

Soft regulation and responsible nanotechnological development in the European Union: Regulating occupational health and safety in the Netherlands

Bärbel Dorbeck-Jung [1]

Cite as: Dorbeck-Jung, B., 'Soft regulation and responsible nanotechnological development in the European Union: Regulating occupational health and safety in the Netherlands', European Journal of Law and Technology, Vol. 2, No.3, 2011

Abstract

Worldwide, soft regulation such as codes of conduct and benchmarks has been introduced to cope with the uncertain risks and benefits of nanotechnologies. However, it seems that these regulations are facing effectiveness problems. For instance, the European Commission's 2008 Nano Code of Conduct has not yet been implemented in the member states. Using the analytical framework of responsive regulation this article explores effectiveness problems of soft regulation that has been established to reduce exposure to nanomaterials at the workplace. The article builds on ongoing research on the effects of voluntary regulation that applies to occupational activities with nanomaterials in the Netherlands. The evaluation of this rich governance arrangement offers indications of potential effectiveness problems. A tentative lesson of the research is that soft regulation can contribute to responsible nanotechnological development if it is specific enough to meet the needs of the regulated parties, if rule compliance is supported by financial and professional resources, and if it is embedded in a culture of social responsible partners, knowledgeable vigilance and adaptation.

1. Introduction

In Science and Technology Studies regulation is often identified with hierarchic command-and-control legislation. Alfred Nordmann, an eminent science philosopher, compared regulation with the driver of a steam machine who intervenes when certain thresholds are exceeded (Nordmann 2009). Nordmann argued that in the case of nanotechnologies certain thresholds are not available and will not be available in the near future. Nanotechnologies do not develop in a linear way and risks are highly uncertain. This is why he concluded that presently nanotechnologies are beyond regulation. Instead of tracking what cannot be tracked he proposed to establish and strengthen vigilance structures (Gammel et al. 2010). Nordmann highlighted fundamental problems of regulating newly emerging technologies. Linear regulation is always lacking behind technological development because it depends on evidence on benefits and risks. When evidence cannot be provided 'linear' regulators have to wait. However, the top down 'steam machine approach' to which Nordmann refers has been proposed only in a few early theories of public administration and law. From the very beginning in the 19th century, technology regulation has developed in a heterarchic mode. [2] Knowing the limits of their technological knowledge governments have built on private standard setting and private oversight activities (Kloepfer 2002). Vice versa, industries have often welcomed regulatory collaboration because of the stability, certainty and property protection public regulation is expected to provide.

Today, the regulation of emerging technologies is taking place in the 'era of governance'. [3] In the socio-legal community the understanding of regulation has evolved from the command-and-control approach of social engineering (Pound 1955) to the collaborative approach of regulatory governance (Ansell & Gash 2008; Gunningham 2009). Nanotechnological regulation is following this approach (See Levi-Faur & Comaneshter 2007). It combines existing legislation with various forms of soft regulation (amongst which codes of conduct, voluntary reporting schemes, standards and benchmarks). [4] Hybrid governance arrangements are expected to enhance responsible technological development. However, investigations of regulatory practices in Europe, the US and Australia show that nanospecific soft regulation is facing compliance and implementation problems. The voluntary reporting scheme of the United Kingdom's Department for Environment, Food and Rural Affairs (Defra 2008), [5] the Australian Government's National Industrial Chemical Notification and Assessment Scheme (NICNAS 2008) and US Environmental Protection Agency's stewardship

program (EPA 2008) have seen underwhelming industry participation. The European Commission's 2008 Nano Code of Conduct has not yet been implemented in the member states (NanoCode 2010). These effectiveness problems raise the question whether and under what conditions soft regulation can contribute to responsible nanotechnological development.

This article explores possibilities and limits of nanospecific soft regulation that has been launched in the European Union at various governance levels to achieve public policy goals. The central research question is: *How can soft regulation contribute to responsible nanotechnological development?* [6] The answers to this question build on the findings of responsive regulation research. In this strand of socio-legal research conditions have been developed to analyse the effectiveness of regulation. Since some pieces of nanospecific soft regulation have been launched only recently an in-depth assessment is not yet possible. Yet, a first evaluation can indicate potential effectiveness problems. These indications can serve to underpin further regulatory policy.

The article has four sections. In the next section discusses the analytical framework of responsive regulation. To give an idea of the regulatory landscape of the case study the body of legislation and soft regulation that applies to responsible nanoscience and nanotechnologies in Europe will be sketched in the second section. The third section depicts the regulatory body that applies to occupational health and safety regulation of research and development (R&D) activities with nanomaterials in the Netherlands. The occupational health and safety case offers a rich governance arrangement which has been evaluated in the past months. [7] To get insight into the contribution of soft regulation to responsible nanotechnological development we can build on the ongoing empirical investigation of this project. In the fourth section I explore effectiveness issues on the basis of the building blocks of responsive regulation. This leads to tentative conclusions regarding the contribution of soft regulation to achieve occupational safety. An important conclusion is that the use of soft regulation is strongly stimulated by certain social pressures and by a strong culture of responsibility. Another core conclusion refers to regulatory certainty employers strongly expect the provisional benchmarks to provide. In a situation of persistent uncertainty about the effects of nanomaterials 'quasi-hard' soft regulation may engender a false sense of certainty that blocks employers to take additional risk minimization measures.

2. Analytical framework: responsive regulation

In this article I explore effectiveness issues of governance arrangements involving hard and soft regulation. A common definition of effectiveness refers to the degree to which certain policy goals are achieved (Opschoor & Turner 1994: 11). Since the interpretation of policy rationales and their achievement are ambiguous and dynamic the effectiveness of regulation is extremely difficult to measure (Griffiths 2003: 21). Regulatory scholars agree that effectiveness depends on regulatory quality and whether the regulated parties follow the established rules. [8] Effectiveness requires that regulators monitor regulatory quality and rule compliance and respond to detected failures (Baldwin & Black 2008). Since regulatory quality and compliance are dynamic phenomena, regulators should keep an eye on the implications of changing rules, regulatory strategies and compliance behaviour. They should respond to undesirable effects. Hence, effectiveness depends also on the vigilance and adaptive capacities of regulators. In the field of nanosciences and nanotechnologies ongoing technological development can require continuous adaptation of policy goals, rules, regulatory strategies and tools. Vigilance is extremely difficult because of the huge uncertainties about the benefits, risks, governability and the acceptance of these emerging technologies. Public regulators depend on the regulated parties' knowledge and their regulatory capacity (Levi-Faur & Comaneshter 2007).

To support the effectiveness of nanotechnological regulation we are seeking for an adaptive and collaborative approach that fosters regulatory quality and compliance under the conditions of uncertain risk problems and benefits, and conflicting interests. To deal with these challenges regulators need a prudent stance. Referring to Aristotle's ideas I would like to emphasise that prudence does not mean to focus on cunning intelligence and economic calculation (Selznick 1992, 60; Dupuy & Grinbaum 2004; Dupuy 2007; Dorbeck-Jung 2007). Prudent regulators rather focus on adequate moral judgments in regulatory practices. They make efforts to strike balances between conflicting interests and normative requirements. They rely on empirical knowledge on technological benefits and risks, as well as on successes and failures of (technological) regulation. Prudent regulators are aware of the limits of evidence based regulation in the context of huge uncertainties. They promote vigilance, collaboration with stakeholders and continuous adaptation of regulation. Prudent regulation is the focus of responsive approaches (Nonet & Selznick 1978; Ayres & Braithwaite 1992; Selznick 1992; Dorbeck-Jung 2007; Baldwin & Black 2008; Black & Baldwin 2010). Responsive regulation attempts to respond to changing regulatory concerns, structures and institutional environments. It commits regulatory institutions to

- 1.enlarge their scope of inquiry to embrace knowledge and of the social contexts and effects of regulatory decisions;
- 2.a style of reasoning that reaches beyond mere rule rule-following by focusing on social consequences; and
- 3.test alternative strategies for the implementation of mandates and reconstructing those mandates in the light of what is learned (Nonet & Selznick 1978; Trubek et al. 2008: 1).

This article builds on the framework of responsive regulation that has been refined elsewhere (Dorbeck-Jung et al. 2010). This framework provides us with conditions for the assessment of the effectiveness of hybrid governance arrangements. Its building blocks refer to regulatory quality, compliance performance and adequate regulatory

adaptation. *Regulatory quality* is determined by whether rules are intelligible, comprehensive, and transparent and whether they are based on coherent and non-contradictory regulatory tools and strategies (Gunningham et al. 1998; Baldwin & Black 2008; Halpern 2009; Black & Baldwin 2010; Dorbeck-Jung et al. 2010). Intelligibility means that the terminology is clear and unambiguous. Rules are comprehensive when they cover all issues that are essential to achieve particular policy goals. In the context of responsible nanotechnological regulation these issues refer to risk minimization, but also support for beneficial development. Transparency means that information on regulation is accessible, relevant and understandable (Heald 2006). Transparency interests, however, must be counterbalanced with the interests of confidentiality, anonymity and autonomy (Heald 2006, 60). Combinations of regulatory tools can be contradictory because of different logics (Baldwin & Black 2008: 71). This would be the case, for example, if one legislative piece of the governance arrangement encourages voluntary regulation, while another piece of legislation severely restricts the voluntariness. When different regulators with different ideas on effective regulation are involved regulatory strategy may be contradictory. Contradictory, incoherent and unclear strategies may create tensions and hamper performance (Gunningham et al. 1998). Requirements of regulatory quality have been primarily developed for regulation that serves to achieve public policy goals. At present scholars agree that they apply as well to private regulation that is used to achieve public policy (Vos 1999; Curtin & Senden 2011; Scott, Cavaggi & Senden 2011).

Compliance performance depends on whether the regulated parties can follow the rules and whether they are *willing to* (Griffiths 1999, 2003; Havinga 2006; Karlsson-Vinkhuyzen & Vihma 2009). First, the regulated parties must know and understand the rules. Furthermore, the ability to follow the rules may depend on financial resources and resistance rules may encounter in practice. Whether the regulated are willing to comply relies on their attitudes toward compliance (Kagan & Scholz 1984; Braithwaite 1995; Gunningham et al. 2002; Baldwin & Black 2008). Willingness to comply may also depend on available sanctions or rewards (Vogel 2009). When private soft regulation is used to achieve public policy goals additional compliance requirements include a strong private interest in rule following, the existence of specific pressures to comply, and a high degree of social responsibility within the sector (Havinga 2006; Dorbeck-Jung et al 2010). [9] Private interests in compliance may be strong when private regulators purport to have similar objectives and when private regulators expect certain advantages (like good reputation, forestalling legislation and other internal advantages (see Baggott 1989, 436). Compliance can be brought about by social pressure on the company to follow soft regulation (Kagan & Scholz 1984), as well as by certain commitments of the regulated parties and by binding force attached to soft regulation. Binding force can arise, for example, from frequent use of the rules concerned (*de facto* governance) and when a quasi-legal status is attached to them. Incentives can facilitate the ability to follow rules and stimulate the willingness to do so. Social responsibility is indicated by trade associations' activities and by a strong business community with a generalized concern for taking soft regulation seriously (Gunningham 1995).

Regulatory adaptation relies on the regulators' ability to respond adequately to deficiencies of regulatory quality and poor compliance rates in the context of ongoing changes of the scientific and technological development. [10] Appropriate responses require continuous sensitivity to these elements and facilities to realign soft regulation if necessary (Braithwaite 2006; Baldwin & Black 2008; Black & Baldwin 2010). Realignment includes regulatory enforcement and the modification of rules, regulatory tools and strategy. It relies on the regulators' ability to assess the workings of soft regulation in the context of the dynamic institutional environment. Oversight facilities at all regulatory levels are crucial to uncover undesirable effects, tensions and imbalances (Kagan & Scholz 1984; Ayres & Braithwaite 1992; Hutter 1997; Aalders & Wilthagen 1997; Braithwaite 2002; Cohen 2002; Haines 2009).

In short, the effectiveness of governance arrangements that serve to achieve public policy goals and that involve hard and soft regulation depend on the following requirements.

Regulatory quality

- Clear, unambiguous, comprehensive and transparent rules
- Synergy of regulatory tools and strategies

Compliance performance

- The ability to obey the rules (knowledge of the rules, financial resources, obstacles in regulatory practice)
- Willingness to follow rules (attitudes toward compliance, sanctions, pressures and incentives available, strong private interests, social responsibility within the sector)

Adequate adaptation

- A high level of effective oversight (including monitoring and performance evaluation in the context of the dynamic institutional environment) and
- Corrective responses (enforcement and realignment).

3. Regulatory governance of responsible development of nanoscience and nanotechnologies in the EU: an overview [11]

According to the 2007 Action Plan on Nanotechnologies the European Commission is committed to responsible development (EC 2007). Generally, responsible development is defined as the balancing of efforts to maximize the technology's positive contributions and to minimize its negative consequences (CRNNI 2006). This broad definition raises the question what 'positive contributions' and 'negative consequences' are about and how optimisation can be undertaken. In Article 3 of the Treaty on the European Union we find the general normative targets of responsible development that apply to the development of nanotechnologies (see Von Schomberg 2011). These are: the promotion of scientific and technological advances, competitive social market economy, sustainable development, high quality of life, high level of protection of human health and the environment, social justice, equality, solidarity and fundamental rights (EU 2010). Referring to the rationales of the European Treaty Von Schomberg (2011) proposes to define responsible research and innovation as a 'transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products.' According to these normative anchor points positive contributions include the support of nanotechnological advances, its contribution to a competitive social market economy and to the other goals of the Treaty. Negative consequences are related to damages to human health, the environment, equality and fundamental rights. Minimising of negative consequences serves also to maximise normative targets of the European Treaty.

In the EU a large body of multi-level and multi-actor regulation is in place that serves to achieve responsible development of nanoscience and nanotechnologies. This body includes general legislation, as well as general and nanospecific soft regulation. *General legislation* involves European consumer, environment, health and safety regulation. With regard to nanospecific legislation, the legislative bodies of the European Union and its Member States have taken an incremental regulatory approach. They have reviewed existing legislation with the intention to adapt it, if necessary, to specific nanotechnological requirements (EC 2008a). To date, nanospecific legislation has been launched in the EU only with regard to cosmetics and food additives. [12] Nanospecific regulatory activities rather concentrate on funding beneficial development, providing information, stimulating stakeholder dialogue and introducing specific soft regulation. [13]

Nanoscience and nanotechnologies are governed jointly by general legislation and (general and nano-specific) soft regulation. Regulatory activities involve public and private initiatives. In many cases of soft regulation government and industry are collaborating, In our understanding soft regulation refers to not legally binding rules that are established by private and public organizations. [14] Usually soft regulation is laid down to implement and enforce existing legislation (e.g. interpretation, enforcement and oversight guidance). Soft regulation serves also to prepare specific legislation. It is set up for specific purposes like standardization and responsible development for which legislation does not seem to be an appropriate tool. In order to implement legislation a huge body of general guidelines apply to activities with nanomaterials. Nanopharmaceuticals, for example, are governed by the guidelines the European Agency and national competent bodies have issued for clinical trials, product approval, manufacturing processes and post-marketing controls. General soft instruments for the implementation and preparation of legislation on nanomaterials are the rules of the Precautionary Principle and the As-low-as-reasonable-achievable (ALARA) Principle. [15] In 2007 nano-specific guidance was launched for the use of nanomaterials in medical devices (N&NET 2007). Other nano-specific soft tools for the implementation and preparation of legislation are the reporting schemes some member states have set up. These schemes serve to collect information on the properties and risks of activities with nanomaterials. Furthermore, on 18 October 2011 the the European Commission issued a recommendation on the definition of nanomaterials.

Other examples of nano-specific soft regulation do not focus primarily on legislative support. They explicitly serve to contribute to responsible development of nanotechnologies. Examples are the EC's Action Plans on Nanosciences and Nanotechnologies (EC 2004; 2007), the principles of the German Nanocommission (Nanokommission 2008), the EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (EC 2008b) and the regulatory activities of some member states on labeling and registration of nanoproducts. A couple of private organisations have established guidelines and best practices in the context of risk management (e.g. UK BSI Bench Marks 2007, [16] AssuredNano 2008, [17] Substances Management Nanotechnologies (Stoffenmanager), [18] IFA benchmarks 2010). [19] Private regulatory initiatives include the publication of lists of users and producers of nanomaterials in certain branches of trade (Construction Work Oversight Body Germany (BG Bau 2010), [20] as well as nanospecific and general codes of conduct (Bowman and Hodge 2009).

Figure 1 gives an overview of the regulation of responsible nanotechnological development in Europe.

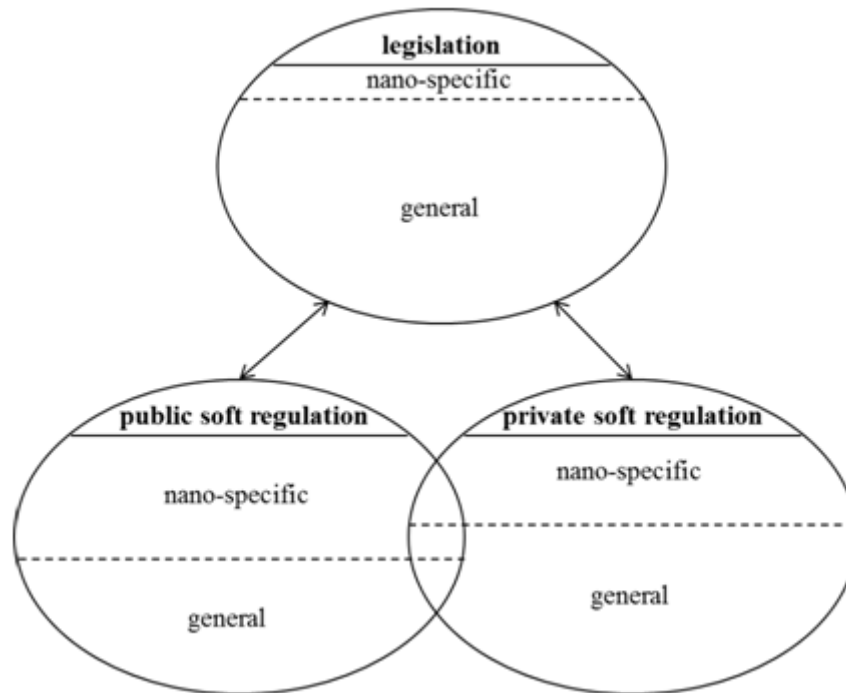


Figure 1 shows that the focus of nanospecific regulatory activities lies on soft regulation. The figure indicates that legislation, public and private soft regulation are closely connected. It shows also that public and private soft regulation is overlapping (e.g. codes of conduct and reporting schemes). The overview focuses on regulation at the EU, national and local level. In addition, the applicable regulatory body includes also soft regulation released by international bodies (among which the International Standardization Organisation (ISO), the OECD and the International Council of Chemical Associations-ICCA).

4. Case study: effectiveness issues related to occupational health and safety regulation in R&D activities with nanomaterials in the Netherlands [21]

This article seeks answers to the question how soft regulation can contribute to responsible nanotechnological development. It focuses on effectiveness issues of soft regulation that applies to nanomaterials. The regulatory overview of the previous section shows that soft regulation is embedded and operates in the context of certain governance arrangements which may include various kinds of legislation. Since the effectiveness of soft regulation depends on the legal context the empirical study covers the whole government arrangement. To reduce the complexity of the inquiry a case study with a rich government arrangement has been selected. The study builds on ongoing research on the effects of nanospecific soft regulation related to occupational health and safety in R&D activities with nanomaterials in the Netherlands. [22] The case study is highly interesting, because recently several forms nanospecific soft regulation have been introduced in the Netherlands to safeguard occupational health and safety. The case study offers a rich governance arrangement which is composed of multi-level legislation (general) and soft regulation (general and nanospecific). Crucial are a couple of legal obligations that are based on the European Directives 89/391/EEG, 98/24/EG, 2004/37/EG in the *Dutch Labour Conditions Act* and in the regulations on hazardous substances of the *Dutch Labour Conditions Decree* (Vogelezang et al. 2010). [23] The implementation of these obligations builds on various forms of nanospecific and general soft regulation.

The entire governance arrangement revolves around the legal obligation of the employer to care for all aspects of safety and health at the workplace according to the state of science. [24] The employer is legally obliged to develop a strategy on occupational safety that focuses primarily on prevention. If risks cannot be prevented with regard to hazardous substances additional measures must be taken. Employers are required to take stock of risks and to evaluate them. [25] This holds also for unknown risks of nanomaterials (Vogelezang-Stoute et al. 2010:282). In practice the obligations of risk inventory and evaluation rest on the producer of nanomaterials. Companies that use nanomaterials

can rely on the information that is provided by the producer if it is comprehensive and complete. Users are required to assess the information they obtained. If it deems that the information of the producer is not sufficient users must undertake additional risk evaluation. Producers and users of nanomaterials are required to proactively obtain knowledge about the state of science and alternative operating procedures. Information on remaining unknown risks must be communicated to the employees (Vogelezang-Stoute et al. 2010:292). Risk management includes risk reduction measures (among which prevention or minimization of exposure to hazardous substances, substitution of carcinogens, labeling of hazardous substances and health control including medical check-up of employees).

Nanospecific soft regulation has been established in the context of the efforts to guide the implementation of these legal duties at workplaces where nanomaterials are produced and used. Soft regulation has also been introduced in the context of corporate responsibility. Implementation guidance is required because of the generality of the legal provisions. It is not clear how company risk policy can be specified with regard to nanomaterials. In regulatory practice questions arise how the state of science, the pillar of risk management, can be specified. How low is it required to minimize the exposure to nanomaterials to achieve a reasonable level? [26] In this context the main problem is that it is impossible to say at this time what a reasonable level is. With regard to the current state of science the Dutch Health Council recommended precautionary measures for work with persistent synthetic nanoparticles (Health Council 2006). [27] More generally, the Council advocated 'appropriate care' in the management of unknown risks (Health Council 2008). However, a fundamental problem is that health-based occupational exposure limits have not yet been developed. In this regard the state of science is uncertain. The lack of health-based standards for nanomaterials combined with their increasing use at many different workplaces and in various products has pressed the need for a reliable temporary risk assessment tool. To allow industry to safely work with nanoparticles precaution-based Nano Reference Values (NRVs) are being developed by analogy with other substances, like for instance asbestos or fine-dust particles. They are considered as benchmarks ('warning levels'). When this level is exceeded measures are required to identify the source and if possible to minimize exposure. In 2010, the Dutch Minister of Social Affairs and Employment recommended to use a particular system of NRVs. [28] In his letter to Parliament the Minister stated that this system is provisionally. NRVs are regarded as part of the current state of science. Since NRVs do not guarantee that exposures below the values are safe the Minister emphasized that they are *pragmatic* benchmark levels that have to be accompanied by additional measures to minimize exposure. The duty to take minimization measures can also be derived from the As-low-as-reasonably-achievable (ALARA) principle. To support the development of company tailored risk management including regulatory compliance of small and medium size companies (SMEs) a free online risk management system, the 'Stoffenmanager Nano' has been introduced by the Dutch Government. [29]

In addition to this Dutch nanospecific soft regulation a couple of regulatory activities of standardization bodies, the European Commission and the chemical industry are included in the governance arrangement. The ISO Technical Report (TR 12885:2008) 'Health and safety practices in occupational settings relevant for nanotechnologies' provides knowledge on good practices to users. The report focuses on the manufacture and use of engineered nanomaterials. It includes R&D activities. It serves to provide information about the characterization, health effects, exposure assessments and control practices in relation to nanotechnologies. Guidance is also provided by the American Society for Testing and Materials 'Standard Guide for Handling Unbound Engineered Nanoscale Particles (UNPs) in Occupational Settings' (ASTM E2535-07). [30] This general guide is intended for use by entities involved in the handling of UNP in occupational settings. It covers handling principles and techniques that may be applied, as appropriate, to the variety of UNP materials and handling settings. These settings include also research and development activities. The guide describes actions that could be taken by the user to minimize human exposures to unbound, engineered nanoscale particles.

Occupational health and safety is one of the objectives of the recommendations of the European Commission voluntary Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (EC 2008b). The code applies to academia and companies that conduct research and development with nanomaterials. The Code provides member states with an instrument to undertake further initiatives to ensure safe, ethical and sustainable development when implementing their national nanotechnological strategy. It lays down guidelines on actions to be taken. The Netherlands is the first European Member State that has introduced the mandatory contractual obligation to comply with the Code in its national funding schemes for nanosciences and nanotechnologies R&D. Researchers and companies that apply for funding have to declare that they implement the Code.

If Dutch chemical companies that manufacture and use nanomaterials have signed the International Council of the Chemical Associations' Global Charter on Responsible Care they are committed to certain principles of product stewardship. [31] The broad objectives of the Global Charter include a commitment to sustainable development through the development of innovative technologies and other solutions to societal problems, as well as improved environmental, health and safety performance, and expanded economic opportunities. Companies which sign the Global Charter are committed to specify the Charter's principles and to adopt a management system of responsible care which is externally verified and assessed by the national association.

Figure 2 gives an overview of the governance arrangement related to occupational health and safety in R&D activities with nanomaterials in the Netherlands.

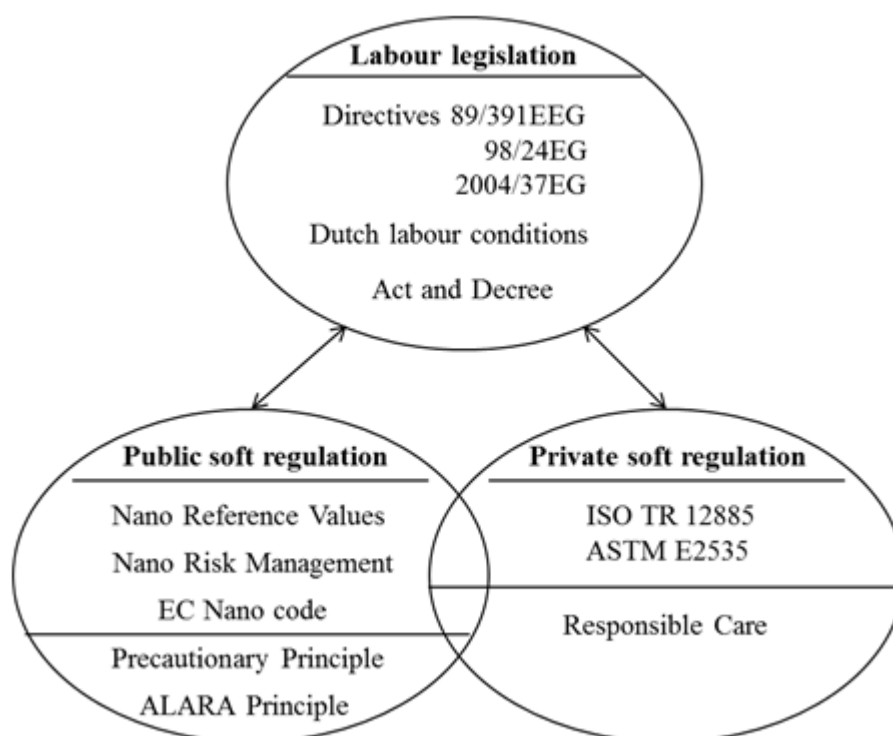


Figure 2 shows that a large body of general labour legislation and soft regulation governs R&D activities with nanomaterials in the Netherlands. It indicates that nanospecific public soft regulation has been introduced at the national and EU level, while the international and regional level is important for nanospecific private soft regulation. Public and private soft regulations overlap in the case of Nano Reference Values which were initiated by a private German organization (IFA) [32] and later adopted by the Dutch Government.

To explore effectiveness issues of this governance arrangement (with a focus on soft regulation) we use the analytical framework of responsive regulation. The exploration is based on an analysis of the relevant legal and policy documents, interviews held in the context of the Dutch Pilot NRVs and secondary analysis. Secondary analysis involves the empirical study on the possibilities and bottlenecks of Dutch regulation on unknown risks of nanomaterials (Vogelezang-Stoute et al. 2010) and the implementation research related to the EC Code of Conduct (NanoCode Project 2010; 2011).

5. Effectiveness issues of the governance arrangement

5.1 First building block: regulatory quality

This section explores whether the rules of the governance arrangement are clear, unambiguous, comprehensive and transparent and whether there is a synergy of regulatory tools and strategies. According to the empirical study on the possibilities and bottlenecks of Dutch regulation on unknown risks of nanomaterials (Vogelezang-Stoute et al. 2010), the terminology of the existing legislation seems to be clear. The study identified a couple of ambiguous legal provisions. One of them is the duty to care according to the 'state of science'. How actively and extensively must the employer seek for new insights into risks, benchmarks etc.? Ambiguity is also engendered by the terminology of 'reasonability'. The study concludes that employers who are required to minimize exposure as low as reasonable achievable diverge about what reasonable measures are (Vogelezang-Stoute et al. 2010: 316). The recommendation of the Dutch Minister of Social Affairs on Nano Reference Values seems to provide some clarity on this issue regarding the current state of science of certain benchmarks. The problem is, however, that these practical benchmarks are provisional. Since the employer who uses NRVs is still required to take additional measures to minimize exposure as low as reasonably achievable the problem of lacking clarity has not been settled. Another problem refers to the ambiguous status of this regulatory tool. It is not clear whether the use of NRVs is voluntary or obligatory. NRVs have been introduced as a voluntary measure which is accompanied by a certain commitment because they are part of the current state of science. After all, employers are legally required to build on the latest state of science and technology. When there are hardly any other scientifically acknowledged tools for risk minimization the benchmarks might be mandatory in practice.

The guidance that is provided by the 'Stoffenmanager Nano' appears to be clear and unambiguous. The large body of soft regulation related to corporate responsibility (guidance of standardization bodies, EC Code of Conduct, Responsible Care regulation of chemical industry) is rather abstract and theoretical. It includes principles that have to be specified by companies, academic organizations and their associations. Whether clarity and ambiguity are provided depends on the specification of these entities.

At first sight the governance arrangement seems to be rather comprehensive. At closer observation, however, we see some regulatory gaps. The first and best known gap refers to the definition of nanomaterials which has not yet included into law. [33] Furthermore, there is no regulation in place to support the user's search for risk information (Vogelezang-Stoute et al. 2010, 317). The information the producer of nanomaterials is legally required to deliver focuses on the data safety sheet which rarely includes information on nanomaterials. In the case of legislation transparency is provided. This holds also for most pieces of soft regulation which are published on websites of the involved organizations. However, the guidelines of the standardization bodies are not publicly available without expenses. With regard to the synergy of regulatory tools problems can arise because of different guidelines of the ISO and the ASTM. Furthermore, the implementation of the Global Responsible Care Charter may not cover all principles of the EC Code of Conduct.

5.2 Second building block: Compliance performance

Since some pieces of the nanospecific soft regulation have been launched only very recently (the 2010 recommendations of the Minister of Social Affairs on NRVs and the 2011 update of the 'Stoffenmanager Nano') it is not yet possible to evaluate the use in regulatory practices. With regard to the nanospecific guidance of the standardization bodies and the implementation of the responsible care charters compliance assessment information is not available. In all these cases, however, we can already explore the potential of rule following on the basis of the conditions related to the ability and willingness of the regulated parties. In the case of the EC Code of Conduct we can rely on the evaluation of the implementation in the Netherlands (NanoCode 2010; 2011).

The ability to obey the rules builds on knowledge of the rules of the governance arrangement, financial resources and whether there are any obstacles that impede rule following. According to the interviews held in the context of the Pilot NRVs, companies are aware of the legal obligations. It is rather questionable, however, whether they are aware of the large body of soft regulation. Companies that participate in the Pilot are informed about the recommendation of the Dutch Minister of Social Affairs on NRVs. They receive information about the 'Stoffenmanager Nano' via the relevant websites and networks. The Dutch Association of Chemical Industry informs their members on the Responsible Care Program. According to the interviews, large companies are aware of the ISO and ASTM guidance. Knowledge of the EC Code of Conduct (CoC), however, is very low (NanoCode 2011). As the last country report contends: 'However, results from in-depth interviews show that many stakeholders, though being aware of the existence of the CoC, are not familiar with its contents and have only very limited knowledge regarding its current status (NanoCode 2011, 8).' Companies that participate in the Pilot NRVs received implementation support. This holds also for the chemical companies that have signed the Responsible Care Program. The Dutch association of the chemical industry offers incentives and support to its members. Additionally, companies participating in Responsible Care are required themselves to provide sufficient resources for implementation. With regard to the EC Code of Conduct implementation support is not provided.

The willingness to follow rules in public-private governance arrangements depends on attitudes toward compliance, available sanctions, pressures and incentives, overlap of private and public interests, as well as on the social responsibility within the sector. With regard to the attitudes toward compliance we only can build on the investigation on the implementation of the EC Code of Conduct. According to the implementation study, the regulated parties mainly take a posture of disengagement. Many of them expect Dutch Government to provide guidelines and other (e.g. financial) support for the implementation. The Labour Conditions Act includes sanctions that apply to the employer's duty to care for health and safety aspects at the workplace. The ministerial recommendation on NRVs and the 'Stoffenmanager Nano' are incentives that can stimulate the willingness to comply. The commitment that the ministerial recommendation implies ('NRVs are part of the current state of science and employers are bound to the current state of science') can function as a pressure to use them. Likewise, pressure can be exerted by the binding force of the contractual obligation that the Dutch Government has introduced to comply with the EC Code of Conduct in relation to nanoscientific and nanotechnological R&D activities. According to representatives of large chemical companies, pressure is put in practice on units to comply with the Responsible Care Program. Companies which sign the program are informed that the commitment is binding. To stimulate compliance the International Council of the Chemical Industry (ICCA) and the Dutch Chemical Association provide rewards (prizes and publication of information) to companies with excellent responsible care performance. Rewards take account of self-interest in rule following. Publication of good responsible care performance can be advantageous for the reputation of the company. However, whether certain private interests to follow soft regulation are indeed strong in regulatory practice cannot be explored at this early stage of implementation. Regarding the numerous initiatives the Dutch social partners have taken together and individually to support the development of nanospecific soft regulation tailored to occupational safety we assume that the social responsibility is high in this specific industrial sector. In academia, social responsibility has been demonstrated by a couple of initiatives to integrate ethical, social and legal aspects into nanoscience and nanotechnological research.

5.3 Third building block: Adequate adaptation

According to the responsive framework, effective regulation of emerging technologies depends on continuous oversight and adaptation. Effective oversight includes monitoring and performance evaluation. It requires knowledgeable and well resourced oversight bodies. In the Netherlands, the existing regulation on occupational safety in relation to activities with nanomaterials has been evaluated in studies of the Health Council (2006; 2008), the Social Economic Council (SER 2009) and the University of Amsterdam (Vogelezang-Stoute et al. 2010). The ongoing project of the Health Council on monitoring the health impact of nanomaterials will provide information for regulatory issues. The National Institute for Public Health and the Environment (RIVM) monitors the existing regulation on nanosciences and nanotechnologies. With its studies on the benefits and risks of nanotechnological applications and on the use of Nano Reference Values this Institute provides important information for regulation. Likewise, the Netherlands Organisation for Applied Scientific Research (TNO) provides information on measurement and exposure. The governmental oversight body, the Labour Inspectorate, has started to monitor nanomaterials at the workplace. The EC Code of Conduct requires the member state to cooperate with the Commission in order to monitor the extent to which relevant stakeholders have adopted and applied the Code. According to the research on the implementation of the EC Code of Conduct, the Dutch funding agency is planning to monitor the compliance through its normal contract procedure. As the Report put it: 'The Ministry will be monitoring the whole program carefully to see if the recipients deliver what they have promised to deliver, not only on the research but also on the ethical side and risk research will be heavily monitored including with regard to the CoC (NanoCode 2011:30)'. In the Responsible Care Program the ICCA acts as 'guardian' of the initiative. ICCA's Responsible Care Leadership Group and the Dutch Association of Chemical Industry monitor implementation.

The 'Stoffenmanager Nano' is continuously adapted to new insights in the field of occupational safety and nanomaterials. Likewise, the RIVM and TNO research activities that provide important information for regulation are constantly making progress. Every two years the European Commission reviews the Code of Conduct in cooperation with the Member States. Adequate adaptation is one of the principles of the Responsible Care Program.

6. Conclusion

Using the Netherlands as a case study this article explores how soft regulation can contribute to responsible nanotechnological development. In the case of Dutch R&D activities with nanomaterials we found a large body of hard and soft regulation on occupational safety. Most of the rules appear to be intelligible and transparent. As a whole, the governance arrangement seems to be comprehensive and synergetic. Since essential pieces of nanospecific soft regulation have been launched only recently, compliance performance cannot yet be assessed. On the basis of this first exploration a tentative conclusion is that the ability to comply potentially exists. Our study, while not necessarily conclusive due to its small sample size, suggests that employers producing and using nanomaterials seem to be aware of the existence of particular legal obligations and the various nanospecific guidelines. The ability of rule following is reinforced through incentives and practical support. The self-interest of companies in compliance appears to be high. Reputational advantages seem to stimulate the use of soft regulation. In the context of impending liability cases the binding character of the provisional NRVs may be another incentive for compliance. Furthermore, rule following is stimulated by the high social responsibility of the sector. Regarding the pro-active monitoring of the Dutch research institutions RIVM and TNO and the monitoring plans of the Research Council NWO the basis for adequate adaptation of regulation seems to emerge. The continuous adaptation of nanospecific guidelines in which the social partners and TNO are involved indicates the potential of alignment. The involved regulatory parties seem to have taken a responsive stance.

The analysis of regulatory quality, compliance performance and regulatory adaptation indicates also a couple of problems that can impede the effectiveness of the governance arrangement. With regard to regulatory quality we examine ambiguity related to the status of Nano Reference Values. Crucial obligations of the employers to search actively for information on the effects of nanomaterials and to take risk minimization measures are not clear. Furthermore, the specific guidelines of the standardization bodies are not transparent. Considering the ability to comply a problem may arise in the future if practical and financial support for risk assessment and risk management is not provided anymore. Another lesson is that abstract principles and rules (like the ones of the EC Code of Conduct) do not stimulate implementation and compliance. They seem to lead rather to disengagement with rule following. By contrast, concrete rules, like the NRV benchmarks, appear to be accepted in regulatory practice. This quasi-hard instrument of soft regulation, however, may engender a false sense of certainty that blocks employers to take additional risk minimization measures

A tentative lesson of this case study is that soft regulation can contribute to responsible nanotechnological development if it is specific enough to meet the needs of the regulated parties, if rule compliance is supported by financial and professional resources, and if it is embedded in a culture of social responsible partners, knowledgeable vigilance and adaptation. More reflection is needed on the false sense of certainty concrete benchmarks may provide. This may lead to a less evidence based approach to the regulation of emerging technologies, and hopefully to crucial innovation in regulatory governance.

7. Acknowledgment

The author thanks Pieter van Broekhuizen and the editors of this Special Issue for their valuable comments.

[1] Bärbel Dorbeck-Jung is Professor of Regulation and Technology (with a focus on medical and nanotechnologies at the University of Twente, Netherlands. b.r.dorbeck-jung@utwente.nl)

[2] Heterarchy is to say that different forms of horizontal and vertical relations between the regulation regimes are mixed and that horizontal structures dominate (Kooiman, 2003; Teubner, 1997).

[3] The 'governance turn' that took place at the end of the twentieth century responded to the critique on the functioning of governments (i.e. to provide remedies for effectiveness, efficiency, and legitimacy problems of collective action). It is an attempt to link the contemporary state to the contemporary society (i.e. to acknowledge increasing internationalization, globalization, and the involvement of markets and civil society in traditional government activities, as well as to respond to demands for more participation in these activities, see Pierre & Peters 2000; Black 2008). As a consequence of this critique a large range of new governance concepts was introduced, among which are 'policy networks' (Rhodes 1997), 'collaborative governance' (Ansell & Gash 2008; Gunningham 2009), 'nodal governance' (Drahos 2004), 'polycentric regulatory regimes' (Black 2008), 'meta regulation' (Parker 2000, 2002, 2006), and 'enforced self-regulation' (Ayes & Braithwaite 1992). These concepts are overlapping and they are often used interchangeably (Pollitt 2003; Kersbergen, van & Waarden, van 2004; Ansell & Gash 2008; Black 2008; Gunningham 2009; Wright & Head 2009).

[4] By soft regulation we understand sustainable rules of conduct which in principle have no legally binding force, but which nevertheless have effects in regulatory practice to achieve certain policy goals (Senden 2004). Hard regulation refers to rules of conduct that are based on legal authority. Soft regulation includes standards, codes of conduct, and benchmarks etc. It can be established by private and public organizations (see, Zumbansen 2011).

[5] See www.defra.gov.uk (accessed on 4 August 2011).

[6] By responsible development I refer to the balancing of efforts to maximize the technology's positive contributions and to minimize its negative consequences (CRNNI 2006).

[7] The evaluation is taking place in the Pilot Nano Reference Values (NRV). The pilot project NRV is organized by the Dutch employers' organization VNO-NCW and the trade unions FNV and CNV to gain experience with the practical feasibility of NRVs for the workplace and to actualize and test the comprehensibility of their practical guide for safe working with nanomaterials. The Dutch Ministry of Social Affairs and Employment facilitates the project. The project is commissioned to the University of Amsterdam, Industox Consult and the University of Twente. The University of Twente explores effectiveness problems of the voluntary use of NRVs.

[8] This article refers to an institutional approach which defines regulation as intentional and focused controls based on rule making, implementation and enforcement (Black 2002; Scott 2002).

[9] See Zumbansen 2011.

[10] Institutional environments are constituted by the organizational and regulatory, normative, cognitive, and resource-driven structures in which the regulators are situated (Scott 2001; van Heffen & Klok 2002; Haines 2005).

[11] An excellent overview of regulation related to nanotechnologies is given by Hodge, Bowman & Maynard 2010. See also Hodge, Bowman & Ludlow 2007 and Dorbeck-Jung 2011.

[12] With regard to cosmetics see, Art. 7a (1) (d) Cosmetics Directive 76/768/EEC http://ec.europa.eu/consu-mers/sectors/cosmetics/cosmetic-products/nanomaterials/index_en.htm#h2-what-are-the-rules-in-europe-for-the-use-of-insoluble-nanoparticles-in-cosmetics? Accessed on 24-07-2011. With regard to food additives see, http://ec.europa.eu/nanotechnology/links_en.html (accessed on 8-08-2011). See also, Van Calster and Bowman 2010.

[13] This is not an exception to the rule. Rather, most governments have opted to retain the status quo at this time.

[14] See note 9

[15] According to the 2000 Communication of the EC on the Precautionary Principle, scientific uncertainty about technological risks is no reason for regulatory inaction if there might be immense adverse effects.¹⁵ The ALARA Principle requires to minimize the exposure to nanomaterials at the work place and the release of nanoparticles into the environment as low as reasonable achievable.

[16] BSI, (2007). BSI-British Standards, Nanotechnologies - Part 2: Guide to safe handling and disposal of manufactured nanomaterials. PD 6699-2:2007, BSI 2007.

[17] Further information can be found at <http://www.assurednano.com/> (accessed 8-08-2011).

[18] <http://nano.stoffenmanager.nl/> (accessed 8-08-2011).

[19] See http://www.dguv.de/ifa/de/fac/nanopartikel/beurteilungsmassstaebe/index.jsp#_top_ (accessed 8-08-2011).

[20] See, www.branchenregelungen.de (accessed 8-08-2011).

[21] The empirical research is based on document analysis (legal documents and relevant literature) and on the interviews that were held in the Pilot NRV (see note 6). The discussion of the legal frame in the Netherlands builds on the report of Voegelezang et al. (2010). In this report the results of an empirical study (Dutch and European legislation and relevant judicial decisions) were published. This study ('Regulation of uncertain risks of nanomaterials - possibilities and bottlenecks of regulation in the field of the environment, consumer protection and labour conditions') was commissioned by the Dutch Ministry of Social Affairs and Employment. In addition, documents of standardization bodies, the evaluation of the EC Code of Conduct on Nanotechnological R&D and the Responsible Care Program were analysed. In the Pilot NRV 27 key persons were interviewed between April and September 2011 (representatives of R&D organisations (2), large companies (4), SMEs (11), branch associations (3), trade union (2), employers association (1), and government (4)). Issues of the semi-structured interviews referred to knowledge on the legal duties of employers and the NRV values, as well as on the willingness to comply with the relevant regulations and governmental measures and experience in this field.

[22] See Note 7

[23] In this case it is not yet clear whether and how far the European Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, 1907/2006) applies (Lee & Vaughan 2010). Furthermore, particular legal duties of employers can be derived from the EC Regulation No 1272/2008 on Classification, Labeling and Packaging of Substances and Mixtures (CLP Regulation), and the Directive on Good Laboratory Practices (2004/10/EC).

[24] Article 3 Dutch Labour Conditions Act.

[25] Article 3 and 5 Labour Conditions Act.

[26] See, Ludlow (2007)

[27] An important legal task of the Dutch Health Council is to advise the Dutch Government on healthy working conditions (see, <http://www.gezondheidsraad.nl/en>, accessed on 16-9-2011). The Council publishes advisory reports on a large number of substances which employees might be exposed to at the workplace (including exposure limits). The Council also issues advice on occupational risks such as employees' physical and psychosocial burden at work. The advices involve independent experts. The Council's reputation is high. Dutch Government usually follows its advice.

[28] Ministry of Social Affairs and Employment, Letter from 10 August 2010 (G&VW/GW/2010/14925).

[29] <http://nano.stoffenmanager.nl/> (accessed 8-08-2011).

[30] The word 'standard' in the title means only that the document has been approved through the ASTM consensus process.

[31] See, <http://www.icca-chem.org/en/Home/Responsible-care/> (accessed on 9-8-2011). All members of the Dutch Chemical Association (VCNI) signed the Global Charter in 2008.

[32] <http://nano.stoffenmanager.nl/> (accessed 8-08-2011).

[33] In 2009, the European Parliament asked for the introduction of a comprehensive science-based definition of nanomaterials in Union legislation (see, Resolution European Parliament on Regulatory Aspects of Nanomaterials (PA_T6(2009) 0328). It called on the Commission to promote the adoption of a harmonised definition of nanomaterial at the international level and to adapt the relevant European legislative framework accordingly. The Commission invited the SCENIHR to provide scientific input on elements to consider when developing a definition of the term 'nanomaterial' for regulatory purposes. The SCENIHR opinion 'Scientific basis for the definition of the term 'Nanomaterial'' was issued for public consultation on 6 July 2010 (see the DG Health and Consumers Website http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm#nano, accessed on 5-08-2011). On 8 December 2010 the DG Environment drafted a recommendation on a definition of the term 'nanomaterial'. On 18 October 2011 the European Commission issued a cross-cutting definition of nanomaterials.

References

Aalders, M. and T. Wilthagen, 'Moving Beyond Command and Control: Reflexivity in the Regulation of Occupational Safety and Health and the Environment', *Law & Policy*, Vol. 19, 1997, pp. 415-444.

Ansell, C. and A. Gash, 'Collaborative Governance in Theory and Practice', *Journal of Public Administration Research and Theory*, Vol.18, 2008, pp. 543-571.

- Ayres, I. and J. Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate*, Oxford University Press, Oxford, 1992.
- Baggot, R., 'Regulatory Reform in Britain: The Changing Face of Self-regulation', *Public Administration*, Vol. 67, 1989, pp.435-455.
- Baldwin R., and J. Black, 'Really responsive Regulation', *The modern law review*, Vol.71, 2008, pp. 59-64.
- Black, J., 'Critical Reflection on Regulation', *Australian Journal of Legal Philosophy*, Vol. 2, 2002, pp. 71-35.
- Black, J., 'Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes', *Regulation & Governance*, Vol. 2, 2008, pp.137-164.
- Black, J. and R. Baldwin, 'Really Responsive Risk-based Regulation', *Law & Policy*, Vol.32, 2010, pp. 181-213.
- Braithwaite, J., 'Responsive Regulation and Developing Economies', *World Development*, Vol.34, 2006, pp.884-898.
- Braithwaite, J., 'Rewards and Regulation', *Journal of Law and Society*, Vol.29, 2002, pp.12-26.
- Braithwaite, J., 'Games and Engagement: Postures within the Regulatory Community', *Law & Policy*, Vol.17, 1995, pp. 225-255.
- Calster, G. van, and D. Bowman, 'A good foundation? Regulatory oversight of nanotechnologies using cosmetics as a case study', in: G. Hodge, D. Bowman and A. Maynard (eds.) 2010, pp. 268-290.
- Cohen, D., 'The Role of the State in a Privatized Regulatory Environment', in K. Webb (ed.), *Voluntary Codes: Private Governance, the Public Interest and Innovation*, Carlton University, Ottawa, 2002, pp.35-36.
- CRNNI (Committee to Review the National Nanotechnology Initiative), *A Matter of Size*. Washington DC: The National Academic Press, 2006.
- Curtin, D. and Senden, L., 'Public Accountability of Transnational Private Regulation. Chimera or Reality?', *Journal of Law and Society*, Vol. 38, 2011, pp. 163-188.
- Drahos, P., 'Intellectual Property and Pharmaceutical markets: A Nodal approach', *Temple Law Review*, Vol. 77, 2004, pp.401-424.
- Dorbeck-Jung, B.R., 'What Can Prudent Public Regulators Learn from the United Kingdom Government's Nanotechnological Regulatory Activities', *Nanoethics*, Vol.1, 2007, pp. 257-270.
- Dorbeck-Jung, B.R. et al., 'Contested hybridization of regulation: Failure of the Dutch regulatory system to protect minors from harmful media', *Regulation & Governance*, Vol. 4, 2010, pp. 154-174.
- Dorbeck-Jung, B.R., 'Regulation of Nanomaterials in the EU', in W. Helweggen and L. Escoffier, *Handbook Nanotechnology Commercialization for Managers and Scientists*, Pan Stanford Publications, Singapore, forthcoming 2011.
- Dupuy, J.P., 'Some pitfalls in the philosophical foundation of nanoethics', *J Med Philos*, Vol.32, 2007, pp.237 -261.
- Dupuy, J.P. and A. Grinbaum, 'Living with uncertainty: Towards a normative assessment of nanotechnology', *Techne*, Vol. 8, 2004, pp.4-25.
- European Commission (EC), *Communication from the Commission on the precautionary principle*, Brussels: COM, 2000.
- , *Communication Towards a European strategy for nanotechnology*, (COMN(2004) 338, 12.5.2004).
- , *Communication on Nanotechnologies Action Plan for Europe 2005-2009*, (COM(2005) 243, 7.6.2005).
- , 2008a. 'Regulatory aspects of nanomaterials' and the accompanying Commission staff document 'Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures'. <http://www.kowi.de/Portaldata/2/Resources/fp7/coop/eu-nano-policy-2004-08-en.pdf> (accessed on 5-08-2011).
- , 2008b. *Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research*, (COM (2008), 7.2.2008).
- Environmental Protection Agency (EPA), 'Notice: Nanoscale Materials Stewardship Program', *Federal Register*, 73(18), 2008, pp. 4861-4866.
- Gammel, S., A. Löscher and A. Nordmann, 'A scanning probe agency as an institution of permanent Vigilance', in M. Goodwin, B-J. Koops and R. Leenes (eds.), *Dimensions of Technology Regulation*, WLP, Nijmegen, 2010, pp. 125-143.
- Gezondheidsraad, *Betekenis van nano technologieën voor de gezondheid*, Den Haag: Gezondheidsraad, 2006/06.
- Gezondheidsraad, *Voorzorg met Rede*, Den Haag, Gezondheidsraad, 2008/18.

- Griffiths, J., 'The Social Working of Legal Rules', *Journal of Legal Pluralism and Unofficial Law*, Vol.48, pp.1-84, 2003.
- Griffiths, J., 'Legal Knowledge and the Social Working of Law: The case of Euthanasia', in H. van Schooten (ed.), *Semiotics and Legislation*, Deborah Charles, Liverpool, 1999, pp. 81-108.
- Gunningham, N., 'The New Collaborative Environmental Governance. The Localization of Regulation', *Journal of Law and Society*, Vol. 36, No. 1, 2009, p.145.
- Gunningham, N., R. Kagan and D. Thornton, *Social License and Environmental Protection: Why Business Go beyond Compliance*, University of California, Berkeley, CA, 2002.
- Gunningham N., Grabosky P. and Sinclair D., *Smart Regulation: Designing Environmental Policy*, Oxford University Press, Oxford, 1998.
- Gunningham, N., 'Environment, Self- regulation and the Chemical Industry: Assessing Responsible Care', *Law & Policy*, Vol.17,1995, pp. 57-109.
- Haines, F., 'Regulatory Failures and Regulatory Solutions: A Characteristic Analysis of the Aftermath of Disaster', *Law & Social Inquiry*, Volume 34, No.1, 2009, pp.31 - 60.
- Haines, F., *Globalization and Regulatory Character: Regulatory Reform after the Kader Toy Factory Fire*, Ashgate, Dartmouth, 2005.
- Halpern, S., 'Hybrid Design Systematic Rigidity: Institutional Dynamics in Human Research Oversight', *Regulation & Governance*, Vol.2, 2009, pp.85-102.
- Havinga, T., 'Private Regulation of Food Safety by Supermarkets', *Law & Policy*, Vol.28, 2006, pp.515- 533.
- Heald, D., 'Varieties of transparency', in C. Hood and D. Heald (eds.), *Transparency. The key to better governance?*, Proceedings of the British Academy 135, Oxford University Press, Oxford 2006.
- Heffen, O. van, and P.J. Klok, 'Institutionalism: State Models and Policy Processes', in O. van Heffen, W.J.M. Kickert and J.J.A. Thomassen (eds.), *Governance in Modern Society*, Kluwer, Dordrecht, 2002, pp. 153-177.
- Hodge, G., Bowman, D. and K. Ludlow (eds.) *New Global Regulatory Frontiers in Regulation: The Age of Nanotechnology*, Edward Elgar, Cheltenham, 2007.
- Hodge, G. and D. Bowman, 'Counting on Codes: An examination of transnational codes as a regulatory governance mechanism for nanotechnologies', *Regulation & Governance* (2009)3, pp. 145-164.
- Hodge, G., D. Bowman and A. Maynard (eds.): *International Handbook on Regulating Nanotechnologies*, 2010.
- Hutter, B.M., *Compliance: Regulation and Environment*, Clarendon Press, Oxford, 1997.
- Kagan, R.A., and J.T. Scholz, 'The Criminology of the Cooperation and Regulatory Enforcement strategies', in K. Hawkins and J.M. Thomas (eds.), *Enforcing Regulation*, Kluwer/Nijhoff Publishing, Boston, 1984, pp. 132-1552.
- Karlsson-Vinkhuyzen S.I. and A. Vihma, 'Comparing the Legitimacy and Effectiveness of Global hard and Soft Law: An Analytical framework', *Regulation & Governance*, Vol. 3, 2009, pp.400-420.
- Kersbergen, K. van, and F. van Waarden, 'Governance as a Bridge Between Disciplines, Cross-disciplinary Inspiration Regarding Shifts in Governance and Problems of Governability, Accountability and Legitimacy', *European Journal of Political Research*, Vol. 43, 2004, pp.143-171.
- Kloepfer, M., *Technik und Recht im wechselseitigen Werden -Kommunikationsrecht in der Technikgeschichte*, Duncker&Humblot, Berlin, 2002.
- Kooiman, J., *Societal Governance: Levels, Models and Orders of Social- Political Interaction, Debating Governance: Authority, Steering and Democracy*, Oxford University Press, Oxford, pp.138-164, 2003.
- Lee, R., and S. Vaughan, 'REACHing Down: Nanomaterials and Chemical Safety in the European Union', *Law, Innovation and Technology* 2(2) 2010, pp. 193-217
- Levi-Faur, D. and H. Comaneshter, 'The Risks of Regulation and the Regulation of Risks: The Governance of Nanotechnology', in G. Hodge, D. Bowman and K. Ludlow (eds.), *New Global Regulatory Frontiers in Regulation: The Age of Nanotechnology*, Edward Elgar, Cheltenham, 2007, pp. 149-165.go_1
- Ludlow, K., 'One size fits all? Australian regulation of nanoparticle exposure in the workplace', *Journal of Law and Medicine*, 15, 2007, pp. 136-152.079 174
- NanoCode 2010: Synthesis Report on Codes of Conduct, Voluntary Measures and Practices Towards A Responsible Development of N&N. <http://www.nanocode.eu>
- NanoCode 2011: Synthesis Report on Codes of Conduct, Voluntary Measures and Practices Towards A Responsible Development of N&N. <http://www.nanocode.eu>

- NanoKommission 2008: 'Responsible Use of Nanotechnologies', in W-M. Catenhusen and A. Grobe, (eds.), *Report and recommendations of the German federal Governments NanoKommission for 2008*, Bonn, Berlin 2009 (German Version: November 2008), available at <http://www.bmu.de/files/pdfs/allgemein/application/pdf/nanokomm>
- National Industrial Chemical Notification and Assessment Scheme (NICNAS) 2008. Industrial Nanomaterials: Voluntary Call for Information 2008, *Australian Government Gazette*, C 10-7 October: 25-38.
- Nordmann, A., 'Beyond Regulation', *Nanomagazine* April 2009, pp- 29-31.
- Nonet, P., and P. Selznick, 'Law and Society in transition', *Toward responsive Law*. Harper, New York, 1978.
- Opschoor, H. and K. Turner, *Economic Incentives and Environmental Policies: Principles and Practice*, Kluwer Academic Publishers, Dordrecht, 1994.
- Parker, C.E., 'Reinventing Regulation within the Cooperation: Compliance- oriented Regulatory Innovation', *Administration & Society*, Vol.32, 2000, pp.529-565.
- Parker, C.E., *The Open Cooperation: Effective Self- Regulation and Democracy*, Cambridge University Press, Cambridge, 2002.
- Parker, C.E., 'The 'Compliance' Trap: The Moral Message in Responsive Regulatory Enforcement', *Law & Society Review*, Vol.40,2006, pp. 591- 622.
- Pierre, J. and B.G. Peters, *Governance, Politics and the State*, Macmillian, Houndsmills, 2000.
- Pound, R., 'The Lawyer as a Social Engineer', *Journal of Public law*, Vol.3,1955, p.294
- Pound, R., *Social Control through Law*, Yale University Press, New Haven, 1942, pp.64-65
- Pollit, C., *The Essential Public Manager*, Open University Press, Maidenhead, 2003.
- Rhodes, R.A.W., *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*, Open University Press, Buckingham, 1997.
- Schomberg, R. von, 'Prospects for Technology Assessment in a framework of responsible research and innovation', in M. Dusseldorp and R. Beecroft (eds.) *Technikfolgen abschätzen lehren: Bildungspotenziale transdisziplinärer Methoden*, Wiesbaden: Vs Verlag, forthcoming 2011
- Scott, C., 'Private regulation of the Public Sector: A neglected facet of Contemporary Governance', *Journal of Law and Society*, 29, 2002, pp. 56-76.
- Scott, C., F. Cavaggi and I. Senden, 'The Conceptual and Constitutional Challenge of Transnational Private Regulation', *Journal of Law and Society*, Vol. 38, 2011, pp. 1-19.
- Scott W.R., *Institutions and Organizations*, Sage Thousand Oaks, CA, 2001.
- Selznick, P., *The Moral Commonwealth: Social Theory and the promise of Community*, University of California Press, Berkeley, CA, 1992.
- Senden, L., *Soft Law in European Community Law*. Hart Publishing, Oxford, 2004.
- SER, *Veilig omgaan met nanodeeltjes op de werkplek*, Den Haag: Sociaal- Economische Raad, SER-advies, 2009/1
- Teubner, G. (ed.), *Global Law without a State*, Dartmouth Gower, Aldershot, 1997.
- Trubek, L.G., J.V. Rees, A.B. Hoflund, M. Farquahr and C.A. Heimer, 'Health Care and New Governance: The quest for Effective Regulation', *Regulation and Governance*, Vol. 2, 2008, pp.1-8.
- Vogel, D., 'The Private Regulation of Global Corporate Conduct', in W. Mattli and N. Woods, (eds.), *The Politics of Global regulation*, Princeton University Press, Princeton, NJ, 2009, pp. 151 - 188.
- Vogelezang-Stoute, E.M., J.R. Popma, M.V.C. Aalders and T. Gaarhuis, *Regulering van onzekere Risicos van Nanomaterialen - Mogelijkheden en Knelpunten in die Regelgeving op het Gebied van Milieu, Consumentenbescherming en Arbeidsomstandigheden (Regulation of uncertain risks of nanomaterials - possibilities and bottlenecks of regulation in the field of the environment, consumer protection and labour conditions)*, STEM Institute University of Amsterdam, The Netherlands, Publication 2010/5, 2010.
- Vos, E., *Institutional Frameworks of Community Health and Safety Regulation - Committees, Agencies and Private Bodies*, Hart Publishing, Oxford, 1999.
- Wright, J.S.F. and B. Head, 'Reconsidering Regulation and Governance Theory: A Learning Approach', *Law & Policy*, Vol. 31, 2009, pp.192- 216.
- Zumbansen, P., 'Neither 'Public' nor 'Private', 'National' nor 'International': Transnational Corporate Governance from a Legal Pluralist Perspective', *Journal of Law and Society*, 38(1), 2011, pp. 50-75.