Nanoethics (2013) 7:55–68
DOI 10.1007/s11569-013-0172-8

ORIGINAL PAPER

Meta-Regulation and Nanotechnologies: The Challenge of Responsibilisation Within the European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

Bärbel Dorbeck-Jung · Clare Shelley-Egan

Received: 18 January 2013 / Accepted: 7 February 2013 / Published online: 12 March 2013

Abstract This paper focuses on the contribution of meta-regulation in responding to the regulatory needs of a field beset by significant uncertainties concerning risks, benefits and development trajectories and characterised by fast development. Meta-regulation allows regulators to address problems when they lack the resources or information needed to develop sound "discretion-limiting rules"; meta-regulators exploit the information advantages of those actors to be regulated by leveraging them into the task of regulating itself. The contribution of meta-regulation to the governance of nanotechnologies is assessed in terms of responsibilisation. Responsibilisation is regarded as a pre -requisite for regulatory actors to internalise social values (such as consumer safety and occupational health) and to ensure that these values are built into regulatory practice. In order to explore the potential of responsibilisation, the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research launched by the European Commission in 2008 is evaluated. The Code is a good case of meta-regulation that aims to steer the self-regulation of nanotechnological business and research organisations. The paper concludes that, while efforts were made on the part of meta-regulators and self-regulators to contribute to responsibilisation, important opportunities for responsibilisation such as dissemination and promotion of the Code, trust-building activities, and failure to provide rewards, incentives and stakeholder guidance were not taken up. In order to foster responsibilisation within the meta-regulatory instrument of the EC Code, a number of crucial activities to be undertaken by meta-regulators are recommended.

Keywords European Commission Code of Conduct for Responsible Nanosciences and Nanotechnologies Research · Meta-regulation · Responsibilisation · Self-regulation

B. Dorbeck-Jung (✉) · C. Shelley-Egan
Law & Regulation Group, Department of Public Administration, School of Management & Governance, Universiteit Twente,
P.O. Box 217, 7500 AE Enschede, The Netherlands
e-mail: b.r.dorbeck-jung@utwente.nl

C. Shelley-Egan
e-mail: c.shelleyegan@utwente.nl

Introduction

For over a decade, an international policy debate has been taking place regarding appropriate mechanisms for the governance and regulation of nanotechnology [31]. The terms of this debate reflect the classic 'too early/too late' dilemma in the regulation of emerging technologies: how to regulate such that the innovative potential of the field is not restricted, while being sensitive to public concerns and to possible emerging risks to health and the environment [18]. The challenges involved in developing such 'anticipatory' governance are considerable. First, current knowledge on

possible eco-toxicological effects of nanomaterials is limited [28]. While nanomaterials and applications are being developed at a very rapid pace, a fundamental understanding of potential environmental and human health risks resulting from exposure throughout the lifecycle of these materials has lagged behind [50].[1] Second, commercial uncertainties regarding the development trajectories of nanotechnology in different sectors abound [15]. In some industries such as the semi-conductor industry, uncertainty exists concerning the balance between 'more Moore' and 'beyond Moore'[2] and what this implies for new product-value chains and industry structure, while there are no concerns about the eventual acceptance of products [31]. The food sector, on the other hand,'is hooked on nanotech's promises, but is also very nervous'[43]. Thus, according to Kearnes and Rip'The simple fact is that though nanotechnology is seen as heralding great promise in individual sectors, the innovation trajectory is, as yet, unclear'([31]: 102). Third, social uncertainties relate primarily to uncertainties about public acceptance of nanotechnologies and concern about the potential for public concern to hold back developments in nanotechnology [31], up to exaggerated concerns about public reactions to nanotechnology as a case of 'nanophobia-phobia' [44]. These uncertainties combine to form a complex situation around the regulation of nanotechnology. Formal regulation will be difficult because of the time taken to learn of the social consequences of the technology and to adapt regulatory structures as instruments of control [33], and because of the technological enhancements at stake which require flexible intervention [38].

Traditional instruments of public regulators such as legislation do not seem appropriate in coping with the challenges of nanotechnologies because they are based on knowledge of the effects of nanotechnological development, evidence of which cannot yet be provided. Thus, public regulators are seeking new strategies. The approach of meta-regulation has been proposed as a means of alleviating regulators' limited access to information and expertise and overcoming the inherent limitations of prescriptive rules [23, 39, 41]. Meta-regulation has been put forward for newly developing markets such as nanotechnologies [13].

Meta-regulation is understood as a process of regulating the regulators, whether they are public agencies, private corporate self-regulators or third party gatekeepers [39]. Meta-regulation entails a shift from direct intervention ('rowing') to indirect intervention ('steering') in terms of enabling, motivating and pressing the regulated parties to regulate and to comply with self-regulation [8]. Meta-regulation is recommended for its potential in terms of cost-effectiveness, facilitation of innovation and responsibilisation of regulatees [11, 14, 23, 41]. However, the success of meta-regulation is also contested. Commentators argue that the involved actors may not be willing or able to invest in the demanding regulatory activities meta-regulation requires [2, 11, 14, 23]. Furthermore, according to Parker, committing business to social goals may be extremely difficult ([39]: 25).

This paper explores the opportunities and challenges of meta-regulation in the regulation of nanotechnologies. In doing so, the paper focuses on the contribution of meta-regulation generally in responding to the regulatory needs of a field characterised by fast development, heterogeneity and uncertainties [5, 34]. The contribution of meta-regulation to the governance of nanotechnology will be assessed in terms of responsibilisation. Responsibilisation is regarded as a prerequisite for regulatory actors to internalise social values (such as consumer safety and occupational health) and to ensure that these values are built into regulatory practice [39]. This paper aims to provide insights into the way in which responsibilisation can be taken up within meta-regulatory strategies related to nanotechnologies. In order to explore the potential of responsibilisation, the Code of Conduct for Responsible Nanosciences and Nanotechnologies Research launched by the European Commission in 2008 [21] is evaluated. The Code is a good case of meta-regulation that aims to steer the self-regulation of nanotechnological business and research organisations. It was set up as a meta-regulatory instrument, through which 'governments can allocate tasks and

[1] Indeed it has been estimated that costs for toxicity testing of existing nanoparticles available in the United States will range from $249 million to $1.18 billion and the time taken to complete testing will be significant (35–43 years) [10].

[2] The "More than Moore" domain refers to a set of technologies that enable non-digital micro/nanoelectronic functions such as radio frequency (RF) communication, power control, passive components, sensors and actuators. These technologies are based on, or derive from, silicon technology but do not necessarily scale with Moore's Law. "Beyond Moore" refers to a set of disruptive functions—from progress in nanometre-sized functions—that, in the long term, will complement or replace conventional silicon technology.

roles to all actors involved in technological development, hence organizing collective responsibility for the field' [51].

The paper reviews insights into stakeholder responses to the Code, offered in the reports of two European projects, namely NanoCode and FramingNano. The review is based on an analytical frame encompassing circumstances that seem to foster responsibilisation. In order to develop this frame, an understanding of the potential advantages and drawbacks of meta-regulation is required.[3] To that end, the first section outlines the characteristics, opportunities and challenges of meta-regulation. Next, the meta-regulatory features and workings of the EC Code of Conduct are described in The EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research section. Prerequisites for Responsibilisation—Analytical Frame section offers a discussion of the prerequisites for 'regulatory responsibilisation'. The EC Code is evaluated according to these prerequisites in the Responsibilisation Within the EC Code section. The analysis leads to tentative conclusions regarding the opportunities and challenges of the responsibilisation of the regulatory actors involved in the Code.

Meta-Regulation—Opportunities and Challenges for Nanotechnologies

Characteristics of Meta-Regulation, Advantages and Obstacles

Meta-regulation comprises part of a governance arrangement that serves to achieve certain policy goals. In this governance arrangement, interactive and co-evolutionary processes take place when meta-regulators and self-regulators respond to regulatory activities. Meta-regulatory activities attempt to induce self-regulatory parties to align their actions and outcomes more closely with broader social goals [23, 40]. Such activities involve standard-setting, implementation, oversight and enforcement. [4] Meta-regulators steer through dialogue, incentives, rewards, shaming and sanctions. Meta-regulation is not only employed by public regulators; industry associations or central divisions that aim to motivate companies to control themselves in a responsible manner can also employ meta-regulation.[5] Meta-regulation shifts discretion regarding how to regulate from the regulator to the self-regulator. [6]

Meta-regulatory strategies presuppose learning and continuous improvement of all regulatory actors [39]. They have both discursive and structural properties [4, 36]. Discursive properties refer to deliberation [39]. In Parker's view, successful meta-regulation requires 'permeable' self-regulation in which corporate management critically reflects on past and future actions in the light of legal responsibilities and impacts on shareholders and constantly seeks to improve compliance with its responsibilities ([39]: 292). As Parker puts it: 'The open corporation is the good corporate citizen in deliberative democracy' ([39]: 293). Structural properties involve a certain distribution of responsibilities for both meta-regulators and self-regulators. For example, meta-regulators are tasked with responsibility for assessing the quality of self- evaluations and the actions self-regulators take on the basis of their assessments. In addition, meta-regulators are expected to conduct their own assessment of the efficacy of the self-regulator's control systems via direct inspection and by soliciting the feedback of experts and relevant stakeholders [23]. Meta-regulators are expected to learn about the industries and the problems they endeavour to manage; moreover, they should encourage experimentation and provide self-regulators with good practices [23]. On their side, self-regulators are tasked with the responsibility of identifying risks and devising internal control systems, continuously evaluating the efficacy of their internal systems and incrementally improving these systems in light of this evaluation [23, 39]. Under meta-regulation, each self-regulator is required to lay down a set of rules tailored to the specific context of the organisation; these rules will be scrutinised by the meta-regulatory agency. Self-regulators are expected to inform meta-regulators about detected risks, their internal control systems,

[3] Our argumentation is based on reviews of the literature, policy documents and empirical studies.

[4] With this broad view on regulatory activities, we follow Parker who maintains that meta-regulation can entail any form of regulation that regulates any other form of regulation [41]. Narrow views focus only on oversight [30] or on enforcement activities [1, 7].

[5] See, for instance, the Responsible Care programme [14].

[6] Along a continuum of forms of regulation, starting with complete discretion to acting according to self-interest ('freedom'), and ending with command and control, to aligning to social goals ('control'), meta-regulation can be placed in the middle (15).

self-evaluations and the measures they have taken to improve self-regulation. If self-regulators fail to regulate or to align their actions with social goals, public meta-regulators are responsible for taking corrective action. The potential advantages of a governance arrangement with combined meta-regulation and self-regulation are said to be numerous [2, 12]. According to these accounts, meta-regulation enhances compliance performance and external inspection. Moreover, meta-regulation allows for cost reduction and removes barriers to innovation [11]. However, empirical studies are also critical of the effectiveness of meta-regulation. Such studies indicate that meta-regulators and self-regulators often do not take their responsibilities seriously. Meta-regulators face problems with monitoring self-regulation, assessing self-evaluations, keeping up to date with developments in practice and building independent expertise [23][7]. Self-regulators appear to have problems developing self-regulatory capacity and committing to social policy goals, as opposed to self-interest [25, 27, 29, 35, 36].

Regulators are confronted with obstacles when seeking to cope with these problems. Reviews of the performance of meta-regulation indicate that the greater the level of uncertainty over the nature of risks, the higher the evaluation costs and the risk of incongruence between implementation and regulatory goals [23]. Ongoing investment is required to support continuous collection and analysis of information, experimentation and improvement can be expensive and even impossible to sustain. A further difficulty is that meta-regulators have limited experience with new and innovative techniques [35]. It may be difficult for them to build capacity so as to independently assess the validity of the provided information [23]. Furthermore, they may be unable to identify flaws in information provided by self-regulators; such information will be shaped by the self-regulators' own conceptualizations of risk, risk assessment and management [22].

[7] These studies review process-oriented regulation which includes management-based regulation and meta-regulation [23]. Process-oriented regulation involves the steering of the regulatory process. Unlike management-based regulation, meta-regulation focuses on systematic regulatory learning which seems crucial for the regulation of emerging technologies with complex uncertainties.

Meta-Regulatory Approach to Nanotechnologies

Meta-regulation can be advantageous in dealing with the problems of nanotechnological regulation if the challenges that have been addressed in other regulatory fields are taken seriously. Critical commentators maintain that potential advantages can be realized if regulators invest in overcoming the obstacles that have been observed in regulatory practice [14, 23, 46, 47]. They strongly advocate learning lessons from the problems of meta-regulation in order to enhance the use of this promising regulatory approach. Given the challenges pertaining to the control of nanotechnologies, indirect steering by meta-regulation seems to be an appropriate strategy. The regulation of nanotechnology is beset by huge uncertainties concerning the risks, benefits, and possible development trajectories of nanotechnology, as described in the Introduction. Moreover, regulators lack the *expertise* required to understand the risks relating to the different characteristics of engineered nanomaterials. A lack of expertise challenges the *regulatory capacity* of the competent authorities [17]; different applications of nanotechnology put pressure on the capacity of regulators to keep pace with the development of new science, new applications and risk assessment. Regulators must find a way of addressing such regulatory challenges. Traditional command and control approaches to regulation appear to be challenged by the speed of development within the nano field, its heterogeneous nature and uncertainties [5]. Moreover, regulators cannot afford to wait until the effects of technological applications are known to fill in knowledge gaps. European regulators are committed to responsible nanotechnological development [19] which has become an important feature in regulatory approaches. Responsible development offers an overarching framing of the governance of nanotechnology as fundamentally defined by its ability to *enable* research whilst balancing negative consequences [31]. Public regulators thus have to search for adequate instruments with which to deal with these problems.

As mentioned already in the Introduction, there is an inherent temporal dilemma in the governance and regulation of nanoscience and nanotechnologies: regulating too soon may potentially stifle innovation and cut off the emergence of beneficial technologies, while a 'wait and see' approach to regulation may lead to a catastrophe which could have been anticipated or dealt

with more effectively [42]. As a hybrid form of regulation which sits at the interface between state-based and civil-based modes of regulation [5], meta-regulation facilitates a flexible approach to evolving regulatory needs of nanotechnologies. Meta-regulation can contribute to the regulation of nanotechnologies by offering a regulatory tool with which regulators can avail of the resources and expertise of experts, facilitate flexible intervention, and foster an enabling innovation environment through 'steering' rather than 'rowing' [54]. If regulators of nanotechnologies learn from successes and problems that become visible in other regulatory fields, compliance with regulation, governance oversight and steering can be enhanced.[8]

The EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research

The European Commission's Code of Conduct for responsible nanosciences and nanotechnologies research is a good example of meta-regulation. This instrument was selected as it provides an opportunity to explore responsibilisation. [9]The Code of Conduct was launched on 7th February 2008. It serves to enable safe and beneficial nano innovation with the aim of supporting' integrated, safe and responsible nanosciences and nanotechnologies research in Europe for the benefit of society as a whole' [23: 3]. In its consultation paper for the Code, the EC [20] emphasised that the code 'is part of the European Commission's ambition to promote a balanced diffusion of information on nanosciences and nanotechnologies and to foster an open dialogue, involving the broadest range of interested parties' and that the 'Code of Conduct would offer those following it recognition of a responsible approach towards nanosciences and nanotechnologies, making their actions more visible at a European level' [22:2]. The Code implicitly communicates a notion of responsible nanoresearch that rests on adherence to seven principles [32]. In putting forward a set of general principles and guidelines for actions to be taken by nanosciences and nanotechnologies (N&N) stakeholders, the Commission is deliberately seeking to induce regulatees to develop their own internal, self-regulatory responses to the call for safe and responsible nanoscience and nanotechnologies research. The Code 'should facilitate and underpin the regulatory and non-regulatory approaches outlined in the 2005–2009 Nanosciences and Nanotechnologies Action Plan for Europe, improving the implementation of current regulation and coping with scientific uncertainties' (Annex: 5). As a meta-regulatory instrument, the Code aims to achieve this objective by assigning responsibilities to actors beyond governments and promoting those actors' active involvement [52] in the regulation of responsible nanoscience and nanotechnologies research. Such an approach highlights the importance of the insights and cooperation of societal actors in the governance of new technologies and the need for researchers' involvement in providing knowledge and expertise about engineered nanomaterials.

The Code as a meta-regulatory instrument involves a number of steering activities. It stimulates meta-steering activities of the Member States and facilitates self-regulation. In the first instance, the Recommendation provides Member States with an instrument with which to undertake further initiatives to ensure safe, ethical and sustainable N&N research and aims to contribute to the coordination of regulatory activities across Member States. Thus the Commission recommends that Member States be guided by the general principles and guidelines on actions to be taken (as set out in the Annex of the Code) when implementing their national regulatory research and development strategies or developing sectoral and institutional research and development standards. Moreover, the Commission recommends that Member States view the general guidelines and principles as a crucial aspect of institutional quality assurance mechanisms for funding schemes, as means for the auditing, monitoring and evaluation processes of public bodies, and as an instrument with which to encourage dialogue 'at all governance levels' [23: 4]. Another recommendation is that Member States encourage the voluntary adoption of the Code amongst all relevant stakeholders while endeavouring to ensure that stakeholders contribute to safe, ethical and effective development of nanoscience and nanotechnologies.

The Code of Conduct sets out what is expected of self-regulators, that is, Member States, N&N research funding bodies (public and private), research organisations, researchers and standardisation bodies, on the basis of recommendations and principles. The Code is based on a set of general principles which underpin guidelines on actions to be taken. The principles

[8] For meta-regulation in general see [47].

[9] Other meta-regulatory instruments include voluntary reporting schemes such as the Defra programme which aim at facilitating the collection of data on the potential hazards posed by engineered nanoparticles (see [6]).

include meaning, sustainability, precaution, inclusiveness, excellence, innovation and accountability.[10] The three guidelines — 1) Good governance of N&N research; 2) Due respect for precaution; and 3) Wide dissemination and monitoring of the Code of Conduct—are meant to give guidance and offer an indication of the main responsibilities for action.[11] The Code encompasses different layers of regulation, including the European level (European Commission), the national level (Member States and N&N research funding bodies (public and private)) and the local level (research organisations and researchers).[12]

The Code sets out certain meta-regulatory and self-regulatory responsibilities, an overview of which is provided in Table 1 below:

In the Responsibilisation Within the EC Code section, we explore how this meta-regulatory arrangement works in terms of enabling the responsibilisation of relevant N&N stakeholders. First, we offer an analytical frame that sets out the conditions necessary to support regulatory responsibilisation.

Prerequisites for Responsibilisation—Analytical Frame

With regard to the challenges of meta-regulation, responsibilisation seems to be a crucial means of transcending self-interest and committing organisations to social goals. Generally, responsibilisation is about predisposing actors to assume responsibility for their actions [49]. Responsibilisation is related to the moral agency of regulators which presupposes care for the duties and uncoerced application of certain values as a root motivation for action [48]. Responsibilisation implies that self-interest is moderated and redirected, not forgotten or extinguished [48]. In the context of meta-regulation, responsibilisation rests on activities to motivate regulators to build and enhance regulatory capacity. It involves particular activities that stimulate self-regulators to internalise social values and to ensure that these values are built into self-regulatory activities.

A basic prerequisite for responsibilisation is that meta-regulators and self-regulators are *aware* of their responsibilities. This can be supported by providing information and communicating on meta-regulation, good practices and the workings of self-regulation. Furthermore, a *relationship of trust* between meta-regulators and self-regulators seems to be crucial for responsibilisation [23]. Meta-regulators must feel that they can rely on self-regulators to take their responsibilities seriously, while self-regulators must be confident that meta-regulators are not simply trying to shift costs and that meta-regulation enjoys political support [23]. Trust can be built through preparatory debates, low relational distance between the meta-regulator and the self-regulator [45], and performance agreements that orchestrate responsibilisation [8].[13]

Commitment to social goals can be stimulated through deliberation,[14] linkages with economic rationality and through the extension and strengthening of the net of vigilance, oversight, enforcement and accountability. Meta-regulators can encourage commitment to social goals through *linkages with economic rationality* (e.g. by using rewards and incentives, as well as putting emphasis on the benefits to be gained). They can grant public recognition to high-performing organisations (e.g. through the publication of best practices and certification; [2]). Meta-regulators may grant areas of freedom of inspection to trusted organisations [26]. Self-interest can be enlisted by highlighting the advantages self-regulation has to offer (lower input costs, improved productivity of workers, good

[10] Meaning, for example, is defined as follows: *'N&N research activities should be comprehensible to the public. They should respect fundamental rights and be conducted in the interest of the well-being of individuals and society in their design, implementation, dissemination and use'* [23:6]. Innovation is described as follows: *'Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth'* [23:7].

[11] Thus, for example, for the good governance of N&N research, N&N research organisations and researchers 'should ensure that scientific data and results are duly peer-reviewed before being widely disseminated outside the scientific community in order to ensure their clarity and balanced presentation' [23:7].

[12] The Code is also meant to provide guidelines for responsible nanoresearch to employers and all individual and civil society organisations involved or interested in nanoscience and nanotechnologies research ("all stakeholders").

[13] Such a performance agreement, for instance, commits meta-regulators to giving particular rewards and incentives, while it commits self-regulators to information provision and certain self-regulatory activities.

[14] The use of mediators is proposed as a means of enabling more 'genuine' *deliberation* [3]. Mediators are expected to stimulate responsibilisation by translating various interests and 'world views' in order to facilitate communication across the different stakeholders.

Table 1 The Code: meta-regulatory and self-regulatory responsibilities

Actors	Meta-regulatory responsibilities	Self-regulatory responsibilities
European Commission	• Regular monitoring & revision of Code every two years	
Member States	Encourage	• include general principles & guidelines in national N&N research strategies & quality assurance mechanisms
	• voluntary adoption of the Code	• cooperate with Commission to maintain an open & pluralistic forum for discussion & to devise adequate measures for monitoring of the Code
	• private & public sector laboratories to share best practices in N&N research	• enhance communication on benefits, risks & uncertainties of N&N research
	• field of N&N research with broadest possible positive impact	• make easily understandable & accessible all N&N scientific research knowledge & related information
	Ensure	
	• N&N research is conducted at highest levels of scientific integrity	
	• appropriate resources are dedicated to application of relevant laws & regulations to N&N research	
	• cooperate with Commission in order to review Rec. biannually	
	• monitoring of adoption & implementation of Code	
	• provide good practices	
	• support wide dissemination of Code	
N&N research funding bodies (public & private), research organisations & researchers; standardisation bodies	• ensure wide dissemination of the Code (N&N research funding bodies)	• specify general & specific principles regarding good governance of research & due respect for precaution

practices, strong rewards,[15] enforcement), as well as by regulatory goals that are close to business goals. The meta-regulator can offer practical guidance and technical assistance.

Those meta-regulators devising strategies of responsibilisation can learn from failures of self-regulation. In order to motivate organisations to take their responsibilities seriously, *widening and strengthening the net of vigilance, oversight, enforcement and accountability* is proposed [9, 14, 36, 39, 41, 45]. According to Parker, responsibilisation can be stimulated 'by inducing corporate crises of conscience through regulatory enforcement action, legal liability and public access to information about corporate social and legal responsibility' ([39]: 246). External pressures (economic, social and regulatory) seem to be necessary in order to responsibilise self-regulating parties. Some proponents of meta-regulation place an emphasis on embedding the governance arrangement in structures of accountability, and using liability to increase an organisation's commitment to self-regulation [2, 9, 39, 41]. Strategies with varying degree of coerciveness have been proposed, beginning with adverse publicity and ending up with legal sanctions [1, 26]. However, there is no consensus as to whether a 'big' stick is still a prerequisite for the 'softly spoken regulator to be effective'. According to Scott [45], meta-regulators have to rely on allying themselves with self-regulators or other meta-regulators, as well as on creating competition amongst self-regulators rather than on coercion.

This discussion of prerequisites for responsibilisation allows us to develop the following questions (in Table 2 below) which serve to shed light on why and

[15] Recent research shows that weak forms of rewards such as public recognition call responsibilisation into question [14].

how responsibilisation works or does not work in the context of meta-regulatory governance arrangements.

In the next section, we explore responsibilisation within the EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, employing a number of prerequisites, namely awareness of responsibilities, trust-building activities, links with the rationality of self-regulators, and activities encompassing vigilance, oversight, enforcement and accountability. We make tentative inferences about the trust relationship between meta-regulators and self-regulators based on checking whether stakeholders' responses to the consultation appeared to impact further versions of the Code, as evinced in the text of the final (2008) Code. The selection of these particular prerequisites of responsibilisation is based on the information that can be garnered from the empirical studies of the Code. Secondary sources of data are mobilised in order to analyse and evaluate the code. Empirical analyses of the Code drawn on here include reports derived from European projects, namely the NanoCode[16] and FramingNano[17] projects. Based on the information provided, we cannot offer any evaluation regarding deliberation or professionalisation of regulators.

Responsibilisation Within the EC Code

Analysis

Awareness of Responsibilities

A basic element in the responsibilisation of actors is that they should, in the first instance, be *aware* of their responsibilities. Awareness of responsibilities requires knowledge of the existence of regulation. Only about half of the total of 304 NanoCode survey participants reported that they had been aware of the existence of the Code prior to the survey. This degree of awareness was independent of whether N&N experts from EU or non-EU countries were asked and independent of the level of N&N activity pursued in the country. [18] Indeed, the authors of the Synthesis Report assert the following: 'After more than 2 years of debate about the EU CoC, the data suggests that the awareness is limited to a narrow community of selected key experts. The EU CoC is not embedded in the everyday life of the large majority of N&N researchers in Europe' (p.6). Strikingly, stakeholder responses to the first Framing Nano Delphi consultation held in July 2009[19] indicated that the vast majority of stakeholders—34 respondents out of a total of 40—were aware of the Code (however, there was a high level of uncertainty with regard to possible actions to be taken

[16] The aim of the NanoCode project—funded by the European Commission's Framework Programme 7 (FP7)—was to develop a strategic framework (the MasterPlan) aimed at guiding the further development and implementation of the Code of Conduct, in addition to the development of a practical implementation assistance tool to help stakeholders assess their performance in complying with the Code's principles. A March 2011 Synthesis Report [24] presents the findings of the international, quantitative and qualitative NanoCode survey about the Code. The results summarised in the Synthesis Report and MasterPlan offer insight into stakeholders' patterns of awareness, their expectations, attitudes and appraisals. In all, 304 European and international experts contributed to the *NanoCode* survey in the period August-October 2010. In addition, around 150 experts were involved in qualitative interviews or focus groups in the different countries between October 2010 and January 2011. All project partners contributed to identifying relevant stakeholders and prepared a catalogue of national stakeholders, in addition to participants from different national organisations. Furthermore, each partner was responsible for inviting the identified experts to participate in the electronic survey through a personal mailing procedure. Key experts were defined as persons with a role in planning, managing or funding of activities in research and development (R&D), its safety, quality of corporate responsibility or communication issues in their organisation; or a role in planning or managing of international/national/regional or sector specific regulations, guidelines, voluntary measures and policies or funding strategies. A large number of stakeholders (62 %) were involved in research (in academia, industry and public research institutions), 16 % derived from business and the rest belonged to institutions (governmental departments and agencies, R&D governing bodies, regulatory and standards agencies, etc.) and civil society (non-governmental organisations (NGOs), consumer associations, labour associations). According to the report, the results show a "surprisingly unambiguous tendency", given the large and heterogeneous sample.

[17] The FramingNano project [53] was another FP7 project which had the objective of defining a governance framework aimed at supporting responsible development of nanoscience and nanotechnology through international multi-stakeholder dialogue amongst the scientific, industrial, non-governmental and broader public communities. A multi-step approach was taken in the *FramingNano* project, which included a two-stage Delphi exercise and a multi-stakeholder workshop used to collect the opinions of stakeholders. Stakeholder opinions on regulation included opinions on the EC Code.

[18] Countries were distinguished between those with relevant activities in N&N (Type A countries such as France, Switzerland, the UK, the Netherlands, Germany, etc.) and those with a quantitatively lower level of activity in N&N (Type B countries such as Italy, Spain, Czech Republic, Argentina, South Africa, etc.)

[19] See http://www.framingnano.eu/index.php?option=com_content&task=view&id=163&Itemid=84

Table 2 Prerequisites for responsibilisation

Awareness of meta-regulatory & self-regulatory responsibilities	• Do meta-regulators have information regarding their responsibilities?
	• Do self-regulators receive information regarding their responsibilities?
	• Do they understand their responsibilities?
Trust relationship between meta-regulators & self-regulators	• Are self-regulators consulted in the making of meta-regulation?
	• Is there dialogue about mutual responsibilities?
	• Is the relational distance short or long?
	• Have performance agreements been made?
Deliberation	• Who is included in the dialogue on regulatory responsibilities?
	• Is a mediator involved?
Links with the rationality of self-regulators (rewards, benefits & incentives)	• Are the advantages for self-regulators clearly set out?
	• Do meta-regulators offer (strong) rewards and incentives?
	• Do meta-regulators provide good practices on compliance performance? ('implementation assistance tools')
Vigilance, oversight, enforcement & accountability	• Are there mechanisms in place with which to maintain the vigilance of meta-regulators and self-regulators?
	• Is oversight regulated & how is it regulated? (peer-review, self-evaluation, assessment of self-evaluation, etc.)
	• Are there mechanisms in place with which to coerce self-regulators into taking their responsibilities, in the event that they are not doing so?
	• Are there mechanisms in place with which to hold self-regulators accountable?
Professionalisation of regulators	• Is the relevant knowledge of meta-regulators and self-regulators constantly upgraded?

with respect to the implementation of the principles and recommendations of the Code within member countries). However, the *promotion of the Code* by the European Commission and Member States was viewed as unsatisfactory by many FramingNano stakeholders.[20] Finally, the dissemination of the Code with the aim of increasing awareness was an important topic in both the NanoCode and FramingNano projects.

The content of the code appeared quite opaque to readers,[21] according to the NanoCode MasterPlan report. The order of content set out in the Code (foreword, the Commission's recommendations, the code of conduct, the Council's conclusions) seemed to confuse readers and made it difficult to recognise the significance of the document for individual stakeholders. Moreover, details such as an introduction outlining who the Code is aimed at, what it is about, the benefits in using it and who is responsible for its dissemination were seen as lacking by the stakeholders.

Trust-Building Activities

A relationship of trust between meta-regulators and self-regulators is crucial for responsibilisation and can be generated via a variety of initiatives such as consultations, and maintaining a short distance between the meta-regulator and the self-regulator. The European Commission did establish a number of consultation processes prior to and following the issuing of the Code in February 2008. A consultation process held between July and September 2007[22] aimed to provide input into the drafting of the code and was aimed at all stakeholders directly or indirectly involved or interested in nanosciences and nanotechnologies research. The consultation paper comprised questions concerning the added-value of the Code in the nano landscape, the scope of the Code, the sufficiency of the principles, restrictions on N&N research and willingness to follow the Code. 64 valid answers[23]

[20] The number of stakeholders is not provided.

[21] No additional information concerning who exactly these readers are or how many is provided.

[22] http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf

[23] The analysis paper of results from the Consultation does not offer a definition of what might comprise a 'valid' answer. However, the paper notes that 'Many answers were *substantiated* [own emphasis] by (existing or ad hoc) high quality papers representing a significant amount of work' (p.1).

were received, with industry and research being the largest contributors (24 and 19, respectively). A large majority of respondents agreed that the Code would bring added value to N&N research and said that they would be ready to adopt the code. Common suggestions amongst stakeholders concerning the Code included the expansion of the Code to encompass innovation, the wide dissemination of the code, the linking of constraints with the code and the regular monitoring and updating of the code. A second consultation was held between October 2009 and January 2010,[24] in the process of revising the Code after 2 years. Notwithstanding the small number of respondents, the consultation was viewed as enabling 'good indications of the Code of Conduct and the way it should be revised' (p.2). 49 valid answers were received with research and industry being the highest contributors (19 and 18, respectively). We highlight a few of the most pertinent responses here. The large majority of stakeholders –with the exception of policymakers—felt that the Code should be revised. Moreover, a large majority wanted to see the set of principles underpinning the Code amended (although only 42.11 % of researchers wanted this). General comments from the respondents included the following: the Code is welcomed as an 'effective hybrid regulation mechanism' that can be used as a 'basis for global dialogue'; the Code is 'inapplicable' considering the 'present writing' and concern about a lack of specificity of the guidelines (industry); effectiveness and impact will be limited if the Code does not have any 'teeth' (researchers); and financial sanctions are necessary if the Code 'is not respected'. In addition to these consultation processes, conferences on the Code also took place. For example, the first conference on the Code—entitled 'Governance and Ethics of Nanotechnology'—was held in Brussels in May 2008 and included representatives from different research directorates, researchers from EC Framework funded programmes on the governance and ethics of nanotechnology, representatives from industry and civil society, and representatives of (then) new research projects focused on the deliberative framing of nanotechnology.

Links with Rationality of Self-Regulators

Links with the rationality of self-regulators regarding rewards, benefits and incentives appeared largely absent. As mentioned already, in the first instance, NanoCode stakeholders complained that the objectives of the code and *advantages* of using it were not clearly set out.[25] In particular, the advantages for industry in adopting the Code were seen as being particularly important to highlight, given the need to link the rationality of private self-regulators with a public policy goal (NanoCode Synthesis report, 2010). Many (again the number is not provided) NanoCode stakeholders also deemed it necessary to associate the Code with *disincentives* or penalties (in the event of non-compliance); for example, 'naming and blaming' approaches such as a blacklist were suggested, given industry's sensitivity to issues of reputation. More specifically, widespread dissatisfaction with the principle of accountability highlights issues regarding the rationality of self-regulators. 17 % of stakeholders in the NanoCode project disagreed with the 'accountability' principle, arguing that it was *unjustified* and *unrealistic*, given the widespread view that scientists should not be held responsible for what is done with their work by other actors in the medium term or longer term. French and German translations of 'accountability' proved particularly problematic as they were interpreted in terms of implying legal responsibilities. Some stakeholder groups put up a fundamental revision of the accountability principle as a precondition for reconsidering implementation of the Code as a whole. There was also concern about the 'innovation' principle, in relation to *ambiguities regarding the meaning of 'innovation'*, who is addressed by the principle and what is expected to be done to be responsible in terms of 'innovation'. N&N research stakeholders, in particular, considered this principle to be *unnecessary* in the context of N&N research,[26] arguing that research intrinsically strives for innovation, thus *negating the need for such a principle*. In addition, there was concern regarding guideline 4.1.17 on avoiding research involving the deliberate intrusion of nano-objects that may lead to exposure to humans and the environment; this guideline was viewed as being too broad, possibly *de facto* leading to a moratorium, a possibility that is always of concern to these

[24] http://ec.europa.eu/research/consultations/nano-code/results_en.pdf

[25] The *disadvantages* of not taking up the Code were not set out either.

[26] The report points out that the innovation principle appears to be meant to primarily address Member States who are invited to ensure that innovation is pursued to the benefit of society and individuals.

particular regulatees whose main responsibility is to pursue progress in science. Interestingly, for the discussion here on stimulating regulatory capacity of self-regulators, the call for N&N researchers and research organisations to 'launch and coordinate' nanotoxicology research was viewed as being unrealistic in the sense that accompanying research activities and social sciences research would be required in order to provide more adequate options for the different types of N&N research stakeholders.

Despite dissatisfaction with certain, specific elements of the Code, overall, the principles appeared to have been well received, with a large majority of the NanoCode survey participants[27] viewing the Code as an appropriate instrument with which to implement the seven principles. However, the Code has been implemented only to a limited degree: only 21 % of the respondents indicated that their organisations had already adopted the Code. 'Difficult practicability' was cited as a major reason for this.

The Code document sets out *guidelines* indicating the main responsibilities for action, emphasising that 'all N&N stakeholders should contribute to their implementation as much as possible within the scope of their own remit' (p.7); however, the Code was considered to be of 'difficult practicability' in that it does not offer practical criteria and guidance regarding how to put its principles into practice and how compliance might proceed. The NanoCode consultation identified a strong need for supporting materials to help stakeholders to interpret and implement the Code in their respective research environment. To that end, the CodeMeter has been developed with the aim of helping stakeholders to self-assess their compliance with the Code's principles and guidelines on the basis of a set of concrete criteria.[28] A consensus on concrete criteria is viewed as being a prerequisite to allowing any meaningful form of adoption, verification and monitoring of compliance; otherwise, both implicit (meaning that the principles of the EU CoC are fulfilled by other means than the Code's guidelines) and explicit adoption of the Code will remain lip service and equivalence with other (implicit) means of compliance cannot be ensured.

Activities Encompassing Vigilance, Oversight, Enforcement and Accountability

With regard to vigilance, there do not appear to be any mechanisms in place with which to keep meta-regulators and self-regulators vigilant. For example, the Commission as meta-regulator is expected to carry out regular monitoring and revision of the Code every two years, as a means of taking into account global developments in N&N and their integration in European society; however, there is no indication offered of *how* this might actually be done. To that end, the NanoCode project recommends that an official Code information platform be established, so as to inform stakeholders about past, current and future activities (and to transparently document the consultation and revision process) [37].

With regard to oversight activities, there does not seem to be any monitoring/verification of compliance with the Code by the European Commission. As mentioned already in the reporting of NanoCode insights, the Code lacks any concrete or verifiable criteria in the first instance. There are no tools with which to allow self-or independent verification of compliance with the Code, implying that there are no mechanisms with which to hold either self-regulator or meta-regulator accountable.

The majority of the NanoCode survey participants highlighted a *lack of pressure* as a major factor in the limited implementation of the Code. While the voluntary nature of the Code was viewed as adequate to implement the principles, many felt it was crucial to link the Code with some form of enforcing mechanism[29] in order to encourage stakeholders' awareness, adoption and implementation of the Code. The need to

[27] The number or percentage of survey participants is not provided.

[28] In addition, the CodeMeter provides context information about important elements of the guidelines, offers hints as to how to improve compliance and enables monitoring and documentation of compliance over time.

[29] A number of options were identified in the NanoCode consultation, ranging from weak forms of incentives to stronger enforcing and monitoring mechanisms (disincentives) and encompassing the following: a positive label of Code compliance, priority in public research funding, compliance for public research funding, a whitelist/blacklist, and turning the Code into a standard for quality control. Mandatory rules for the implementation of the Code suggested by FramingNano stakeholders included verification that the code is followed by industry stakeholders in the production process, mandatory legislation requiring industry to implement a code, and the use of the code in applications for EU proposals.

link the Code to enforcing mechanisms was seen as requiring assessment in light of the desired degree of implementation within the Code's target groups. Finally, Framing Nano participants discussed soft measures,[30] in addition to mandatory rules, for the improved implementation of the Code.

As mentioned already, making self-regulators *accountable* is a crucial element of a meta-regulatory arrangement. The Dutch government has decided that compliance with the Code will be a prerequisite for governmental funding for both fundamental research and communication activities. [31] Such a contractual obligation implies that researchers will have to give account to the funding agency.

Conclusion and Discussion

The findings of the empirical studies indicate that meta-regulators and self-regulators in this arrangement have made efforts to contribute to responsibilisation, but have also failed to take up opportunities. A crucial point seems to be the insufficient dissemination and promotion of the Code along the governance arrangement chain (European Commission, Member States, governmental bodies, organisations and individual N&N stakeholders). The NanoCode report shows that insufficient dissemination has implications regarding awareness of the existence of the Code. Consequently, regulators and regulated parties will not be knowledgeable about their responsibilities. Furthermore, difficulties in understanding the content of the Code indicate that the regulated parties may have problems comprehending their responsibilities. It seems crucial that all stakeholders are 'on the same page' regarding the meaning and value of the principles and their responsibilities.[32]

While significant efforts were clearly made to generate trust and to bring the meta-regulators and self-regulators together in discussion about the Code, it is doubtful how effective these consultation processes were. The two consultations were held with the purpose of obtaining input for the draft text of the code and the first revision process, respectively; however, it does not appear that stakeholders' responses impacted further versions of the Code. For instance, a suggestion made in the 2007 consultation to broaden the Code to encompass innovation, i.e. to encompass the entire chain of a product's development process and its life cycle, and not only its research stage, is also reported in the NanoCode MasterPlan of March 2011. Moreover, concerns in the 2010 consultation about a lack of 'teeth' and the lack of specificity of the guidelines appear not to have been taken up. [33] With regard to the EC, there are no specific changes to the Code anticipated but a broader approach on Responsible Research and Innovation (RRI) is envisioned. A 2012 Observatory Nano document[34] reports that the EC will, in late 2012, likely publish a recommendation on Responsible Research and Innovation, addressing all Key Enabling Technologies. If this recommendation also builds on pertinent suggestions made during the consultation process, the regulated parties are more likely to feel that they can rely on the Commission. The trust of stakeholders could also be enhanced by assuring political support at the levels of the meta-regulators (EC and Member States) and by explicitly communicating such support to self-regulators. Trust-building can be reinforced by establishing a performance agreement between meta-regulators and self-regulators that orchestrates responsibilisation activities. Such performance agreements did not receive any mention in the empirical studies.

The findings of the empirical studies indicate that the meta-regulators failed to take up another important opportunity for regulatory responsibilisation, that is, links with the rationality of self-regulators. Apparently, the Commission and governments of the Member States failed to convince researchers and research organisations of the reputational advantages offered in implementing and complying with the Code. They failed to provide rewards, incentives and further stakeholder guidance, the

[30] Soft measures included the implementation of an internet homepage, as a forum for frequently asked questions and a platform for stakeholders to exchange experiences with the implementation of the Code and the organisation of regular meetings of different stakeholders to discuss various issues regarding the implementation of the Code.

[31] See http://www.nanopodium.nl/CieMDN/content/NanoCode_Country_Report_NL_Final.pdf

[32] See also DEEPEN report (Davies et al. [16]). Davies et al. argue that filling in what responsible development means in practice is made more difficult by a lack of consensus regarding the meaning of terms such as 'responsibility', 'socially acceptable'; the same may be true for the specific responsibilities of the stakeholders.

[33] Of course it may be the case that it would be premature to have such teeth in such an instrument given the lack of certainty concerning risks that still persists.

[34] See: http://www.observatorynano.eu/project/filesystem/files/ObservatoryNano_Nanotechnologies_RegulationAndStandards_2012.pdf

need of which was highlighted in the FramingNano project. The NanoCode project addressed the need for stakeholder guidance through the development of an implementation assistance tool, the CodeMeter. It seems that the only negative incentive or mechanism with which to hold researchers accountable is that which has been introduced by the Dutch national research foundation, requiring researchers in nanosciences to comply with the Code in order to receive funding. The absence of other mechanisms of vigilance, oversight and accountability at the levels of the meta-regulators and their belief in voluntariness indicate that important opportunities to strengthen responsibilisation have not yet been taken, although they have been strongly suggested in the NanoCode consultation. According to the MasterPlan, such a lack of 'teeth' means that, with regard to concrete implementation of the Code, 'one earns a lot of silence' and 'declarations of intent' rather than real examples of adoption' ([37]: 13).

In order to foster responsibilisation within the meta-regulatory instrument of the EC Code, a number of crucial activities have to be undertaken by meta-regulators, including improved dissemination and promotion, accompanied by examples of best practices, explanations of principles, the overhauling of vague provisions and the setting out of reputational advantages for self-regulators. Meta-regulators should also check whether stakeholders agree on the interpretation. They are recommended to further develop the Code (including guidelines), either in accordance with the suggestions of self-regulators or by offering an explanation for why these suggestions have not been taken into account. Performance agreements, compulsory compliance requirements with the Code and rewards for compliance seem essential for responsibilisation within meta-regulation. Further research on whether the meta-regulators involved are ready to undertake these activities and why the self-regulators involved have not been active to date will shed more light on the opportunities and limits of the approach of meta-regulation.

References

1. Ayres I, Braithwaite J (1992) Responsive regulation: Transcending the deregulation debate. Oxford University Press, Oxford
2. Baldwin R, Cave M, Lodge M (2012) Understanding regulation: theory, strategy, and practice, 2nd edn. Oxford University Press, Oxford, pp 125–137
3. Black J (2001) Proceduralising regulation part II. Curr Leg Probl 54:103
4. Black J (2002) Critical reflections on regulation. Aust J Leg Philos 27:1–46
5. Bowman DM, Hodge GA (2008) A big regulatory tool-box for a small technology. NanoEthics 2:193–207
6. Bowman DM, Ludlow K (2009) Filling the information void: using public registries as a tool in nanotechnologies regulation. J Bioeth Inq 6:25–36
7. Braithwaite J (2003) Meta risk management and responsive regulation for tax system integrity. Law Policy 26:1–16
8. Cherney A, O'Reilly J, Grabosky P (2006) Networks and meta-regulation: strategies aimed at governing illicit synthetic drugs. Polic Soc 16:370–385
9. Cherney A, O'Reilly J, Grabosky P (2006) The multilateralization of policing: the case of illicit synthetic drug control. Police Pract Res 7:177–194
10. Choi J-Y, Ramachandran G, Kanlikar M (2009) The impact of toxicity testing costs on nanomaterial regulation. Environ Sci Technol 43:3030–3034
11. Coglianese C, Lazer D (2003) Management-based regulation: prescribing private management to achieve public goals. Law Soc Rev 37:691–730
12. Coglianese C, Nash J (2004) The Massachusetts Toxics Use Reduction Act: design and implementation of a management-based environmental regulation, Regulatory Policy Program Report RPP-07-2004. Center for Business and Government, John F. Kennedy School of Government, Harvard University, Cambridge, MA
13. Coglianese C (2010) Engaging business in the regulation of nanotechnology. In: Bosso C (ed) Governing uncertainty: Environmental regulation in the age of nanotechnology. Earthscan
14. Coglianese C, Mendelson E (2010) Meta-regulation and self-regulation. In: Cave M, Baldwin R, Lodge M (eds) The Oxford Handbook of Regulation. Oxford University Press, New York, pp 146–168
15. Davies C (2009) Oversight of next generation nanotechnology. Washington DC: Project on emerging nanotechnologies. http://www.nanotechproject.org/process/assets/files/7316/pen-18.pdf. Accessed September 27 2012
16. Davies SR, Macnaghten P, Kearnes M (2009) Reconfiguring responsibility: lessons for public policy (Part 1 of the report on Deepening Debate on Nanotechnology). Durham University, Durham
17. Dorbeck-Jung BR (2011) Soft regulation and responsible nanotechnological development in the European Union: regulating occupational safety in the Netherlands. Eur J Law Technol 2(3):1–14
18. European Commission (2004) Towards a European Strategy for Nanotechnology. Commission of the European Communities, Luxembourg
19. Commission E (2005) Nanosciences and Nanotechnologies: An Action Plan for Europe 2005–2009. European Commission, Brussels
20. Commission E (2007) Towards a code of conduct for responsible nanosciences and nanotechnologies research—consultation paper. European Commission, Brussels

21. Commission E (2008) Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research. European Commission, Brussels
22. Ford CL (2010) Principles-based securities regulation in the wake of the global financial crisis. McGill Law J 55:257–310
23. Gilad S (2010) It runs in the family: meta-regulation and its siblings. Regul Gov 4:485–506
24. Grobe A, Kreinberger N, Funda P (2011) NanoCode WP2 Synthesis Report on Stakeholder Consultations, March 2011
25. Gunningham N (2007) Mine safety: Law regulation Policy. Federation Press, Sydney
26. Gunningham N, Grabosky P, Sinclair D (1998) Smart regulation: designing environmental policy. Oxford University Press, Oxford
27. Haines F (2009) Regulatory failures and regulatory solutions: a characteristic analysis of the aftermath of disaster. Law Soc Inq 34:31–60
28. Handy RD, Owen R, Valsami-Jones E (2008) The ecotoxicology of nanoparticles and nanomaterials: current status, knowledge gaps, challenges and future needs. Ecotoxicology 17:315–325
29. Hutter BM (2001) Regulation and risk: occupational health and safety on the railways. Oxford University Press, Oxford
30. Hutter B (2006) Risk, regulation, and management. In: Taylor-Gooby P, Zinn J (eds) Risk in social science. Oxford University Press, New York, pp 202–227
31. Kearnes MB, Rip A (2009) The emerging governance landscape of nanotechnology. In: Gammel S, Losch S, Nordmann A (eds) Jenseits Von Regulierung: Zum Politischen Umgang Mit Der Nanotechnologie. Akademische Verlagsgesellschaft, Berlin, pp 97–121
32. Kjølberg KL, Strand R (2011) Conversations about responsible nanoresearch. NanoEthics 5:99–113
33. Lee R, Jose PD (2008) Self-interest, self-restraint and corporate responsibility for nanotechnologies: emerging dilemmas for modern managers. Tech Anal Strateg Manag 20:113–125
34. Levi-Faur D, Comaneshter H (2007) The risks of regulation and the regulation of risks: the governance of nanotechnology. In: Hodge G, Bowman D, Ludlow K (eds) New Global Regulatory Frontiers in Regulation: The Age of Nanotechnology. Edward Elgar, Cheltenham, pp 149–165
35. May PJ (2007) Regulatory regimes and accountability. Regul Gov 1:8–26
36. Morgan B (2003) The economization of politics: meta-regulation as a form of nonjudicial legality. Soc Leg Stud 12:489–523
37. Meili C, Widmer M, Schwarzkopf S, Mantovani E, Porcari A (2011) NanoCode MasterPlan: Issues and options on the path forward with the European Commission Code of Conduct on Responsible N&N Research. http://www.nanocode.eu/files/NanoCode-MasterPlan.pdf. Accessed 29 September 2012
38. Pariotti E (2009) Regulating nanotechnologies: towards the interplay of hard and soft law. Notizie di Politeia 25(94):29–40
39. Parker C (2002) The open corporation: effective self-regulation and democracy. Cambridge University Press, New York
40. Parker C et al (2004) Introduction. In: Parker C et al (eds) Regulating law. Oxford University Press, New York, pp 1–12
41. Parker C (2007) Meta-regulation: legal accountability for corporate social responsibility? In: McBarnet D, Voiculescu A and Campbell T (eds) The new corporate accountability: corporate social responsibility and the law. Cambridge University Press, Cambridge, pp 207–241
42. Randles S (2008) From nano-ethicswash to real-time regulation. J Ind Ecol 12(3):270–274
43. Renton A (2006) Welcome to the world of nanofoods. The Observer. http://observer.guardian.co.uk/foodmonthly/futureoffood/story/0,,1971266,00.html. Accessed 1 October 2012
44. Rip A (2006) Folk theories of nanotechnologists. Sci Cult 15:349–365
45. Scott C (2003) Speaking softly without big sticks: meta-regulation and public sector audit. Law Policy 25:203–219
46. Scott C (2012) A meta-regulatory turn? Control and learning in regulatory governance. In: Muller S, Zouridis S, Frishman M, Kistemaker L (eds) The law of the future and the future of law, vol II. Torkel Opsahl Academic Publisher, The Hague, pp 61–72
47. Scott C (2012) Regulating everything: from mega- to meta-regulation. Law Policy 60:61–89
48. Selznick P (2002) The communitarian persuasion. Johns Hopkins University Press, Baltimore, MD
49. Shamir R (2008) The age of responsibilization: on market-embedded morality. Econ Soc 37:1–19
50. Thomas T, Bahadori T, Savage N, Thomas K (2009) Moving towards exposure and risk evaluation of nanomaterials: challenges and future directions. WIREs Nanomedicine Nanobiotechnol 4:426–433
51. Von Schombeg R (2007) From the ethics of technology to the ethics of knowledge assessment. In: Goujon P et al (eds) The information society: innovation, legitimacy, ethics and democracy. Springer, Boston, pp 39–55
52. Von Schombeg R (2010) Organising collective responsibility: on precaution, codes of conduct and understanding public debate. In: Fiedeler U, Coenen C, Davies SR, Ferrari A (eds) Understanding nanotechnology: philosophy, policy and publics. Ios Press, Amsterdam, pp 61–70
53. Widmer M, Meili C, Mantovani E, Porcari A (2010) The FramingNano Governance Platform: A New Integrated Approach to the Responsible Development of Nanotechnologies, February 2010. http://www.framingnano.eu/index.php?option=com_content&task=view&id=161&Itemid=84. Accessed 26 September 2012
54. Williams T (2007) Empowerment of whom and for what? Financial literacy education and the new regulation of consumer financial services. Law Policy 29(2):226–256