Responsibilisation phenomena: the EC code of conduct for responsible nanosciences and nanotechnologies research[1]

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ABSTRACT

The European Commission Code of Conduct for Responsible Nanosciences and Nanotechnologies Research (EC CoC) is a case of soft regulation of an emerging technological field. It can be deemed an instrument of meta-regulation aimed at fostering self-regulatory behaviours, and as an example of the distribution of responsibilities among stakeholders within the Responsible Research and Innovation (RRI) framework. Between 2007 and 2011 three major consultations concerning the Code were launched, and could be regarded as tools to implement compliance with the EC CoC and thus to foster the allocation of obligations. They also permit us to analyze the genesis of the EC CoC from its initial drafting to its adoption and thus to follow for the first time the development of RRI's 'normative anchor points' within a Community instrument, their influence on the principles and guidelines of the Code, and their perception among stakeholders. In sum, consultation processes make it possible to study one possible path for 'anchor points' to enter regulation and to affect stakeholders' behaviour. The consultation processes address some concerns with regard to the language and structure of the EC CoC which have affected negatively the perception of stakeholders and which has limited compliance with the Code's principles and guidelines. This case study reveals the importance of the communication of principles within a self-regulatory instrument designed as meta-regulation, as well as the importance of those goals, such as 'normative anchor points', that drive its formulation.

Keywords: Responsibilisation, Meta-regulation, Responsible Research and Innovation, Normative Anchor Points, Nanotechnology

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1. INTRODUCTION

1. In 2008 the European Commission adopted the code of conduct for responsible nanosciences and nanotechnologies research (EC CoC) (European Commission 2008). The EC CoC is a soft law instrument and it can be deemed as a case of meta-regulation since it was aimed at the distribution of responsibilities among stakeholders (Dorbeck-Jung and Shelley-Egan, 2013). As it has been observed, meta-regulation attempts to constitute corporate *consciences* by getting companies 'to want to do what they should do' (Selznick, 2002: 102). By meta-regulation I mean 'a process of regulating the regulators, whether they are public agencies, private corporate self-regulators or third party gatekeepers' (Dorbeck-Jung and Shelley-Egan 2013: 56). To be more precise meta-regulation tends to regulate the process of self-regulating in order to foster the diffusion of the actors' accountability, whether by tools of state law or other mechanisms (Parker, 2007: 211). In the business sphere to have a case of meta-regulation, the presence of social values anchoring the structure of the organization and its practice becomes crucial (Parker, 2007: 215). Thus the success or the failure of an instrument can (also) depend on how these values are designed and lastly perceived by the recipients. The ability of leading actors to self-regulate and the reference to several EU goals set forth in the Treaty on the European Union (art. 3), such as market competitiveness, technological advance, and fundamental rights (European Union 2010), also makes the EC CoC an interesting instance of *Responsible Research and Innovation*[3] (RRI) (von Schomberg, 2010; Sutcliffe, 2011: 22)[4]. In this sense the presence in the 2008 Commission recommendation on the code of conduct of many EU goals, representing the RRI *normative anchor points*, should be deemed of great importance within perspectives of the stakeholder theory and business ethics.

Normative anchor points are normative filters of EU law expressed in article 3 of the Treaty on the European Union (namely, techno-scientific advance, competitiveness, sustainability, fundamental rights, protection of public health and the environment) which make possible to anticipate policy choices by considering not only risks but also the positive impact of technological development (von Schomberg, 2013: 57). In this sense, the ethical acceptability of research and innovation depends on the work of normative anchor points. But how could we examine the ways these anchor points have been used there?

The main characteristic of the experience of the code is the development of a number of more or less official consultations, that have accompanied it from the beginning. Between 2007 and 2011 three consultations were launched: two directly by the European Commission (in 2007[5] and between 2009/2010[6]) and one, as part of a FP7 funded project (between 2010/2011), I mean the NanoCode project (Meili et al., 2011a). They are all examples of *responsibilisation processes*, namely examples of tools

[3] Despite the fact that no shared definition has emerged in scientific community (Owen et al., 2012: 752), the von Schomberg's definition is often referred to. According to von Schomberg RRI should be defined 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 (in order to allow a proper embedding of scientific and technological advances in our society)' (von Schomberg 2011: 54). It is significant that this definition has been substantially followed by the Experts Group on the State of the Art in Europe on Responsible Research Innovation which confirmed all the main features of the model, namely anticipation, participation, focus on also the positive impacts and ethical acceptability (van den Hoven et al., 2013: 3) and, recently, by Owen (2014).

[4] Recently the RRI model has been adopted by the EU Framework Programme for research and innovation 2014-2020 'Horizon 2020' (European Commission 2011).

[5] See European Commission (2007a).

[6] See European Commission (2010).

aimed at fostering the allocation of the responsibility among stakeholders. In this sense, they are fully part of the meta-regulation dimension. The importance of these consultations also rests on the fact that they allow us to look closely at both the process of the EC CoC setting and its perception by stakeholders: thus they represent the lens through which the code can be analyzed. As acknowledged by Parker (2007: 213) '[t]aking a metaregulatory approach to law might allow us to […] understand better the ways in which law's regulatory goals are achieved or frustrated via regulatory forces outside the law'. In other words they allow us to study the genesis of its principles and guidelines[7], as well as the development of EU goals (i.e. normative anchor points) within a Community tool, by considering also their final outcome (efficacy). In this sense, from the legal standpoint, compliance to them is fundamental here.

In this paper I will argue that from the case study of consultation processes the relevance of the dimension of the communication in a broad sense emerges. At the level of communication we can count mainly the process of code setting which also involves the modes whereby Community goals, as well as the code principles, are reflected into the code itself, the process of the design of values, the specification of goals into principles, and, in turn, the specification of principles into guidelines. Consultation processes show that the formulation of the code is fundamental for the full success of an instance of meta-regulation.

These are the main steps in my argumentation: First of all, I will stress the centrality of the *values design* in each meta-regulatory experience, such as the consultations, and then I will frame the phenomenon of consultations regarding the EC CoC within the context of the new governance turn. In this ambit, a potential conflict between two different tendencies in regulation emerges. On the one hand, there is a process rationality, typical of the experiences of *new governance* which focuses the importance of the modes in which the process is organized (i.e. whether it is negotiated, democratic and so on). From the other, there is a goal rationality which would characterized the old modes of Community governance and would focuses mainly on the goals at the core of the process such as Community ends and above all rights. Then, by cross-checking the data coming from the consultations I will analyze the way in which the EC CoC has been set out, by focusing on the difficulties that survey participants faced with regard to the understanding of code principles and guidelines. In this context a weakness in the communication of the goals at the core of the EC CoC, as well as the code principles, is apparent. Finally, I will conclude that the communication problems regarding the normative anchor points used in the EC CoC show that the process of responsibilisation depends on both the capacity to involve stakeholders (according to a process rationality) and the ability to clearly express the goals and principles at the heart of the process (according to a goal rationality) and to reflect them in its practical realization (e.g. through the code guidelines).

2. THE RESPONSIBILISATION PHENOMENON THROUGH CONSULTATION PROCESSES

2.1 By responsibilisation I mean 'predisposing actors to assume responsibility for their actions. […] In the context of meta-regulation, responsibilisation rests on activities to motivate regulators to build

[7] Principles of the code, meant as the guiding ideas at the core of the self-regulatory effort, should not be confused with normative anchor points, namely the goals of the Union which influenced the process of code setting and thus its principles themselves.

and enhance regulatory capacity' (Dorbeck-Jung and Shelley-Egan, 2013: 60). In this context the ability of goals and principles in engaging stakeholders and inducing them to assume further obligations in addition to those of legal nature is crucial. According to Selznick (2002: 101) '[a] corporate conscience is created when values that transcend narrow self-interest are built into the practice and structure of the enterprise'. In this view the penetration of values into the entrepreneurial practice and structure can occur by: clarifying policies (Selznick, 2002: 101); fostering the recruitment of sensitive staff (Selznick, 2002: 101); inculcating appropriate attitude and habit (Selznick, 2002: 101); establishing special units to implement policies affecting the well-being of employees, the environment or the consumers' protection (Selznick, 2002: 101); cooperating with relevant external groups, such as trade unions and public agencies (Selznick, 2002: 101); but above all the process of building a corporate conscience can be reached by an accurate *values design* within meta-regulating instruments. According to this last aspect regulations can enhance shared value among parties at stake and stimulate innovation by accurately setting the goals that drive the process of the self-regulation (Kramer, 2011: 17).

On the one hand, there is a set of actions that the enterprise needs to do in order to embedding these values within the organization. On the other, the very design of the tool of meta-regulation with regard to those same values is the indispensable prerequisite for motivating stakeholder to achieve them. All these actions contribute to the development of an organizational culture. Thus, the stronger and more rooted this culture is in each component, the more clearly it is perceived by stakeholders. Doubts, ambiguities and concerns regarding social values embedded in the meta-regulating tool can delay and impede the paths of self-regulation. In the background the centrality of the process of setting the values and goals clearly emerges. In this sense predisposing participatory paths of negotiation in view to choosing values for a self-regulating process can foster the emergence of a responsible conscience within the organization (Owen et al., 2013; Stilgoe et al., 2013; Hoolbrook and Briggle, 2014: 62). When values at the core of the meta-regulating mechanisms arise thanks to the involvement of stakeholders, there are wider margins of success[8]. Yet, since the process of engagement cannot involve all stakeholders but just a (more or less) representative part of them, the outcome needs to be easily accessible to all. For this reason, another (complementary) way to strengthen the process of the penetration of values into business can be the accurate design of goals at the core of meta-regulation. 'In other words, the substantive goals at which internal processes are aimed must be adequately specified' (Parker, 2007: 231). This process of specification starts with the setting of the meta-regulating tool and further continues with the reshaping of the practices and structures of the enterprise. As it has been noted by Parker '[i]f the law itself fails to recognize and protect substantive and procedural rights, then the business will doubly fail to do so' (Parker, 2007: 209). In other words the goals at the core of self-regulation need to be fully embedded into the tool which aims at steering the process of self-regulating itself. Since '[r]esponsibility internalizes standards by building them into the self-conceptions, motivations, and habits of individuals and into the organization's premises and routines' (Parker, 2007: 213), the process of values setting cannot but be deemed as its unavoidable precondition. These two phases (design and integration of values into the life and body of the enterprise) are thus part of the same process which ends with the allocation of responsibilities among different actors[9]. As the experience of the EC CoC has been shown, these two moments are closely intertwined.

[8] This outcome can be reached through multi-stakeholder approaches such as the U.K. *Responsible Nano Code*, an initiative launched by the Royal Society, Insight Investment, Nanotechnology Industries Association, the Nanotechnology Knowledge Transfer Network (Royal Society et al., 2008). On this initiative see, e.g., D'Orazio (2011).

[9] If 'n]either the process nor the goals are adequately set from outside the business, […] we cannot expect meta-regulation to make business accountable for anything' (Parker, 2007: 229).

2.2 The process of responsibilisation can be reached through the design of rules and by other means, such as consultations thus having an instrumental relationship with regard to the objective of making actors accountable for their actions. Consultation processes, as well as the code itself, should be deemed as an application of the *new governance turn* in the field of nanotechnologies (Kearnes and Rip, 2009). New governance is a model that arose at both the Community and the national level in occupational and environmental fields, characterized by informality, flexibility, heterarchy, the stakeholders' participation in contrast with the sate-centric and command-and-control styles (Scott and Trubek, 2002; Peters and Pagotto, 2006; Lyall and Tait, 2005; Eberlen and Kerwer, 2004; Mandel 2009; Marchant et al., 2008)[10].

According to a post-Weberian legal thought this transformation of the global framework led to 'the eclipse of regulation and the decentralization of state and economy' and the rise of a 'new mode of governance based on a logic of informal negotiated processes within social and sociolegal networks' (Heydelbrand, 2003: 326). This new mode of governance characterized by trends of privatization of the public sphere and processes of governance with the progressive delegation of regulatory power to business, testifies to the rise of a different form of rationality; a (negotiated) process rationality. 'Colloquially, this is often interpreted as getting the right people at the table, and one will get substance' (Heydelbrand, 2003: 238). On the contrary, a goal rationality would try to preserve 'the constitutional promise of rule of law', by privileging the substance through procedural or formal conceptions of the process (Heydelbrand, 2003: 236). In this regard while process rationality endorses the phenomena of negotiation and participation with a view to fostering the problem solving to the democratic contribution of all parties at stake, the goal rationality believes that the act of the setting of the process purposes is fundamental in achieving the final outcome. Efforts towards a further democratization of the process should be interpreted as aimed at securing 'forms of general and public communication' (Habermas, 1970: 57). According to this line of interpretation, '[o]ur problem can then be stated as one of the relation of technology and democracy: how can the power of technical control be brought within the range of the consensus of acting and transacting citizens?' (Habermas, 1970: 57)[11].

According to the goal rationality the prerequisite for the success of a process are the goals, namely the ends which the process aims at reaching. Rules and procedures are worthy inasmuch as they are aimed at meeting those values and for this reason the balance among goals needs formal (and controllable) processes instead of informal ones. Process rationality pursues the informality in situations where normal solutions cannot work. Uncertainty, the complexity of the whole framework suggest the deployment of alternative ways of problem solving. Yet, advantages of the process rationality might come at a considerable cost: focusing on the informality of the process also runs the risk of fostering a process of the deconstruction of 'procedural and substantive rights' at play (Heydelbrand, 2003: 234). The process is worthwhile since the parties taking part in it will produce values under which they can self-regulate. In this context to fix values upstream would run the risk of slowing down both the process and the final solution. Thus, in instances of legal, scientific uncertainty and moral relativity the only good to preserve is the right to the democratic participation in the problem solving.

[10] Criticisms of the tendency to identify a close link between the stakeholders' participation and democratic outcomes are found in Simsmans (2008).

[11] In the Habermas's view, this issues needs to be framed within the process of the colonization of the lifeworld by systems, namely as the typical distortion of modern societies where the sphere of everyday communicative interaction (lifeworld) is increasingly structured by the media-regulated rational institutions such as the market, research and technology (the system) by distorting the normal means-ends relationship (Habermas, 1970; 1989). This process of the progressive colonization of systems can be seen, for example, in the ways corporations have empowered themselves to restrict the access to the artifacts of the culture (Lessig, 1999). On this see Gur and Wiley (2005).

These two approaches apparently seem to conflict.

In the framework of the new governance turn soft forms of regulation, as well as spontaneous processes of self-regulation, are widely encouraged by using both old tools such as comitology, agency networking, and ethical codes, and new ones, such as third party certification, social dialogue and consultations. In this regard also the model of the RRI would also be framed within the umbrella of the new governance due to the stress on participatory processes, the anticipatory character and the preference for informal modes of governance, but with a renewed attention to the centrality of goals which are deemed necessary for building the ethical acceptability of research and innovation. In this sense RRI presents both aspects of process rationality, such as informality, the preference for participatory paths in building co-responsibility outcomes, and aspects of goal rationality, such as normative anchor points.

3. CONSULTATION PROCESSES REGARDING THE COMMISSION CODE OF CONDUCT

3.1 The consultations processes launched both by the European Commission (through its Directorate-General for Research) and outside it represent an attempt at governing the emerging field of nanotechnologies by triggering spontaneous routes of co-responsibility among stakeholders. They show the centrality of goals in the context of the process of fostering self-regulatory attitudes in stakeholders and the importance of the process of the code formulation in meta-regulating actors' responsibilities. In this sense a phenomenon of blurring involving both the goals and the principles of the code could have weakened compliance.

Consultations are not fully homogeneous. The Commission's first 2007 consultation was aimed at drafting the code of conduct by involving a representative section of stakeholders. The Commission's second consultation, as well as the NanoCode survey, was aimed at investigating the stakeholders' perception of the code. Finally, the NanoCode survey was also aimed at construing a concrete path of the implementation of the code (i.e. the NanoCode Meter (Meili et al., 2011b)) and thus fostering the compliance with its norms. As examples of responsibilisation phenomena, in the Commission's two consultations key actors in the responsibilisation process were the EU authorities and member States, which had the task of involving all stakeholders (mainly research and industry), thus playing a brokering role among the actors addressed by the code. In the latter survey (i.e. the NanoCode survey) the key actor was the academia, which provided tools for supporting the implementation of the EC-CoC. While these consultations were carried out using different methodologies, by taking into account different respondents' samples and were of a different extent and composition[12], the indicators that emerge from their data are quite convergent and permit us to identify some trends.

First of all, there is likely to be a low level of compliance with the EC CoC. From the NanoCode survey emerges that up to 2011 only The Netherlands provided a set of measures implementing the EC CoC (Mantovani et al., 2010). This data seems to be consistent with the fact that at that time only 21% of

[12] While the 2007 consultation had 64 participants, and the 2009/2010 survey only 49 participants, the 2010/2011 survey involved more than 400 participants. The composition of these samples were different. Whilst the two official consultations involved representatives coming from all member States, the NanoCode survey involved only representatives coming from seven key member States and three from outside the Union. Furthermore the documents attached to each consultation were different, meaning that the surveys' epistemic frameworks were variable.

NanoCode participants had adopted the EC CoC (Grobe et al., 2011)[13]. Difficulties in this regard emerge also in the second consultation launched by the Commission where only about 19 participants (nearly 40% of 49 respondents) 'said they were applying it' (European Commission, 2010: 3). In this context it is to be noted that the engagement of the EU and member States appeared quite low, as the interviewees report by referring, for example, that there is no official platform providing information about the EC CoC and helping stakeholders in complying with EC CoC principles and guidelines (Meili et al., 2011a:. 7). These data need to be correlated with those on the goals and principles of the EC CoC.

It is possible to interpret these consultations in the light of normative anchor points, namely the EU goals expressed in the code, because it is possible to analyze the documents attached to each survey (in which some EU goals are explicitly referred to) and to consider how the opinion of stakeholders has (or might have) mutated accordingly between 2007 and 2011. In this sense it is possible to follow the process of setting the code norms and how their perception among stakeholders has (or might have) then influenced compliance.

The attached documents represent the epistemic framework common to all groups of respondents. Thus, while the 2007 survey launched by the Commission was held on the basis of the sole Commission consultation paper (European Commission, 2007a) since it was aimed at drafting the code, the second official survey was held on the basis of the 2008 recommendation on EC CoC (European Commission, 2008) and of the Council conclusions of 2008 (Council of the European Union, 2008). Finally the NanoCode survey was launched on the basis of the sole 2008 recommendation (Grobe et al., 2011). Notwithstanding these differences it is possible to follow the genesis and development of the normative anchor points mentioned above and of the code norms through consultations.

3.2 The consultation paper is the starting point of the process of the formulation of the code, by being the base of the subsequent 2007 consultation which led to the setting of the code principles. In this document the Commission drew reference points for a future consultation '[i]n order to promote safe and responsible nanotechnology research and pave the wave to its safe and responsible application and use' (European Commission 2007a: 1). In this text the Commission explained the reason for limiting the scope of the code on research: '[o]n the one hand it develops new technologies for application in industry […] on the other hand it investigates the potential risks and establishes the appropriate measures to take' (European Commission, 2007a: 1). In other words research is at the basis of both industrial advance and university inquiry. This choice reflects a more concrete and (in my view) realistic attitude, by avoiding too ambitious attempts that could have led to a foreseeable failure (for example, by providing a code of all emerging technologies or a code for overall research and innovation). This choice came at some (remediable) costs: the perception of an unfair distribution of responsibilities.

In the consultation paper, among other normative anchor points, the role of fundamental rights and the precautionary approach among other normative anchor points emerge at the core of the Commission action since 'confidence in its safety' and 'public acceptance are preconditions for the application and commercialization of nanotechnology-based products' (European Commission, 2007a: 1). In this framework the EC CoC and the first consultation promoted by the EU in 2007 appear coherent with the 2004 communication of the Commission (2004) which outlined the basis of a safe, integrated and

[13] This outcome is also consistent with the data provided by Kjølberg and Strand (2011: 107): 'The first [i.e. obstacle for the EC CoC] is that it is dependent upon distribution (through national states, research councils, university administration etc.) which in the case of the nanoresearch community at our university [i.e. University of Bergen] seem to have failed'.

responsible approach, and with the nanosciences and nanotechnologies Action Plan 2005/2009 (European Union, 2005) proposing the adoption of a code of conduct (European Commission, 2007a: 2). This centrality of fundamental rights was progressively weakened in the other documents attached to the subsequent consultations, namely the 2008 recommendation and the Council conclusions. For example in the 2008 recommendation normative anchor points of promotion of techno-scientific advance, sustainability, competitiveness are explicitly referred to in several part of the preamble (e.g. the first, second, third, fourth, eighth *whereas*), whilst fundamental rights are implicitly referred to only when ethical issues are at stake, remaining thus in the background (European Commission, 2008: 2-3). Yet in the Council conclusions the focus is especially on market competitiveness and techno-scientific advance (Council of the European Union, 2008). These variations in the use of anchor points might have contributed to weakening the effectiveness of the communication of EU goals, especially in the Commission's 2010 consultation where the normative anchor points at the center of the two attached documents (e.g. the 2008 recommendation and the Council conclusions) are not fully coincident. Furthermore, we need to consider the fact that the 2008 recommendation contains the EC CoC together with a set of norms and provisions of a different nature which could have contributed to weakening the communication of the code itself.

3.3 According to the consultation paper contributions to the draft of the future code of conduct were 'expected from a broad cross-section of European society', including member States, industry, universities, funding organizations, researchers and other interested parties to follow EC CoC principles (European Commission, 2007a: 1). Outcomes of the 2007 consultation influenced the drafting of the EC CoC. In fact, while there were only three principles at the core of the consultation, namely 'precaution', 'inclusiveness' and 'integrity' (European Commission, 2007a: 3), in the final version of the code there are seven principles (i.e. 'meaning', 'sustainability', 'precaution', 'inclusiveness', 'excellence', 'innovation', 'accountability'). During the 2007 consultation principles of 'meaning', 'accountability', 'excellence' and 'innovation' and provisions regarding nanofood and feed were suggested by respondents and then accepted in the final version of the code[14].

We can notice that there has been a lively debate on the principles of the code starting from the first consultation in 2007, meaning that the moment of the goals setting was correctly perceived as fundamental during all the three consultations. For example, before the adoption of the code, in the 2007 survey about the 50% agreed with the principles suggested (European Commission, 2007b: 1). In the 2009/2010 consultation 61% 'would amend the set of principles founding the CoC' (European Commission, 2010: 4). Finally, the NanoCode survey showed a broad consensus on both the EC-CoC principles and the use of the instrument of a voluntary code of conduct for fostering public dialogue (Meili et al., 2011a: 8), meaning that the proposed route towards the self-regulation and the chosen principles were finally accepted by stakeholders.

An (apparently) different trend involved the issue of the limited scope of the code. In the 2007 consultation 'a nearly half-half divide' thought that the proposed scope was sufficient (European Commission, 2007b: 1); in the second Commission consultation three quarters of the respondents (75,51 %, in particular 89,47 % of researchers) thought that the EC COC should not be limited to research (European Commission, 2010: 5), while the NanoCode survey of 2011 testifies to the existence of concerns relating the limited scope of the code (Meili et al., 2011a: 20). These concerns need to be

[14] EGE's suggestions concerning applications aimed at enhancing human performance and cosmetics were also accepted (EGE, 2007: 62, 55).

correlated with those on the accountability principle[15] and unveil the existence of a need for a (formal) revision regarding the whole code. In fact, the limited scope makes researchers into key player, but it tends to shift the weight of responsibilities onto one group. Notwithstanding the clear support for the EC CoC principles, the wording of some principles was criticized by participants, in particular, the accountability principle[16] with regard to the broad reference to future generations[17]. Thus the prior revision of these principles was addressed by some key actors (i.e. governments and organizations) as 'a precondition for further engagement and the possible future adoption of the EC-CoC' (Grobe et al., 2011: v). From the detailed analysis of the second Commission consultation some analogous data emerge (especially from the group of policy makers since researchers did not add hardly any comments) (European Commission, 2010: 6). Accordingly, even in the 2007 consultation some respondents pointed out that the 'issue of *liability* should be clarified' (European Commission, 2007b: 3 – italics mine). In this sense, what emerges from these surveys seem to be some concerns regarding the fair distribution of responsibilities among stakeholders[18]. According to von Schomberg (2010: 56), for example, it 'is unethical and even unreasonable to make anyone individual responsible for the consequences and/or (adverse) side effects of our collective (especially technological) actions'. We need to ask ourselves whether this could have concurred in impeding the process of compliance with the code principles.

3.4 Concerns regarding the accountability principle lead us to consider aspects relating to the structure and language of the code, namely the *forma codicis* (Latin). Its wording and language have been criticized by participants of the NanoCode survey, but this aspects also emerges in other consultations. In particular the language of the Commission limited the comprehensibility of the code especially in the preamble and the text of the 2008 recommendation, namely the document containing the code itself (Meili et al., 2011a: 10). We have to remember that the document annexed to all the consultations (with the exception of that of 2007), i.e. the 2008 recommendation, is made up of several parts of which only the annex was the code of conduct. In fact the 2008 recommendation is made up of a preamble where the Commission illustrates how the code has been framed within EU goals, followed by a part where the Commission recommends a set of actions mainly to member States, and finally the annex constituted by the code itself (in turn made up of principles and guidelines). It is clear that concerns regarding the language of the Commission involve those parts of the 2008 recommendation, such as the preamble, where the Commission refers directly to EU goals, namely normative anchor points, in a rather bureaucratic style (Meili et al., 2011a: 26). Thus, in this regard the communication of normative anchor points does not seem to have been so effective for respondents[19]. Moreover, as pointed out above, some confusion can be due to the communication of the entire recommendation instead of the

[15] See for example Jones (2009): '[o]ne can, for example, imagine many scientists who might be alarmed at the statement in the code that 'researchers and research organisations should remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations''.

[16] It must be noted that during the NanoCode survey problems regarding the translation of the word 'accountability' became apparent. In fact 'the French and the German translations of the 'accountability' principle as 'responsibility' earned mistrust as they were interpreted with a connotation of *implying legal liabilities* as well as suggesting that scientists are held responsible for what is done with their work by decision outside their control or by other actors in the future' (Meili et al., 2011a: 6 - italics mine).

[17] This also concerned the innovation principle, as well as the precaution, sustainability, inclusiveness principles (Meili et al., 2011a).

[18] As Jones (2009) pointed out '[m]any scientists believe in a division of moral labour – they do the basic research that, in the absence of direct application, remains free of moral implications; technologists and industrialists then take responsibility for the consequences of applying that science, whether those are positive or negative'.

[19] Difficulties in communication are also addressed by Kjølberg and Strand (2011: 107).

code alone, namely the only part which the stakeholders were interested in. If the aim was to communicate the EU goals at the baseline of the code, then this aim probably failed.

Yet, with regard to the code, the EC CoC seems to lack of the typical code structure[20]. 'There is no introduction, outlining who should be addressed and what the benefits of using the EU-CoC are' (Meili et al., 2011a: 10). Thus it seems that the *forma codicis,* the mere code writing itself, can be deemed an element which can influence the acceptance of the CoC. Furthermore there is a lack of correlation between the principles and the guidelines. In this regard the authors of the NanoCode survey complained that each principle is not reflected in all the guidelines (Meili et al., 2011a: 26). As the case of the accountability principle shows, notwithstanding the clear support for the EC CoC principles, the wording of the principles was criticized by participants. This outcome seems to be convergent with the outcomes emerging from the other surveys. In particular in the second Commission consultation some pointed out the risk of the code being 'inapplicable considering the 'present writing'' for the code and complained about the 'un-specificity of principles' (European Commission, 2010: 5). In this sense a phenomenon of semantic confusion affected the code drafting. For example, in the preamble of the 2008 recommendation fundamental rights are implicitly referred to when the Commission deals with '*ethical* aspects of nanomedicine', '*ethical* and sustainable nanosciences and nanotechnologies research in the European Union' (sixth, thirteenth *whereas*) (European Commission, 2008: 3 – italics mine). But what are these 'ethical aspects' which need to be considered? Furthermore in the annex fundamental rights occur in the principle of 'sustainability' in which the Commission recommends that 'research should be safe, *ethical*' or objectives of the Community 'should not […] create a biological, physical or *moral threats*' (European Commission, 2008: 6 – italics mine). These broad and vague references were directly addressed as troublesome by several respondents[21].

3.5 In general terms, we can conclude that 'an unambiguous demand for increasing its specificity and practicability' emerges (Meili et al., 2011a: 23)[22]. Thus, to ensure that the principles of the CoC are fulfilled by some means other than through the EC CoC guidelines (i.e. a case of implicit adoption) a set of 'sufficiently concrete, verifiable criteria' and 'guidance about how to put its principles into practice and how to measure compliance' needs to be set out (Meili et al., 2011a: 26). In this sense with the exception of few substantial corrections needed (e.g. with regard to the accountability principle and its reference to future generations), it could be useful simply to create a new (and clearer) formulation of the code (a press release).

Concerns about the perceived need for more specificity regarding both principles and guidelines seem to be in contrast with the concern over the limited scope of the EC CoC addressed above. This inconsistency could be overcome by repeating the (finally positive) experience of the EC CoC with regard to other scientific domains and other sectors of the innovation chain (i.e. manufacturing, distribution, retail and production) (von Schomberg, 2011: 55). This direction, for example, was also

[20] In other words we need to bear in mind that the code is a literary work which has its own rules of writing and ordering and it definitely cannot be confused with a mere recommendation, (Mantovani et al., 2010: 27).

[21] For example, in the NanoCode survey some criticized the term '*moral* threat' with regard to the 'sustainability' principle and asked for further specification of the terms '*ethical* research' (Grobe et al., 2011: 8 – italics mine). Moreover, in the second Commission consultation an excess of generality and vagueness is stigmatized with regard to the identification of '*unethical* or unsafe areas' by both industry and researchers (European Commission, 2010*:* 12, 14 – italics mine).

[22] For example, guideline 4.1.17 was criticized since it risks *de facto* leading to 'a moratorium on certain types of research in nanomedicine and nano-enabled personal care'. It was also criticized for the absence of 'criteria and indicators to clarify how to apply it' (Meili et al., 2011a: 28). Moreover guideline 4.2.6 was also criticized since 'it seems unrealistic to require all N&N researchers to 'launch and coordinate' nanotoxicology research' (Meili et al., 2011a: 29).

addressed by the EGE in its opinion on synthetic biology (EGE, 2009: 36 and 37). In this framework a graduated scale of the available implementation tools of the code can be provided. In line with the positive example of the set of incentives and rewards which emerges from the experience of The Netherlands (Mantovani et al., 2010; Dorbeck-Jung, 2011), there is a wider range of options from weak forms of incentives to stronger enforcing and monitoring mechanisms such as disincentives (Meili et al., 2011a: 30-31). EU authorities could thus introduce a 'label of EU CoC compliance'. They could give priority in the funding of research on nanosciences and nanotechnologies to those who ensure compliance with the EU CoC or they could set out compliance as a precondition to be eligible to receive public funding for research. They could provide a white list of organizations adopting the EC CoC or a black list according to 'naming and blaming' approaches. Again, the EC CoC could contain a set of practical and concrete criteria for monitoring, verifying and assessing the degree of compliance with its principles and guidelines. Finally, the provision of a *stage gate architecture* in the light of normative anchor points and code principles, can help the process of stakeholders' compliance with the code. I mean a structure where the whole process of compliance can be guided through the provision of phases with a progressive realization according to a set of pre-fixed goals (Owen, 2014: 13). In this sense there is ample room for the implementation measures of the EC CoC.

In sum, three lessons emerged from the study of consultation processes. The first deals with the conditions of implementation of an instrument of meta-regulation, while the latter two deal with its formulation.

> 1) The engagement of public authorities can be deemed as the pre-requisite of a successful allocation of responsibilities. Although consultation processes can steer the phenomena of the distribution of responsibilities among stakeholders, they are *per se* not sufficient. As the experience of the implementation of the EC CoC in The Netherlands teaches, several soft mechanisms of implementation (such as those of incentives, rewards, and disincentives) can help the compliance with the code, and thus the process of the distribution of responsibilities.
>
> 2) Processes of responsibilisation also concern the opinions that stakeholders have about what the fair distribution of tasks and responsibilities should be. The reluctance of researchers to accept the accountability principle and its reference to future generations seems to be meaningfully linked with the issue of the limited scope of the EC CoC: the limitation of the code to the research domain could have negatively influenced the perception of the distribution of responsibilities, by making it seem unfair.
>
> 3) Communication turns out to be crucial. The language and structure of instruments of meta-regulation are fundamental to involve stakeholders by gaining their trust and commitment. Furthermore, communication also appears crucial with regard to normative anchor points: EU goals need to be clearly expressed within Community instruments and thus to be effectively communicated to stakeholders.

4. CONCLUSION

The analysis of consultation processes addresses the relevance of the dimension of communication broadly understood. As the case study of the EC CoC has highlighted, in meta-regulating instruments an attentive design of values which are at the core of the responsibilisation process is fundamental in

achieving the allocation of responsibilities among stakeholders. In this sense, the goal rationality, a logic which focuses the role of principles rooted at the core of the process, seems to emerge as a crucial aspect of this experience of the new governance turn. This result seems to lead to the resolution of the apparent conflict between goal and process rationality. The efforts to widen the participation of all parties towards greater democratization, cannot but pay the due attention to the level of designing of values, namely to that level where communication begins and finds its foundation. Instead of a mere contradiction between a process-based rationality and a goal-based rationality, we must acknowledge that processes of goal setting need to be adequately specified. In other words the juxtaposition between form and substance is merely apparent since goals can be reached only if the formal preconditions of the communication are respected, namely if there is a full conceptual clarity with regard to goals at the center of the process of actors' motivation. Uncertainties and shortcomings regarding both RRI normative anchor points and code principles have probably weakened compliance with the EC CoC and the distribution of responsibilities in the field of nanotechnologies.

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