responsibly') with the risk problems of nanotechnologies than the traditional static, endogenous regulation approach. In the fourth section I explore what can be learned more specifically from risk assessment approaches to nanotechnology and regulatory experience. This leads to conclusions regarding the regulatory strategy I am developing.

2. Characteristics of nanotechnological risk problems

2.1 What is nanotechnological development about?

Nanotechnology refers to the development and application of structures, materials, devices and systems with fundamentally new properties and functions which derive from their size in the range of about 1 to 100 nanometers (Siegel et al., 1999). Following Roco (2004), four overlapping generations of nanoproducts can be identified with the potential for development in the period 2000-2020: passive nanostructures (first generation: mainly after 2000; e.g. nanostructured coatings); active nanostructures (second generation: after 2005; e.g. targeted cancer therapies), integrated nanosystems (third generation: after 2010; e.g. artificial organs built from the nanoscale), and heterogeneous molecular nanosystems (fourth generation: after 2015/2020; e.g. nanoscale genetic therapies). In the *first generation* inert or reactive nanostructures have stable behavior and quasi-constant properties during their use, while in the *second generation* the nanostructures' properties are designed to change during operation, so behaviour is variable and potentially unstable. In the *third generation* passive and active nanostructures are integrated. *Fourth generation* applications are expected to emerge fundamentally new functions and processes from engineered nanosystems and architectures that are created from individual molecules or supramolecular components.

2.2 Speculation about nanotechnological risks

In the development of strategies of public regulation a first step is to categorize risk problems. According to influential commentators, 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 (ICGC, 2006: 19). With regard to the impact of nanotechnologies 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) scientists expect that nanotechnology will have far-reaching effects on our health, environment, safety and constitutional freedoms. However, there is little evidence about risks. Several studies have experimentally shown that there are human health risks, for example that large doses of nano-particles can cause cells and organs to demonstrate a toxic response (IRGC, 2006: 15, 41). The higher surface reactivity and surface-area-to-volume ratio of nanopowders seems to 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.[8] A major problem is that there is much speculation, but hardly any certainty about human development risks (e.g. change of human identity through nanotechnological applications) and the ability of the regulatory environment to react rapidly on the new technologies. The assessment of the social, ethical and legal consequences relies more on hypothetical assumptions than on rigorous scientific analysis. Nanotechnology is still in an early stage of development.[9] Furthermore, in the appraisal of risks stakeholder concerns, perceptions and suspicions related to the impact of nanotechnology, industry's motives and governmental regulatory ability play an important role. In the next subsection a sophisticated categorization of nanotechnological risk problems will be discussed (IRGC, 2006). This categorization can serve as a basis for a regulatory strategy.

2.3 Categorising nanotechnological risks problems

Following Renn and Roco, 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. In a second step this categorization is refined by relating the general categories to the generations of nanotechnological development.

[8] In effect creating non-biodegradable pollutants which, due to the small size of the nanomaterials, will be hard to detect (see, Renn and Roco, 2006: 15).
[9] Applications already exist in paints, food additives, cosmetics etc. (see, Jopp, 2003).

Categorisation according to knowledge about the impact of nanopruducts

Regarding the knowledge about the impact of nanoproducts we can distinguish between *simple, complex, uncertain and ambiguous* risk problems. According to Renn and Roco (IRGC, 2006: 34), the first three categories relate to the properties of our knowledge about nanostructures being able to generate specific hazards. In contrast, ambiguity is a property of knowledge related to human responses to the hazards. As will be shown below, these types of risk problems are intertwined and can be overlaid on each other.

Simple risks refer to products where there is a clear cause-and-effect connection to behaviour of materials and their implications. As concerns *complex* risks this causality is difficult to identify, because of a multitude of potential causal agents and specific observed effects in a system or a system component. Nanotechnological development follows paths of extremely complex design and theoretic modelling. Scientists and technologists have insufficient knowledge about the cause-and-effect chains of technological development as well as their possible impacts on the various areas of nanotechnology applications.

Uncertainty about risks is a general feature of technological development. Even in the event of products where there is a rather clear causal connection unexpected effects can occur. Human knowledge about technological development is always incomplete and selective (Ravetz, 1999). In the case of nanotechnology, scientists, engineers and other experts are confronted with risk problems that they do not (completely) understand. There is much uncertainty about the effects of nanotechnology. Experience, well-understood and well described causality chains are no longer characteristics for the "framing" of risks: uncertainty at different steps of product development and the product's use are the rule rather than the exception (Ladeur, 2003: 1461). Also due to the complexity of nanotechnological development, there is hardly any certainty about the nature of the particular evolution paths. In addition, nanotechnological evolution follows other time frames than conventional technologies. Technological development is taking place more rapidly. As a consequence, risk assessment can be quickly out-of-date.

In the context of risk regulation *ambiguity* refers to the variability of reasonable interpretations of effects, as well as the variability of normative evaluation with respect to the acceptability of observed effects on a given value or norm. When the first aspect is concerned, questions are asked like: Can the ability of nano-particles to penetrate brain tissues without causing any observable harm be interpreted as an adverse effect or is it just a bodily response without any adverse health implications? The acceptability of risks is concerned when we ask whether the observed effects violate or meet values or norms. Answers to this question often lead to new questions about the values that are at issue and about how essential these values are and for which

groups. According to Renn and Roco, high complexity and uncertainty favour the emergence of ambiguity, but there are also quite a few simple and highly probable risks than can cause controversy about human responses to the hazard (IRGC 2006: 34).

Categorisation related to the generations of nanotechnological development

In the development of a risk regulation strategy the next step is to relate the categories of risk problems to the stages of nanotechnological development. According to Renn and Roco, in the *first generation* (stable behaviour of nanostructures) there is uncertainty and increasing complexity (IRGC, 2006: 24). Potential high-risk products are nanoparticles in cosmetics or food with large scale production and high exposure rate, and ultrafine powders. In the *second generation* the nanostructures' properties are designed to change during operation, so behaviour is variable and potentially unstable. Examples of potential high-risk products are: nano-bio interface devices, neuron-prosthetics, reactive devices placed in the environment, active devices in the human body, and devices for surveillance. Potential higher-risk areas are nano-biotechnology; neuron-electronic interfaces; and agriculture and food systems. The integration of passive and active nanostructures in the *third generation* is expected to lead to unpredictable behaviour because of the complexity of systems with many components and types of interactions. Examples of potential high-risk products include: emerging behaviour robots, evolutionary artificial organs, and brain modification. Potential higher-risk areas include: nanorobotics; regenerative medicine; brain-machine interface; and nano-engineering in agriculture. Unpredictable behaviour is as well expected from the *fourth generation* applications, in which fundamentally new functions and processes emerge from engineered nanosystems and architectures that are created from individual molecules or supramolecular components. Examples of potential high-risk products are: evolutionary cells: and self-replication of large nanostructured systems. Potential higher-risk areas include: neuromorphic engineering, and human-machine interface. Through the second to the fourth generation risk problems are characterized by increasing complexity, uncertainty and ambiguity.

Conclusion. As concerns the regulatory strategy we are searching for this categorisation can be useful to distinguish between regulatory measures related to the first generation and measures related to the second to fourth generation of nanotechnological development. This is the approach Renn and Roco advocate when they discuss two frames of risk governance (IRGC, 2005; 2006). Considering the characteristics of risk problems in the first stage of nano-development and the fact that the extent of knowledge about risks, as well as the ability to control nanostructure

behaviour is more advanced for frame 1 (first generation) than for frame 2 (second to fourth generation) our regulatory strategy could distinguish between rather concrete regulatory measures (first generation) and regulatory action of monitoring risk assessment and the evolution of nanotechnology (all generations). Regarding the unexpected effects that can also occur in the first stage, as well as the rapid development of nanotechnology and the increasing complexity of risks I conclude that a strict division of regulatory measures into two frames does not seem to be appropriate. Our regulatory strategy must be based on an integrated and dynamic approach to regulatory action. In this approach public regulators explore the potential of concrete regulatory measures (for example, a self-reporting systems of risks or an act related to nanotechnological development and risk governance) and the possibilities of anticipatory action rather synchronically than sequentially.

3. Theoretical framework of regulatory strategies

3.1 Rationales of public regulation of nanotechnology

When we develop a regulatory strategy another basis question is why we need public regulation. According to economic theory, the rationale of public regulation is to correct perceived deficiencies in the market system in meeting collective or public interest goals (Ogus, 1994: 2). [10] The many types of public regulation (i.e. legislation, incentives, communication) can be assigned to the categories of economic or social regulation (Sunstein, 1990). 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. According to economists, market failures, such as failure of competition, under-provision of public goods and information failures, occur due to actors' self-seeking behaviour and lack of incentives to act co-operatively (Hahn, 2000).

This is why, then, the principal functions of public regulation are to facilitate nanotechnological development, as well as to protect public interests like health and safety, environmental protection, and consumer protection. More specifically, basic functions of public regulation are:

[10] 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)" (Black, 2002). 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 (Selznick, 1985: 363).

(1) to reduce risk and uncertainty, to create trust, and (2) to provide possibilities for technological innovation.[11] Law and regulation are constraining and enabling technological development.

With regard to the first basic function we seek for a regulatory strategy that can minimalize risks and uncertainty about nanotechnological development and can create trust about nanoproducts. In this regulatory strategy the tolerability of (potential) risks is a key issue. A product is generally considered safe when its attendant 'risks' are judged to be 'acceptable' (Asch, 1988). As indicated above, the notion of 'acceptable risk' is a difficult value- laden concept to define (Vos, 1999). It depends on normative 'choices' of society, which can be different from country to country. Experts and laypersons perceive risks differently (Wiedemann a.o., 2003).[12] Risk governance has strong political overtones that cannot be furnished primarily by experts (Coglianese and Marchant, 2004; Vos, 1999: 4).

Conclusion. Considering the complexity, uncertainty and ambiguity of risk problems and the lack of knowledge about the paths of nanotechnological development, the focus of regulatory action lies on creating spaces for desirable technological development. Our regulatory strategy must as well provide measures to break through (undesirable) irreversibilities of nanotechnological evolution.

3.2 Reflective learning of public regulators

Above we saw that a major challenge to public regulation is that regulatory action needs to be undertaken before most of the properties of nanoproducts and their societal risks are known. Another major challenge is to anticipate emerging (undesirable) irreversibilities of technological development. In situations in which the regulation subject is complex, uncertain and ambiguous the design of public regulation must be based on learning strategies.[13] In the development of regulatory strategies a first question is *how* public regulators can learn. Which modes of learning are productive for regulatory action?

Learning modes

Following Huber, we speak of learning processes if knowledge is constructed and existing knowledge is reconstructed in interactions between the actors involved (1991). Governing entities

[11] See, Van Waarden, 1996:4; Hoffmann-Riem, 2000.

[12] According to Wiedemann a.o. (2003: 286), experts see risks as possible chains of cause-and-effect. They regard risks as indicators of hazard potentials. Laypersons perceive risks primarily in a social and relationship-oriented context.

[13] In his essay about public regulation of innovation Hoffmann-Riem speaks of a learning function of law (2000: 166).

learn when they adjust their repertoires of regulation instruments, modes of their implementation, as well as the regulation goals and processes in response to past experience and new information.[14] Following Argyris and Schön (1996), we distinguish between the modes of (1)single-loop learning, (2) double-loop learning and (3) deuterolearning.[15]

(1)By *single-loop learning*, we refer to processes of instrumental learning in which regulatory expectations and actions are 'mechanically' adjusted to new knowledge and experience regarding nanotechnological risks, as well as the effects of particular regulatory instruments. Single-loop learning happens, for example, when regulators, due to new insights into the toxicity of a first generation application of nanotechnology, modify their expectations and assumptions regarding their regulatory instruments. In this example, regulatory action goes through a single 'feedback loop'. In this loop the detected error about the properties of certain nanoproducts is connected to the regulatory structures. Regulatory instruments, standards, goals and underlying values, however, remain unchanged.

(2) In contrast, *double-loop learning* can result in changes of the regulatory repertoire. The double loop refers to two feedback loops. In addition to the first loop, a second feedback is taking place. In the second loop the new insights are connected to the specific policy goals and underlying values. Double-loop learning involves reflection about the appropriateness of regulatory instruments, standards, strategy, policy norms and values. It includes as well an analysis of the risk problem. In our case, new insights about the toxicity of certain nanoproducts would result, for example, in replacing 'light' regulatory instruments by tighter instruments (mandatory regulation instead of self-regulation, more specific mandatory regulation instead of general mandatory regulation etc.) or by more stringent ways of implementation of existing regulatory instruments. Double-loop learning would require reflection about the nature of the risk problem, and also about the legitimacy and effectiveness of the regulatory tools. This could lead to fundamental normative questions about the acceptability of nanotechnological risks and public values.

[14] See, Hall, 1993: 278. Hall employs a learning approach to analyse changes of public policy. Thinking of policymaking as a process, he distinguishes between the three central variables of policy goals, the techniques or policy instruments used to attain those goals, and the precise settings of these instruments. These three variables serve to disaggregate the concept of social learning. Regarding the characteristics of regulatory governance, the variables of regulation goals, instruments (legal regulation, information, private regulation etc.) and the modes of implementation (including modes of interpretation, enforcement etc.) are relevant.

[15] Argyris and Schön's well-known framework has been developed for organisational learning. Argyris and Schön admit that organisations learn only through the experience and actions of their members. Their framework has also been applied to policy learning (see, Hall, 1993).

(3) *Deuterolearning* means to 'learn how to learn'. [16] It occurs when regulatory actors modify the learning repertoire of an organisation. This would be the case, for example, if regulatory actors add new methods related to the assessment (for example, scenario's) and communication of nanotechnological risks to the knowledge system of the governmental organisation.

Modes of learning in regulatory strategies related to nanotechnological risks

Single-loop learning seems to be appropriate for simple policy problems. Does this mean that in the first generation of nanotechnological development, in which risk problems occur to be less complicated than the problems in the other generations, the focus lies on this learning mode? Considering the rapid and unpredictable development of nanotechnology and the fact that unexpected risks can also occur in the first generation, I conclude that reflective modes of learning are required with regard to all nano-generations. Furthermore, a regulatory strategy that is attracted at integrating anticipatory and corrective regulatory measures, all the three modes are relevant. Single-loop and double-loop learning primarily can underpin corrective regulatory action, while anticipatory regulatory action refers to deuterolearning and (partly) to double-loop learning. The question which (combinations of) learning modes are productive for regulatory action depends on the evolution of nanotechnology and regulation. The subjects of the regulator's reflection may be different according to the four nano-generations, because of the various methods of risk assessment and management that are used.

3.3 Responsive regulation

Co-evolutionary orientation of regulatory strategy

In the introduction I claimed that a responsive regulatory strategy based on interactive and reflective social learning can cope more effectively and legitimately with the risk problems of nanotechnologies than a static, endogenous regulation approach. Responsive regulation seeks to respond 'critically' to regulatory structures that emerge in practice (Selznick 1992; Dorbeck-Jung, 1999; Dorbeck-Jung and De Jong, 2000: 120). Responding 'critically' means to evaluate emerging structures from the angle of the principles of effective and legitimate public action. In his approach to responsive law Selznick assumes that taking account of 'forces in the environment' can contribute more effectively to problem-solving than concentration on formal legal structures. Established structures, rules, methods, and policies are seen as undergoing a continuous process of revision. Regarding the normative requirements of the rule of law that

[16] Deuterolearning is regarded as second-order learning (Argyris and Schön, 1996: 29), while single-loop and double-loop learning are conceived of as first-order learning.

constitute the legitimacy of public action, revision of regulatory action, however, must take place in a principled way.[17] Responsive regulation denotes a critical and controlled adaptation to structures that emerge in practice. Public regulation is developed by testing them to policy goals and principles of legitimacy and by discussing its effects.

As concerns the structures that emerge in practice of technological development the concept of *de facto* governance is highly interesting (Rip, 2006b). This notion draws attention to coordination processes in which institutional structures evolve.[18] In this view, regulatory structures evolve in a process of co-evolution. 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 (Rip, 2006b). In our case actors are: regulators, scientists, technologists, entrepreneurs, and citizens. Co-evolution implies mutual dependencies of actors. Does this mean that the regulatory strategy we are exploring must not be based on the assumption of autonomous action of public regulators? According to Giddens' concept of the duality of structure the structural properties of the social systems are both medium and outcome of the practices they repeatedly organize (1984: 25). Duality means that structure is viewed as being internal and external to actors. Governance processes reflect an internal dynamic, which, nevertheless, is affected by external stimuli and, in turn, influences the external environment. Hence, public regulators are dependent, but also partly autonomous.

Organizing responsive regulation

Regarding the aim of this paper the next question is how the (presupposed) partial autonomy of public regulators can be used to cope with the complexity, uncertainty, ambiguity and potential irreversibilities of nanotechnological development. Since reflective learning seems crucial in the risk governance of nanoproducts a conclusion is that public regulation should focus on the creating of spaces for reflective learning. Following Rip, I conclude that public regulators are equipped to constitute these spaces, because of their distance to the performing actors (Rip, 2004a; 2004b; 2006b). Public regulators are entitled to do so because of their regulatory authority (Dorbeck-Jung and De Jong, 2000).[19] In the creation of these spaces a major concern is to

[17] This is what Selznick means when he speaks of 'reflexive responsibility' (1992: 338; see, Dorbeck-Jung, 1998)

[18] Governance is defined as steering and coordination of interdependent (usually collective) actors based on institutionalised rule systems (Benz, 2004).

[19] Authority is seen as having a rightful claim to deference or obedience (Selznick 1992: 266). Authority generates a kind op power but its distinctive basis is a recognized claim of right. This claim is 'rightful'if and only if it is based on the consent of the community at stake.

anticipate lock-ins of further desirable technological evolution, which can be the result of processes of *de facto* governance. Undesirable irreversibilities of nanotechnological development can be arise from lock-ins, which could be difficult to escape. By providing incentives, for example, public regulation can stimulate a variety of evolution paths. Concurring alternatives of nanotechnological development can provide insights into what might be a productive path or what might be an unproductive, undesirable path. Another anticipatory measure is precautionary action in cases where serious risks and potential irreversible damages for health and the environment of nanotechnological development cannot be excluded. In addition to anticipatory regulatory measures, reflective learning implies adaptive and corrective measures, such as the revision of existing legal instruments, which do not match with the properties of nanoproducts.[20] For example, one corrective measure could be the revision of the EU registration system of Chemicals (REACH[21]).

Responsive regulation refers to *de facto* governance, as well as to aspects of legitimacy of public regulation, which serve for the justification of public action. Requirements of legitimacy can be derived from the principles of good governance, which include openness, participation, legality, accountability, effectiveness and coherence of public action (European Commission, 2001). In the process of the creation and revision of existing ones public regulators are bound to the requirements that can be derived from these principles.

4. What public regulators can learn

In the previous section we dealt with the questions *why* public regulators should adapt a learning attitude with regard to nanotechnological governance, *how* they can learn and *how* we can conceptualise reflective learning in interactive regulation processes. In the development of our regulatory strategy the next question is *what* can be learned from methods of risk assessment and regulatory experience. In the process of regulating nanotechnology, public regulators can learn from advanced approaches to risk governance and technology assessment, as well as from the potentials of certain methods, modes and instruments of regulation. Lessons can also be drawn from regulatory failures and successes in other (previous) examples of technology regulation.

Learning from advanced methods of risk governance and technology assessment

[20] In this context Rip refers to 'repair work' (2006).
[21] See http://europa.eu.int/comm/environment/chemicals/reach.htm. On the revision of this regulation with regard to nanoproducts, see Koops a.a., 2005.

For public regulators the Risk Assessment and Management Framework of the International Risk Governance Council for Nanotechnology (IRGC, 2006) is very useful. This approach is highly interactive and based on the idea of social learning. It adopts a holistic, adaptive and corrective view on risk governance. Risk regulation is integrated in a cyclical process. This process includes the steps of pre-assessment, appraisal and management of nanotechnological risks.[22] It can be expected that this approach provides more knowledge about critical risk problems and concerns than traditional risk assessment. For example, the outcomes of the new phase of pre-assessment (problem framing, early warning, and screening) probably enable public regulators to anticipate the need for regulatory measures. The combination of pre-assessment and (traditional) risk assessment (including hazard identification and estimation, exposure and vulnerability assessment and risk estimation) seems to be a sophisticated attempt to reduce the uncertainty of risks, which we mentioned above as a primary function of public regulation. Furthermore, the outcomes of concern assessment, which is a novel element in the phase of risk appraisal, can underpin regulatory measures that aim at creating trust. The same holds for the step of communication which accompanies all phases of the risk assessment and management process. To anticipate regulatory action projected scenarios are an important method, which lies also in the very heart of Constructive Technology Assessment (Rip, 2004a).

Learning from the public governance discussion

In the responsive approach to public regulation, the making of rules and legislation is only one way among many to implement public policies. Legal authority is widely delegated. The ideal is to achieve the maximum level of self-regulation that is feasible. In this approach and the debate about new public governance[23] the assumption is that negotiation, dialogue and compromise can contribute at least as effectively to problem-solving than hierarchical legislation. The current public governance debate distinguishes between methods of traditional regulation and methods of new governance. *Traditional regulation* strongly relies on mandatory rules. *New governance* draws attention to more non-legal methods of coordination. Its methods establish norms and achieve compliance by encouraging the participation of stakeholders and by requiring

[22] See, IRGC, 2006: 36. The appraisal step includes traditional risk assessment and the novel element of concern assessment. Between risk appraisal and risk management there is an interim phase, comprising the characterisation and evaluation of risk, which can be assigned to either the appraisal or management phase. Risk management is constituted of the implementation of governance measures and decision making. As the IRGC notes, the clear sequence of phases and steps offered by their framework is primarily a logical and functional one and will not always correspond to reality.

[23] For an overview of the discussion of public governance, see Frederiksson and Smith, 2003; Héritier, 2003; Kersbergen and Van Waarden, 2004; Kooiman, 2003; Mayntz, 2004; Pierre and Peters, 2000; Treib, Bähr and Falkner, 2005.

transparency and accountability of those participating in decision-making processes. In these methods of regulation, government still holds a strong position, although a different one. Governmental intervention is required, for private actors cannot be relied on to give appropriate weight to public interests over private ones. But the government no longer is acting on the basis of command and control, but is taking the role of coordinator and facilitator of social action. New public governance seeks to find the right mix of traditional regulation and 'soft' coordination. It is closely related to instruments of soft law.[24] It is characterised by *hybridisation* of governance methods, instruments and institutionalisation. Regarding our regulatory strategy we can learn from this debate that we need a tailored mix of mandatory and 'soft' regulation to cope effectively with the challenges of nanotechnology. This is why legally structured and conditioned self-regulation is a crucial concept of our regulatory strategy (Dorbeck-Jung, 1993).

Learning from experiences with technological regulation

In the operationalisation of our regulatory strategy an important step is to select instruments, which provide spaces for desirable technological evolution and which as well can break through undesirable lock-ins. This means that a voluntary reporting scheme, which the UK is advocating, would not be appropriate alone. It should be embedded in a legal frame, which provides structure and conditions to self-regulation that enable public regulators to intervene in undesirable cases. In the operationalisation process we can learn from experiences with other technological regulation (amongst which biotechnology, pharmaceuticals) by evaluating the successes and failures of the regulatory instruments that have been used in these examples, and by assessing the ways through which public regulators have (not) been able to build trust.

Since nanotechnological development is highly international and globalized (IRGC, 2006), in the institutionalisation of public regulation special attention should be paid to the organisation of the harmonisation of standards related to the safety and quality of nanoproducts. This means that international standardisation is very important. In this regard we can learn, for example, from the successes and failures of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceutical for Human Use (ICH). [25] The study of the

[24] See Senden, 2004: 111-113; 2005: 15. Senden distinguishes between three categories of soft law. These are: 1. prepatory and informative instruments, 2. interpretative and decisional instruments, and 3. steering instruments. However, soft coordination refers also to non-hierarchical instruments like partnership ('co-regulation'), peer pressures, social dialogue, and the 'open method of coordination' that are not covered by soft law. It involves a large range of non-hierarchical tools.

[25] In 1990 the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceutical for Human Use (ICH) was established as a joint regulatory/ industry project of the EU, Japan and the United States. Aims of the ICH are to improve, through harmonisation, the efficiency of the

ICH I am conducting in another project indicates that this approach to standardisation is rather effective, but problematic with regard to aspects of legitimacy. Problems refer to concern assessment (i.e. participation of patients in the standardisation process) and to the fact that standards are soon out-of-date because of the rapid technological changes.

5. Conclusions

In this paper I discussed a strategy of public regulation that can cope with the risk problems of nanotechnological development without disproportionally constraining desirable development. The regulatory strategy is based on the idea that basic functions of public regulation are to reduce risk and uncertainty, to create trust and to facilitate technological innovation. Considering the complexity, uncertainty and ambiguity of risk problems and the lack of knowledge about the paths of nanotechnological development, the focus of regulatory action lies on creating spaces for desirable technological development. Our regulatory strategy must as well provide measures to break through (undesirable) irreversibilities of nanotechnological evolution. This is why I advocate, unlike the UK approach, to embed self-regulation in a legal frame, which enables public regulators to intervene in undesirable cases. The concept of legally structured and conditioned self-regulation I am proposing is based on the approach of responsive regulation. In this approach *de facto governance* of nanotechnological development is critically evaluated with regard to the principles of effectiveness and legitimacy of public action.

As concerns the operationalisation of our regulation strategy I conclude that a strict division of regulatory measures into two frames according to the risk problems related to the stages of nanotechnological development does not seem to be appropriate. Considering the rapid and unpredictable development of nanotechnology and the fact that unexpected risks can also occur in the first generation, I conclude that reflective modes of learning are required with regard to all nano-generations. Our regulatory strategy must be based on an integrated and dynamic approach to regulatory action. In this approach public regulators explore the potential of concrete regulatory measures and the possibilities of anticipatory action rather synchronically than sequentially. In the process of creating legally conditioned and structured self-regulation public regulators can learn from the Risk Assessment and Management Framework of the International

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process for developing and registering new medicinal products in Europe, Japan and the United States, in order to make these products available to patients with a minimum of delay. The ICH brings together the regulatory authorities and experts from the pharmaceutical industry in those regions, to discuss scientific and technical aspects of the regulation of pharmaceuticals. It makes recommendations with respect to greater harmonisation of such technical requirements, with a view to avoiding duplication in the testing needed for new pharmaceuticals, as well as reducing regulatory costs and regulatory bureaucracy in the approval procedures.

Risk Governance Council for Nanotechnology (IRGC, 2006). Regarding the call for international standardisation I propose to establish an organisation that is similar to the ICH. However, we should learn from the failures of this organisation and provide participation of all stakeholders, as well as transparency of the regulatory process and take measures to anticipate regulatory capture.

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