The consolidation process of the EU regulatory framework on nanotechnologies: within and beyond the EU case-by-case approach

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ABSTRACT

The field of nanotechnologies has been the subject of a process of wide-ranging regulation, which covers two different trends. From the 2000s the European Commission and Parliament agreed on a type of adaptive, experimental and flexible approach, which had its apex with the Commission code of conduct on responsible nano-research developed through a set of consultations. In 2009 this initial agreement subsequently broke down and the EU started to develop a set of regulatory initiatives of a sectoral nature in several fields (cosmetics, food, biocides). Thus, the current arrangement of governance in the field of nanotechnologies appears to be a hybrid, which mixes forms belonging to the new governance method (consultations, self-regulation, agency, comitology committees, networking), working like a lung in the framework of EU policy, with more traditional tools belonging to the classic governance method (regulations, directives). This model of governance based on a case-by-case approach runs the risk of lacking coherence since it is exposed to sudden changes of direction when risks emerge and it has a weak anticipatory dimension due to both its excessive dependency on data collection and its insufficient use of upstream criteria, such as human rights, which should be used earlier, to allow anticipated intervention with a less intense use of hard law solutions.

Keywords: Nanotechnologies; Regulation; New governance; Classic governance method; Human rights

1. INTRODUCTION

According to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) 'nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not' (SCENIHR, 2009: 56). This means that it is not possible to have a general paradigm of risk assessment applicable in the case of nanomaterials (i.e. nanomaterials are not generally harmful or good), but we need to distinguish case by case [2] . In other words, there is no substantial equivalence with other common materials existing in nature, but we cannot generalize as regards nanotechnologies. Since at the atomic/molecular level matter displays uncommon properties depending on its size, shape, chemical bonds, polarity etc., engineered nanomaterials are all different with different physical and ethical implications with regard to risks and benefits. For this reason it is more appropriate to talk of nanotechnologies in the plural, instead of simply nanotechnology (Ruggiu, 2013a: 203).

While it is appropriate to talk of a case-by-case approach as regards the risk assessment of nanotechnologies, on the governance on nanotechnologies this case-by-case approach is not the only possibility. There are various possible approaches to this matter, ranging from the precautionary to the proactive, or the new model of Responsible Research and Innovation (von Schomberg, 2011; 2013; Owen et al., 2012; Owen et al., 2013; Ruggiu, 2015). Yet the case-by-case approach seems to be the leitmotiv of the EU regulatory framework on nanotechnologies (Widmer et al., 2010; Stoke and Bowman, 2012), able to shift from an initial stage characterized by soft law tools to one where hard law tools seem to be the privileged form of governance (Kurath et al., 2014). This approach seems to have led to a hybrid landscape where new forms of governance [3]coexist with more traditional tools, which appear to be the final stage of this process of evolution. From the standpoint of governance theories, it represents a case of coexistence of the new governance method and the classic Community Method with a slightly increased preference for the second style. In this context, new tools of governance, characterized by informality and a-typicality, are aimed at involving stakeholders through a more accurate distribution of responsibilities. By thus enlarging participation, they work like a bellows in the framework of EU policy with a view to consolidating EU regulation. Yet they seem to be merely provisional in favour of the more stable sectoral legislation. Besides, this approach with its unforeseen shifts reveals a lack of coherence since it largely depends on the incremental process of knowledge, and it is exposed to sudden changes of mood of public institutions. Finally, it shows weak anticipatory structures since its evolution broadly depends on sudden events that can cause the gradual stiffening of governance tools, by privileging those of a sectoral nature (hard law). This means that in future nanotechnologies will be regulated according to forms of more traditional regulation, but the cost (in terms of rules, policy change, the restraint of innovative processes, and even economic factors) of these abrupt unforeseen shifts has not been considered.

In this paper I will follow the growth and the development of the European Union strategy on nanotechnologies from its premises (the safe, integrated and responsible approach) in the 2000s to its subsequent consolidation in forms of hard legislation today. In particular I will describe the initial agreement between the Commission and the European Parliament with

the development of an adaptive, experimental and flexible model of governance, which had its climax with the Commission code of conduct on nanotechnologies, and the subsequent and abrupt direction change with the progressive adoption of a series of sectorial EU initiatives of a hard law nature in the field of cosmetics, nanofood and feed, and biocides. I will argue that the current model of governance is a hybrid, which structurally mixes forms belonging to the new governance paradigm (consultations, self-regulation, agency, networking) with more traditional tools (mainly directives, regulations) in order to progressively reach a sectoral regulation of the rising sector of nanotechnologies. This model is characterized by the decreasing use of new governance tools, working like a bellows within the framework of the EU policy, in favour of the traditional governance method. Finally, I will argue that this model of governance based on a case-by-case approach runs the risk of incoherence since it is exposed to sudden changes of direction following the increase of knowledge and has a weak proactive dimension due to its excessive dependency on data collection and its insufficient use of upstream criteria, such as human rights, which would allow anticipated intervention with a less massive use of hard law solutions.

First of all, I will describe the rise of the safe, integrated and responsible approach launched by the European Commission in 2000. Then, I will analyse the Commission code of conduct on nanotechnologies, developed through a set of consultation processes, which represent a significant innovation in the field of the governance of emerging technologies. I will then follow the change of direction given by the 2009 Parliament resolution with which the European Parliament broke its initial agreement with the Commission on the initiatives to be contained in the EU policy on nanotechnologies. In this instance I will describe the progressive adoption of regulatory initiatives in several fields (cosmetics, food, biocides) of a traditional nature up until the start of the revision process of REACH. Finally, I will give an overview of the current arrangement of governance at the EU level as a mix of new governance and classic governance methods and assessing its strengths and its limits.

2. REGULATING UNCERTAIN FIELDS

The impossibility of encompassing all nanotechnologies under the same definitive (positive or negative) judgment prevents the regulator from adopting simplistic solutions of a trenchant nature, such as a general ban or a general green light. Rulemaking in this field has become difficult due to the uncertainty which characterizes each emerging technology. In this field, besides scientific uncertainty there is also a state of unavoidable regulatory uncertainty. The uncommon features of nanotechnologies leave some open questions, representing a limit for the regulator.

In general terms, there is a lack of data regarding the implied risks of nanomaterials (and the way to overcome them). There is no shared definition of nanomaterial; and there is great uncertainty with regard to terminology, classification and metrology (there is the need for common standards with which to measure them) (Marchant, Sylvester and Abbott, 2008; Kearnes and Rip, 2009; von Schomberg, 2011). Moreover, although nanotechnologies do not act in a regulatory vacuum (as some have noted, the existing regulations apply in this sector [van Calster, 2006]), given their novelty, there is uncertainty with regard to both their

adequacy and efficacy. There is also the need for further legal, ethical, and sociological studies on their implications (Mandel, 2009; Rip, 2002).

Without wishing to generalize or scaremonger, it is true that, along with their undoubted advantages, nanotechnologies imply a number of risks we need to consider. Indeed studies have revealed the existence of a criticality regarding the toxicology and the ecotoxicology of some engineered nanomaterials. For example, there are studies addressing the allegation that carbon nanotubes (both single and multi-walled) can cause lung inflammations (Shvedova et al., 2005), as well as granulomas once insert into abdomen of mice (Poland et al., 2008) [4] ; other studies address dangers to health and the environment with regard to silver nanospheres (Mwilu et al., 2013; SCENIHR, 2014), titanium dioxide nanoparticles included in several sun creams (Zhang et al., 2007), or the use of nickel nanoparticles in the working environment which could cause allergic reactions in a setting without any specific respiratory protection or control measures (Journeay and Goldman, 2014).

Nanotechnologies are not only promising future technologies: they are also a reality already present in our lives. Despite the multitude of current studies on nanotechnologies which promise to revolutionize medicine (e.g. cancer treatments), electronics (micro and nano-chips, ultra-powerful processors), environmental pollution (water purification systems, nanoremediation of oil spill), and energy generation and storage (fuel cells, batteries, photovoltaic cells), nanotechnologies are already widely commercialized in cosmetics, electronics, the automotive industry, the fields of food and agriculture (ingredients, food storage systems, feed), paints, and biocidal products (such as pesticides, insect repellents, disinfectants etc. - Throne-Host and Strandbakken 2009). [5] If there is any risk regarding commercialized nanomaterials, it is true that, to some degree, it could already be present (Ruggiu, 2013a). In this regard it is quite difficult to bring under identical regulation the whole range of the nanotechnologies world, which is made up of research and markets with very different needs.

This complex framework makes the task of regulating even more difficult since the legislator would have to create a toolkit able to give different responses (to present and future needs) and do different things (Ruggiu, 2013a).

3. THE EU STRATEGY IN THE FIELD OF NANOTECHNOLOGIES

Taking into account the lesson learnt from the case of biotechnology (Metha, 2004; von Schomberg, 2013), in the 2000s the EU strategy in the field of nanotechnologies was characterised by caution. At that time, although they had been discovered roughly fifteen years previously, nanotechnologies were at their infancy [6] . Uncertainty was so widespread at all levels (scientific, ethical, regulatory) so as to discourage any attempt at regulating this field by resorting to classic hard legislation measures (Mandel, 2009; Pariotti and Ruggiu, 2012). Besides, there was the widespread belief that, given the increasing influence of private actors within global governance, it was increasingly difficult to ensure the success of any governance tool without the cooperative action of stakeholders (Kooiman and Van Vliet, 1993; Kearnes and Rip, 2009; Pariotti and Ruggiu, 2012: 112). In this context,

in fact, there was a need for tools devised for strongly motivating actors beyond mere compliance with legal provisions. Thus there was the need for tools other than those of hard legislation.

The action of the European Union started from this recognition. The strategy adopted by the Commission was initially to wait and see: i) whether there were risks and what they were; ii) whether the existing regulation was adequate for this rising field; iii) whether and how the principal actors were developing spontaneous forms of self-regulation. The EU authorities would then have adopted the necessary measures. In this context we can frame a number of tools such as communications, resolutions, recommendations that were aimed at increasingly giving responsibilities to stakeholders (Dorbeck-Jung and Shelley-Egan, 2013). On the basis of this mix of *wait and see* and *case-by-case* logic (Widmer et al., 2010; Stoke and Bowman, 2012), the European Commission initially was in agreement with the European Parliament. Yet, as we will see later, this initial agreement did not last indefinitely.

Behind this strategy there was the hope of fostering a general climate of responsibility and cooperation among stakeholders, most of all for entrepreneurialism and industrial innovation. At the core there was the belief that the market would be able to quickly develop and, if possible, self-regulate, at least until the moment when scientific data would be complete or sufficiently robust for developing a more stringent regulatory framework in this promising field. It was an adaptive, flexible and (slightly) inclusive approach of an experimentalist nature that would have had to accompany the growth of the entire sector until it reached its maturity (Roco, 2006; Kearnes and Rip, 2009; Widmer et al., 2010; Mandel, 2013).

This route starts with the 2004 Commission communication Towards a European Strategy for Nanotechnology where the Community authorities laid the basis of the *safe, integrated and responsible approach* [7] (European Commission, 2004). The Commission communication adopted an integrated strategy able to build a bridge between the public and the private sector. 'This require[d] efforts by the public as well as the private sector', and the prompt consideration of '[a]ny negative impacts on public health, safety or the environment […] as an integral part of the technological development process' (European Commission, 2004: 1). This approach was thus aimed at fostering a process of responsibilisation by enlarging the involvement of all parties in order to create the premises of a general self-regulatory attitude (Dorbeck-Jung and Shelley-Egan, 2013; Ruggiu, 2014).

With the subsequent 2005 communication, the Commission elaborated 'a series of articulated and integrated actions for the immediate implementation of a safe, integrated and responsible strategy for' nanotechnologies (European Commission, 2005: 3). In particular, it proposed: doubling the FP7 budget compared to FP6 especially in the nanoelectronics sector; boosting toxicological and ecotoxicological studies on the impact of nanoparticles on health and the environment; ensuring that EU funded projects in nanotechnologies are subjected to ethical review so as to respect 'fundamental ethical principles' in order to help build confidence in decision-making; developing simultaneously ethical, legal, and sociological studies in this matter (ELSI studies) in order to anticipate their impact at an earlier stage; asking the EGE to carry out an ethical analysis of nanomedicine;

promoting measures to minimise the exposure of workers, consumers and the environment; supporting existing infrastructures and transnational networks among universities, research organizations and industry in order to assemble critical mass through distributed poles of excellence; fostering the exchange of best practices in industry and the increase of industry involvement in EU R&D projects on nanotechnologies; establishing a monitoring system of patents in this sector; coordinating and strengthening actions in the standardization process and the development with member States, international organizations, European agencies, and the industry of terminology, guidelines, models, and standards for risk assessment throughout the whole lifecycle of nanoproducts; boosting an inclusive, aware, public dialogue on the impacts of nanotechnologies; using the pattern of the Open Method of Coordination (i.e. new governance) as the best way for the exchange of information; increasing dialogue at international level, especially with industry, to create a code of conduct on the use and development of nanotechnologies; and reviewing and, where appropriate, proposing adaptations of the existing regulation at the both the EU and the national level.

In sum, the main directions of the safe, integrated and responsible approach were i) to boost networking infrastructures for research and development of the sector, ii) to develop a better integration between research and its ethical dimension, iii) to involve all stakeholders in the development of nanotechnologies and their regulation, and in the meantime iv) to apply the current regulatory framework by checking its adequacy.

With the 2006 Parliament resolution, the approach proposed by the Commission was substantially accepted (European Parliament, 2006). In particular, according to the European Parliament, a responsible strategy on nanotechnologies required integrating knowledge on social, health and safety aspects with technological development. For this reason it was better to engage the Commission, member States and industry in an effective dialogue with all stakeholders in order to steer nanotechnology developments along a sustainable path. In this inclusive approach, industry needed to take into account risks posed to human health, to consumers, workers, and the environment during the whole lifecycle of nanoproducts, and contribute to the dissemination of information concerning their use and risks.

In the same year the European Union launched the Seventh Framework Programme (FP7), which identified nanotechnologies as one of the key areas to be widely encouraged in order to build a 'strong industrial base' in Europe and improve industry competitiveness (European Union, 2006: 17). FP6 invested around €1,36 billion in nanotechnologies, while FP7 dedicated €3,5 billion to this research field (EGE, 2007: 7). For this purpose, the FP7 built a broad ethics framework in which to develop European research and innovation. Thus, for key enabling technologies, such as nanotechnologies, it tried to foster greater integration between disciplines and different areas by 'broadening the engagement of researchers and the public at large […] with scientific related questions, to anticipate and clarify political and societal issues, including ethical issues' (European Union, 2006: 34). In this regard any supported research was required to respect the 'fundamental ethical principles including those reflected in the Charter of Fundamental Rights of the European Union', as well as the EGE's opinions and the Protocol on the protection and welfare of animals (European Union, 2006: 41). In conformity with the direction initially adopted by the European Union, the

anticipatory dimension of the EU policy rested mainly on a process of wide social inclusion in order to build the premises for a general dialogue regarding the social and ethical aspects of technological development.

Accordingly, in 2007, the EGE delivered its opinion on nanomedicine (EGE, 2007). In this it underlined 'the need to establish measures to verify the safety of nanomedical products' at both the national and the EU level (EGE, 2007: 5). It expressed the need to launch wide public participation concerning uncertainties and the knowledge gap, and it addressed the opportunity of fostering interdisciplinary research in this field by also including ethical, legal and sociological studies according to the pattern developed by the Commission in 2000s. In this regard it assessed the existing regulatory structures as adequate, but suggested the Commission should consider make changes within this framework, and addressed the risk of overlapping between different regulations (EGE, 2007: 6).

4. THE EXPERIENCE OF THE COMMISSION CODE OF CONDUCT

The high point of this approach should have been a code of conduct on nanotechnologies (Ruggiu, 2014). In this framework the Commission code of conduct and the first consultation promoted by the EU in 2007 appear to be coherent with the 2004 communication of the Commission (European Commission, 2004) which outlined the basis of a safe, integrated and responsible approach, and with the Nanotechnologies Action Plan 2005/2009 (European Commission, 2005) which proposed the adoption of a code of conduct (European Commission, 2007a: 2). Yet, instead of dealing with the entire innovation cycle (research, production, commercialization, recycling), the 2008 Commission code of conduct only dealt with research. The reason for this choice will become clearer later. It represents the final stage of the process of stakeholder engagement triggered by the 2004 Commission communication, the maximum effort of the European Union in involving a key group of stakeholders engaged in nanotechnologies: researchers. Yet the outcome of this ambitious initiative was only partially successful.

The Commission code of conduct for responsible nanosciences and nanotechnologies research [8] (EC CoC) is the result of an experiment in governance, which adopts the new governance method in the field of emerging technologies for the first time, since it was reached through a consultation process launched by the Commission in 2007 (Ruggiu, 2014). It can be also deemed as the first case of the application of Responsible Research and Innovation (von Schomberg, 2011; 2013; Owen et al., 2012; Owen et al., 2013; Ruggiu, 2015) within the EU.

In a landscape where risks are scattered (Beck, 1986) and the relevant actors are distributed over the global sphere (Stoke 1998: 21; Pariotti and Ruggiu, 2012: 112), responsibility also needs to be distributed (von Schomberg 2010: 56), especially in the face of the current process of erosion of the State capacity for global regulation (Grande, 2001). In this regard, experiences of self-regulation, such as codes of conduct, are clearly part of 'responsibilisation phenomena', since they aim at distributing the responsibility among stakeholders (Parker, 2007; Dorbeck-Jung and Shelley-Egan, 2013; Ruggiu, 2014). In this perspective, self-

regulatory tools, such as codes, are a form of meta-regulation (Coglianese and Mendelson 2010), meaning '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). In other words, meta-regulatory tools enact norms regulating the process of regulation, namely, in the case of the code of conduct, self-regulation (Parker 2007: 211). Any tool aimed at steering the law-making process (regulation, self-regulation such as codes of conduct), either public (statute law) or private (societal dialogue, networking, consultations), belongs to the dimension of meta-regulation. In this sense, consultation processes aimed at drafting the EC CoC can represent an effective example of a meta-regulatory tool (Ruggiu, 2014).

Between 2007 and 2010 the Commission launched two consultations: one in 2007 aimed at drafting a code of conduct on nanotechnologies (European Commission, 2007b) and one between 2009 and 2010 aimed at detecting stakeholders' opinions on this self-regulatory experience (European Commission, 2010). The consultation processes launched both directly by the European Commission (through its Directorate-General for Research) and, indirectly, outside it (e.g. the NanoCode project through the FP7 [9]) represent an attempt at governing the emerging field of nanotechnologies by triggering spontaneous pathways of co-responsibility among stakeholders. In this sense, the Commission code of conduct should be interpreted within the larger framework of the new governance method in the field of emerging technologies (Ruggiu, 2014; 2015).

The first 2007 consultation was launched on the basis of a document, called a 'consultation paper', that was meant to represent the starting point in the process of drafting the code (European Commission 2007a). In this drafting process stakeholders should have been actively involved. The consultation paper was thus the trigger for the process of the code formulation, as it was the basis of the subsequent 2007 consultation that led to the formation of the code principles by selected groups of stakeholders. The aim of the consultation paper was to indicate EU goals (the 'normative anchor points' according to the Responsible Research and Innovation terminology (von Schomberg, 2013)) that should have driven the whole process of code setting: techno-scientific advance, market competitiveness, the protection of human health and the environment, EU fundamental rights (Ruggiu, 2014; 2015). Among these goals the code of conduct should have struck a fair balance.

In this document the Commission outlined reference points for 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). 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 had an across-the-board nature, by being at the basis of both industrial advance and university inquiry. Yet, the outcome of this restriction of the scope of the code was to involve in the process of responsibilisation only researchers.

The choice of restricting the scope of the code probably reflects a more concrete and realistic approach, avoiding excessively ambitious attempts that could have led to foreseeable failure

(for example, by providing a code for all emerging technologies or a code for overall research and innovation). Yet it came at a (remediable) cost: the perception of an unfair distribution of responsibilities (Ruggiu, 2014: 7). As noted on emerging technologies, the development of nanotechnologies depends on the involvement of many actors: public authorities (EU and member States), enterprises and industry, research organizations (both public and private), funding organizations (both public, e.g. the EU and States etc., and private, e.g. banks, foundations), civil society organizations (trade unions, consumers', patients', environmental organizations, animal rights organizations), and the public at large (Ferrarese 2010: 40 ff.). In this sense, researchers represent only a small part of the entire audience of stakeholders in the field of nanotechnologies.

It must be noticed, too, that the attention to fundamental rights has varied throughout the different stages of the whole process of code drafting. In the consultation paper, the role of fundamental rights and the precautionary approach 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). This centrality of fundamental rights was progressively weakened in the 2008 recommendation on a code of conduct where fundamental rights are not included in the set of principles of the CoC and are merely mentioned in some provisions of code guidelines.

As a metaregulatory tool, consultations were successful. The relevance of the consultation process within the framework of this initiative was indeed very encouraging. While there were three proposed principles of the consultation paper ('precaution', 'inclusiveness' and 'integrity'), this number rose to seven in the final version ('meaning', 'sustainability', 'precaution', 'inclusiveness', 'excellence', 'innovation', 'accountability') thanks to suggestions arising from the consultation participants (European Commission, 2007a: 3; European Commission, 2008a; Ruggiu, 2014: 8). Moreover, some suggestions regarding the limitation of those applications aimed at enhancing human performance, nanofood and feed were also embraced, meaning that the 2007 consultation reached its goals (Ruggiu, 2014).

At the beginning of 2008, the code of conduct was adopted with a recommendation (European Commission, 2008a). The nature of the code was mainly practical. While we can distinguish between a code of conduct and a code of ethics (Arrigo, 2006), we have to conclude that the EC CoC belongs to the first type. In fact, by the first type, we mean a *ruled-based* tool, that is, a set of rules aimed at driving the conduct of recipients in order to solve the various problems in an enterprise's existence (such as harassment in the workplace, mobbing, safety etc.). The latter, instead, is *value-based*, namely a set of principles (such as the protection of the environment, health, non-discrimination), without specifying how these values should be concretized (Arrigo, 2006: 93). In this regard, although it was made up of a set of principles and a set of guidelines, the Commission code of conduct had a clear practical aim.

The responsible action in nanotechnologies research rests here on a set of principles, identified by stakeholders through the consultation process, which should clarify the goals of the code of conduct rules (i.e. the guidelines), what they aim to do. First of all, research

has to pursue the aim of being comprehensible to the lay public (*meaning*). Research needs to be safe and ethical and contribute to the sustainable development of the EU, by avoiding representing either a danger for human health and the environment or 'a biological, physical or *moral* threat' (European Commission 2008a: 6 - italics mine) (*sustainability*). It must respect the precautionary principle, that is, while there are risks, it must anticipate the impact at an earlier stage by adopting the necessary measures related to the level of protection and the benefits of scientific research (*precaution*). Research needs to ensure openness to all parties, transparency and information exchange (*inclusiveness*). It must pursue the highest scientific standards by avoiding data falsification, plagiarism, self-plagiarism (*excellence*). It needs to grant the maximal creativity (*innovation*). Researchers and research institutions need to be accountable as regard implications to health and the environment in the face of future generations (*accountability*). Yet this last principle was contested during subsequent surveys (Ruggiu, 2014). While all the principles were generally well-accepted, the principle of *accountability* was criticized with regard to the wide reference to future generations. For example, 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 as *implying legal liabilities* as well as connoting that scientists could be held responsible for what is done with their work by decisions outside their control or by other actors in the future' (Meili et al., 2011: 6 - italics mine) [10] . In this sense the restriction of the scope clearly affected the process of sharing code principles (Ruggiu, 2014).

Since, as stated above, it is not a mere container of values (that is, it is not *value-based*), the code is also accompanied by a set of guidelines that should steer the organization in all its existence by explaining what to do and what not to do and who is responsible for the compliance with code provisions. Unfortunately, there is a lack of correlation between the principles and the guidelines that weakens the dimension of their practicability. In this regard the authors of the NanoCode survey complained that not every principle is reflected in all the guidelines (Meili et al., 2011: 26). As attested by the NanoCode survey, there is 'an unambiguous demand for increasing its specificity and practicability' (Meili et al., 2011: 23). Furthermore, some guidelines are not well formulated and seem to lead to unintended consequences or not to the intended ones. For example, guideline 4.1.17 [11] was criticized since it risks *de facto* leading to 'a moratorium on certain types of research in nanomedicine and nano-enabled personal care' (Meili et al., 2011: 28). It was also criticized for the absence of 'criteria and indicators to clarify how to apply it' (Meili et al., 2011: 28). Moreover guideline 4.2.6 [12] was also criticized since 'it seems unrealistic to require all N&N researchers to "launch and coordinate" nanotoxicology research' (Meili et al., 2011: 29). In this sense the process of communication of the code cannot be deemed to be effective (Ruggiu, 2014).

These difficulties concerning mainly the wording of the code are also reflected in other parts of the code. 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., 2011: 10). This result was amplified by the fact that the recommendation containing the code was made up of several parts while the code was only one part of it, though the most important, but the entire recommendation was

submitted to stakeholders, not the code alone. In particular, the 2008 recommendation is made up of a preamble where the Commission illustrates how the code has been framed within EU goals (i.e. 'normative anchor points'), 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). In this sense the annex was the only part regarding stakeholders. It is clear that concerns over the language of the Commission involve those parts of the 2008 recommendation, such as the preamble, where the Commission refers bureaucratically to EU goals that evidently were perceived as being far from its core, namely the code (Ruggiu, 2014: 9). Yet, with regard to the code, the Commission code of conduct seems to lack the typical code structure. 'There is no introduction, outlining who should be addressed and what the benefits of using the EU-CoC are' (Meili et al., 2011: 10). Thus, it seems that the *forma codicis,* the mere code writing itself, can be deemed an element which can influence the acceptance and the dissemination of this instrument [13] . In other words, the process of stakeholders' responsibilisation (i.e. the adoption of the code) is also influenced by *how* values at the core of a meta-regulatory instrument (i.e. the code) are proposed to stakeholders (Parker, 2007: 215; Ruggiu, 2014). It is not a coincidence that subsequent surveys reveled difficulties in the compliance process. In fact, from the NanoCode survey it emerges that up until 2011 only The Netherlands had provided a set of measures implementing the Commission code of conduct (Mantovani et al., 2010). This data seems to be consistent with the fact that at that time only 21% of NanoCode participants (more than 400 people) had adopted the Commission code of conduct (Grobe et al., 2011) [14] . The process of responsibilisation triggered by the 2004 Commission communication finally led to a disappointing result, surely not in line with initial expectations.

This unexpected outcome can be ascribed to a set of causes. i) The engagement of the EU and member States appeared to be low, as the interviewees' report stated by referring, for example, that at that time there was no official platform providing information about the code and helping stakeholders to comply with code principles and guidelines (Meili et al., 2011a: 7). Furthermore the code could have been accompanied by a system of incentives and disincentives (such as a white list, a black list, funding distribution linked to the compliance with the code, a set of practical criteria for monitoring, assessing, and verifying the compliance degree etc. (Dorbeck-Jung and Shelley-Egan, 2013; Ruggiu, 2014). ii) Moreover, there were difficulties with the process of the distribution of responsibility. Since the scope of the Commission code of conduct was limited to research, the weight of responsibility seemed to lay on the shoulders of research alone. This outcome seems to be confirmed by the detected concerns about the accountability principle that mainly involved the researchers' group (Meili et al., 2011: 6). This limit could be overcome, as subsequently observed in 2009 resolution (European Parliament, 2009), by replicating the experience of the code of conduct on nanotechnologies research in the other sector of the innovation chain, namely production, commercialization and recycling (von Schomberg, 2011: 55; Ruggiu, 2014: 10). In this regard the process triggered by the EC CoC should be deemed as partial. iii) Finally, what emerges from official and non-official surveys is a weak communication dimension in its broad sense, which would need to be strengthened by amending the accountability principle and realizing a press release of the code outside the framework of the 2008 recommendation (Ruggiu, 2014: 10). There are reasons to argue, in fact, that the

perception of the code among its addressees could have been weakened by its inclusion in the body of the Commission recommendation, generating a state of confusion for recipients (Ruggiu, 2014: 9-10).

5. THE TURNING POINT IN EU REGULATION ON NANOTECHNOLOGIES

From 2009, EU governance on nanotechnologies characterized by the case-by-case approach suddenly started shifting (Ruggiu, 2013a). After the only partially positive experience of the EC CoC, the initial agreement between the Commission and the European Parliament broke down and the Parliament started taking a position notably different from that of the Commission.

While in 2008 the Commission in its first review of the regulatory aspects of nanomaterials still stated that 'that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework' (European Commission, 2008b: 3), the development of nanotechnologies seemed to reveal a different image.

Immediately after the discovery of the first case of the death of two female workers in a paint factory in China, which was reported in 2008, presumably due to exposure to nanoparticles (Song et al., 2008), Parliament adopted a critical resolution with which it asked the Commission for a strategy change in EU policy (European Parliament, 2009). In this act the Parliament noted that while there are multiple expected benefits, nanomaterials still 'present significant new risks due to their minute size' (European Parliament, 2009: point D), and there is 'a significant lack of knowledge and information' concerning definition, size, properties and 'the actual use of nanomaterials in consumer products' (European Parliament, 2009: points F and H), meaning that 'current funding for research into environmental, health and safety aspects' is 'far too low' (European Parliament, 2009: point M). In this regard, it was noted that 'SCENIHR [15] identified some specific health hazards as well as toxic effects for environmental organisms for some nanomaterials' (European Parliament, 2009: point L). For these reasons it called for the adoption of specific regulation that applies the precautionary principle, the principle of producer responsibility and the 'polluter-pays' principle 'to ensure the safe production, use and disposal of nanomaterials before the technology is put on the market' (European Parliament, 2009: point Q). In addition, it asked for the legislation on chemicals (REACH) (European Union, 2006), the main regulatory sector involved in the development of nanotechnologies, which 'reveals several further deficiencies to deal with nanomaterials', to be reviewed (European Parliament, 2009: point S), as well as the Community legislation on food, workers' conditions, air quality and waste, which also needed to address nanotechnologies as well (European Parliament, 2009: point V). Furthermore, it highlighted the need for a new EGE opinion on the convergence of nanotechnology with biotechnology, biology, cognitive sciences and information technology, thus assessing as insufficient the scope of its previous 2007 opinion on nanomedicine (European Parliament, 2009: point Y), and it called for the adoption of a code of conduct by 'all producers intending to manufacture or place goods on the market' (European Parliament, 2009: point Z). According to Parliament's view, the entire

innovation cycle (production, commercialization and recycling) should have been involved in a process of further responsibilisation, by resorting, again, to the tools of self-regulation.

The consequence of this act of Parliament was an immediate and significant change of direction in EU policy on nanotechnologies and the adoption of a set of legislative initiatives of a hard law nature in this field (Ruggiu, 2013a). First of all, regulation on cosmetic products containing several provisions specifically referring to nanomaterials (European Union, 2009) was adopted (Bowman, van Calster and Friedrichs, 2010). According to this new EU act, anyone who wants to place a new cosmetic product containing nanomaterials on the market has to provide the Commission with safety information six months earlier (art. 16.3). Moreover, safety information needs to be notified to the European Commission for those products containing nanomaterials, which are already on the market. Furthermore, the regulation stipulates specific mandatory labelling [16] , according to which the names of the ingredients present in the form of nanomaterials must be followed by the word 'nano' in brackets (art. 19.1(g)). Finally, the European Commission was asked to create a publicly available 'catalogue of all nanomaterials used in cosmetic products placed on the market … and the reasonably foreseeable exposure conditions' (art. 16.10 (a)).

On this basis, Cosmetics Europe, an industry trade association, including more than 4000 cosmetics companies and national associations in this sector, laid down a set of guidelines integrating the EU regulation on cosmetic products. In particular, the 2011 Colipa guidelines on cosmetic products have integrated information requested in labelling when nanomaterials are present in cosmetics, helping in this way enterprises in complying with Community provisions (Cosmetics Europe, 2011). Moreover, the 2012 guidelines have provided further indications for identifying a subject responsible for the actuation of labelling commitments, thus strengthening companies' process of compliance with the EU regulation (Cosmetics Europe, 2012). Given the overlapping between the action of EU authorities and private actors, this fact brought about an interesting integration of self-governance patterns (Sørensen and Triantafillou, 2009) within EU governance arrangements. These two self-regulatory tools have greatly contributed to fostering the process of stakeholder compliance with EU provisions and distributing a consistent part of the responsibility to the private sector, thus creating positive integration with the EU action of governance.

Accordingly, in 2011 the EU introduced a first provision regarding nanomaterials in electronic equipment (European Union, 2011) requiring, with a rather questionable wording, as soon as the data was sufficient, the substitution of nanomaterials 'by more environmental friendly alternatives' and the modification of the list of restricted substances (art. 16). It also launched a consultation involving all stakeholders on the impact on small and medium-sized enterprises. Yet this sudden change in a key sector of the European economy ran the risk of stopping the development of nanoelectronics in Europe, a sector where the probable benefits of nanotechnologies are enormous both in terms of economic competitiveness and technological advance, without gaining any specific advantage in terms of health and safety in the workplace or waste recycling (since electronic articles would have come into Europe from abroad in any case). In this regard the EU action showed alarming oscillations, by

shifting from initially favouring a deregulated framework to an over-specified framework based on irrational bans.

In the same year, the Commission faced the unsolved terminological question regarding nanomaterials and it issued the first definition of nanomaterials in EU legislation to be used by member States, EU agencies and companies (European Commission, 2011). According to the definition, '"nanomaterial" means a natural or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% […] one or more external dimensions is in the size range' between 1 nm and 100 nm. Yet some nanomaterials can reach higher or lower thresholds and this makes the use of this definition problematic. Wisely this definition has a certain degree of flexibility since there is the possibility of assessing in a case-by-case fashion the inclusion of other materials which do not conform to these criteria. In fact, the threshold of 50% may be replaced by a lower one for concerns involving the environment, health, safety or competitiveness. The definition set out by the recommendation should be applied, in particular, in the case of legislation on chemicals (REACH) and in the regulation on the classification, labelling and packaging (CLP) of hazardous substances and mixtures (European Union, 2008). With regard to the EU legislation on consumer products, the Commission was committed to implementing its definition of nanomaterial.

Subsequently, the European Union adopted a new regulation on food labelling explicitly considering nanomaterials (European Union, 2011). The food sector is a field where nanotechnologies represent a significant factor in development, especially in mass production and large consumption goods (e.g. junk food) but where information is insufficient (Marrani, 2013). Yet, this regulation does not deal with the entire food sector, but only food labelling. In this regard, more attention to this delicate matter directly involving consumers' health and safety could probably have been paid, since 'risk, associated with nanoparticles, is determined by exposure' (Kuhlbash, 2011: 1). As in the cosmetics sector, the regulation contains a provision stipulating specific mandatory labelling, according to which the names of the ingredients present in the form of nanomaterials must be followed by the word 'nano' in brackets. Yet this provision, fundamental in preserving consumers' freedom of choice, as well as that of information, entered into force only in December 2014, after a (relatively long) period when enterprises had the necessary time to achieve the conditions for complying with it (and, consequently, consumers were not informed) (art. 18.3).

It is also worth noting that the Commission started to collect data in this sector. Indeed, at the request of the Commission, the European Food Safety Authority (EFSA) adopted a guidance document clarifying the data to be provided when submitting an application dossier for nanomaterials to be incorporated in food and feed (EFSA Scientific Committee, 2011). Furthermore, since 2006 it is committed to provide an annual report on the risk assessment of nanotechnologies in food and feed (e.g. European Food Safety Authority, 2015). It must be remembered that, in the current regulatory arrangement, food safety risk assessment is performed by the EFSA. Where nanomaterials are at stake, according to the EFSA, the general risk assessment methods do apply, but 'the assessment on a case by case basis is performed if no "common risks" are identified', something that is not easily determined (Marrani, 2013: 180).

The European Parliament and the Council are currently discussing a Commission proposal for new regulation on novel food and novel food ingredients, which should replace Regulation (EC) No. 258/97 by also covering nanomaterials.

The process of consolidation of the EU regulatory framework also considered other key fields where nanotechnologies are relatively widespread. At the beginning of 2012, another resolution of the Parliament on biocidal products (pesticides, insect repellents, disinfectants, spermicides and substances which can be also used in food contact materials) also considering nanomaterials (European Parliament, 2012), triggered a revision process in this matter by requiring nano-specific mandatory labelling (art. 58.3(d)). This new intervention of the Parliament led the gradual replacement of the entire legislation on the question of biocidal products in 2012 (European Union, 2012a; 2014). The new regulation rests on the principle that '[t]reated articles should not be placed on the EU market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved' for this use (second whereas). Then, with regard to the authorisation for the commercialization of a biocidal product 'where nanomaterials are used in that product, the risk for human health, animal health and the environment has to be assessed separately' (art. 19.1 (f)). In this regard, a simplified authorisation procedure is required, unless the biocidal product contains nanomaterials (art. 25 (c)). Also in the case of biocides, specific mandatory labelling, in the case of nanomaterials, is also required according to the specific request of the Parliament. In this case the label must indicate 'the name of all nanomaterials contained in the biocidal products followed by the word "nano" in brackets' (art. 58). Furthermore, member States must monitor the biocidal products and the treated articles, which have been placed on the market by constituting special documentation including the information on the use of nanomaterials and their potential risks (art. 65.2 (d)).

In the meantime the Commission went back to deal with electronic devices with a 2012 directive on waste electrical and electronic equipment (WEEE) (European Union, 2012b) which stipulates the principle according to which all waste needs to return to the distributors to be collected and treated. In this instance the directive asked the Commission for assessing whether a 'specific treatment may be necessary' (eighteenth whereas) for waste containing nanomaterials due to health concerns (art. 8.4).

The attention drawn by the EGE on nanomedicine in 2006, triggered a process of adaptation of the current EU regulation. In 2012 the European Commission delivered a proposal for regulation on medical devices, which stipulates the adoption of special care 'when [medical] devices contain or consist of nanomaterials that can be realised into the patient's or user's body' (European Commission, 2012b: art. 3). Special labelling indicating 'where devices contain or consist of nanomaterials' should be provided, unless they are encapsulated or bound in a manner that they cannot be released into the patient's or user's body (art. 19.2 (f)). In this case they are addressed by a specific classification (class III), becoming subject to the most severe conformity assessment procedure, together with more invasive devices, devices in direct contact with the heart, implantable devices, breast implants, spinal disc replacement implants and so on (Rule 19). In this regard we can note a higher (and less coherent) attention threshold compared with the field of nanofood, which has greater

diffusion compared to the (low) degree of information available. Several medicines based on nanotechnology have already been approved by the European Medicines Agency (EMA) [17] and were subsequently commercialized within the EU market (e.g. Caelex containing doxorubicin, Mepact containing mifamurtide, Myocet containing doxorubicin, Abraxane containing paclitaxel, Emend containing aprepitant, Rapamune containing sirolimus) [18] .

No consideration, on the other hand, has been shown regarding the growing sector of health self-monitoring systems, which many private companies are developing nowadays. For example, large companies are researching systems of self-screening which use nanoparticles (e.g. tiny iron-oxide particles) in the human body that can be monitored through a wearable device such as a watch (Barr and Wilson, 2014). This search raises concerns not only with regard to health, the use of personal data (which can be easily hacked), but mainly with regard to the patient/physician relation (which can be completely bypassed when a device is freely sold without medical consultation). This aspect was also neglected by EGE's opinion on nanomedicine, but today it acquires significant relevance due to the fast development of the market.

6. FROM THE SECOND REGULATORY REVIEW TO HORIZON 2020: TOWARDS THE FUTURE REVISION OF REACH?

After the first regulatory review and the experiment of the Commission code of conduct, at the end of 2012 the Commission concluded the second regulatory review on nanomaterials (European Commission, 2012c). It followed a report, the Commission Working Staff Paper (European Commission, 2012a), detailing essential information on definition of nanomaterial, the nanomaterial market, the uses, benefits, health and safety aspects, risk assessment, and information and databases on nanomaterials.

At this time the broad sector of chemicals, where nanotechnologies are widely used, was also addressed for amendment. With the revision of REACH [19] the process of consolidation of the EU regulatory framework was almost concluded, with the slow and final transformation of a new governance pattern into a more traditional one made up of a set of sectorial and articulated legislations.

As pointed out by the Parliament in 2009 there were doubts on the suitability of REACH's simplified registration for nanomaterials manufactured or imported below one tonne, on whether they can be deemed as new substances that require the need for a chemical safety report with exposure assessment for all registered nanomaterials, as well as the need to set out notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles (European Parliament, 2009: 7). As recognised by the Commission: '[m]any registrations for substances known to have nanomaterial forms do not mention clearly which forms are covered or how information relates to the nanoform. Only little information is specifically addressing safe use of the specific nanomaterials supposed to be covered by the registration dossiers' (European Commission, 2012c: 6). In this regard the Commission promoted a Commission Working Staff Paper (European Commission, 2012a)

inquiring into aspects connected to the definition, the use and the diffusion of nanomaterials into the market, and two reports, RIPoN 2 (Hankin et al., 2011) and RIPon 3 (Aitken et al., 2011), dealing with fulfilling information requirements and exposure assessment and risk/hazards characterisation for nanomaterials under REACH. These two reports should have been followed by specific consultation processes involving members of the REACH Competent Authorities Sub-Group on Nanomaterials (CASG-Nano) and the relevant experts from Member States, industry and non-governmental organisations (NGOs) nominated by REACH and Classification, Labelling & Packaging (CLP) Competent Authorities (CARACAL), meaning that new governance patterns are still considered strategic in this process of consolidation.

During 2013 it promoted a consultation among all interested parties (in particular enterprises) on the modification of the REACH annex on nanomaterials [20] , which was to be accompanied by an impact assessment. In this sense the process of revision of REACH appears to be articulated according to a stage gate architecture [21] (Cooper 1990), which is a typical tool of the Responsible Research and Innovation model (Stilgoe et al. 2013: 1573; Owen 2014: 13) used to assess the adequacy of the proposal for revision thanks to inputs stemming from stakeholders. In this regard there is a more structured architecture of the process of law-making compared to that provided for the EC CoC in 2007 and after. For example, to ensure the transparency of participants' interest in the consultation a public register was created. Furthermore, the Commission encouraged the European Chemicals Agency (ECHA) to develop new guidance for registration since 'REACH sets the best possible framework for the risk management of nanomaterials' although 'more specific requirements for nanomaterials within the framework have proven necessary'. This conclusion was reached on the basis of the conviction that 'nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not', and there are '[p]ossible risks […] related to specific nanomaterials and specific uses'. In this regard the Commission is still persuaded that 'nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information' (European Commission, 2012c: 11). In the Commission's view current risk assessment methods are thus still applicable.

The monitoring activity of the Commission triggered by the 2009 resolution also invested other key fields some years later. As regards health at work when nanomaterials are involved, the Advisory Committee on Safety and Health at Work started working on a draft opinion on risk assessment and management of nanomaterials in the workplace, to be subsequently endorsed by the Advisory Committee. Similarly to that provided by the EFSA, guidance has also been provided by the Scientific Committee on Consumer Safety for cosmetic products (Scientific Committee on Consumer Safety, 2012).

At the end of 2013 the Union launched the Horizon 2020 Framework Programme where nanotechnologies research and innovation represent one of the key areas of development within the EU 2020 strategy (European Union, 2013). The expressed priority is to fill the gap between knowledge and the market since without excellent research there can be neither progress nor development in the European economy (Berger, 2013). In order to boost both economic growth and occupational development, the EU proposed €80 billion for the period

2014-2020, by harnessing research and innovation at this aim. This budget included about €24,6 billion for science, €17,9 billion for industrial innovation and €31,75 billion 'targeted at the most pressing issues facing Europe such as climate change, sustainable transport, renewable energy and the medical care requirements of an ageing population' (European Commission, 2013: 40).

It is worth noting that with this EU act, Responsible Research and Innovation (RRI) (von Schomeberg, 2011; 2103; Owen et al., 2012; Owen et al., 2013; Owen, 2014) has been officially endorsed at the EU level (Ruggiu 2015: 217). As anticipated, it subsumes the safe, integrated and responsible approach under the RRI framework, which has been 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). RRI should thus be considered as the subsequent step of the previous EU approach launched in the 2000s with the aim of re-modulating the whole EU regulatory framework. For this purpose Horizon 2020 has also built a strong ethical framework as the basis for both research and innovation, as well as paths for integrating 'society in science and innovation issues, policies, and activities in order to integrate citizens' interest and values' (European Union, 2013: 167). Accordingly, research and innovation have to respect the 'fundamental ethical principles', the EGE's opinions and take into account the objectives of reducing animal testing and 'ensuring a high level of human health protection in accordance with Article 168 TFEU' (European Union, 2013: 107). 'Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection'. (European Union, 2013: art. 19). In particular, stem cell research, both adult and embryonic, is 'subject to stringent ethical review' and '[n]o project involving the use of human embryonic stem cells research should be funded that does not obtain the necessary approval by Member States' (European Union, 2013: 107).

In sum, with Horizon 2020 a large part of the proactive dimension of the EU model tends to rest on the work of this ethical framework in the process of the allocation of EU funds.

An overview of the arising EU regulatory framework shows a considerable effort in coping with the challenge thrown down by nanotechnologies. There is no doubt that the EU authorities have created the most regulated landscape at the global level. This is probably the most articulated and complex system of rules, one which is growing in this field. Yet we have to abstain from drawing any conclusion from this fact and analyse it further.

The current European model of governance is dominated by the case-by-case approach, which has ensured the necessary flexibility to cope with the challenges of the fast development of science and innovation, but it also has given us an unstable system exposed to sudden and unforeseen changes, with a high risk of inconsistency and incoherence. It arose as a safe, integrated and responsible approach under the initial agreement of the Commission and the European Parliament by privileging 'new' forms of governance

characterized by the absence of a mandatory nature such as communications (2004 and 2007 Commission communications and Action plan 2005-2009), resolutions (2006 and 2009 Parliament resolutions), and recommendations (2008 Commission recommendation). In this framework the 2008 EC CoC, realized in part thanks to a stakeholder consultation, launched with a Commission communication in 2007, was the summit of this trend inspired by the new governance turn, as well as the first application of the RRI pattern within the EU. In this case we have observed the simultaneous use of EU goals and forms of stakeholder engagement (such as consultations) for building a framework of shared responsibility and triggering self-regulatory behaviors. In this framework the EU resorted to old and new tools such as agency and comitology by involving EMA (2006), EFSA (2011), EGE (2007) in order to consolidate this climate of positive cooperation in the field of nanotechnologies. In the meantime this ambitious attempt at experimenting new forms of governance founded on the existing regulation on chemicals, novel food, cosmetics, drugs and medical devices, which showed itself to be largely insufficient *vis à vis* the challenges of nanotechnologies. Thus, while the progressive data collection on the risks of nanotechnologies became public (e.g. Shvedova et al., 2005; Poland et al., 2008; Mwilu et al., 2013; Zhang et al., 2007; Song et al., 2008; Journeay and Goldman, 2014), the insufficiency of the existing regulation became apparent and the climate of collaboration that had initially characterized the work of EU institutions abruptly changed. In this sense the EU approach did not appear to be adequate for the complexity of a field where risks, unknown consequences and opportunities are inextricably intertwined (Ruggiu, 2013b), in particular as regards the protection of individual rights such as consumer rights (information, not only in cosmetics and food), the right to health (REACH, safety at the workplace, novel food), and the right to a healthy environment (nanoelectronics, the recycling of electronic equipment and electric waste). Thus, with the 2009 Parliament resolution the EU governance arrangement profoundly changed by shifting from an adaptive, flexible and slightly inclusive model to a hybrid one, which mixes traditional with new modes of governance and even forms a self-governance arrangement. In the actual governance framework we can notice increasing recourse to traditional forms of hard legislation (new regulation on cosmetics 2009, new regulation on food labelling 2011, new regulation on biocides 2012, the plan to revise the legislation on chemicals) together with classical tools of new governance such as consultations and communications (e.g. second regulatory review 2012), meaning that the final stage of this process is the sectorial legislation. In this framework there is still room for the experimentation of tools typical of the Responsible Research and Innovation model such as consultations launched for the revision of REACH (2013). Accordingly, despite the use of hard legislation, room for positive interactions with stakeholders of a spontaneous nature (self-governance) are also opened up (2011 Colipa guidelines). Yet in this framework new governance tools seem to have a merely provisional nature, working as a lung in order to prepare the growth of traditional regulation of a hard law nature (REACH, safety at the workplace). In this sense new governance tools seem to be destined to progressively disappear, to be substituted by sectoral legislation on nanotechnologies.

Some shortcomings appear evident here, and they are analysed below:

1. First of all, what emerges in this approach is the difficulty in maintaining the consistency of the regulatory choices within the framework of EU policy on

nanotechnologies. In its initial stage the safe, integrated and responsible approach seemed to foster the self-regulatory capacity of the market in order to boost the entire sector of nanotechnologies and make the EU economy one of the most competitive in the world. Then, under the impulse of the Parliament it abruptly changed direction and started to regulate several sectors in detail (e.g. cosmetics, food labelling, biocides and so on). The direction of this consolidation process is clear. The wide-ranging activity of the EU agencies and committees is also leading towards a rather slow consolidation process of the regulation on nanotechnologies, in particular as regards chemicals. In this regard, this arrangement is neither a case of the new governance method, nor of a classic governance method traditionally pursued by the European Union through regulations and directives, nor does it appear to be stable.

2. This governance arrangement seems to lack homogeneity due to its case-by-case nature. Measures seem to grow without an overall vision and there is the lack of coherence. There is increasing attention to some sectors, such as electronics, nanomedicine, cosmetics, biocides with regard to information, labelling and risk-assessment, but there appears to be less focus on other sectors, in which human exposure [22] is high (e.g. food and feed, safety at the workplace, chemicals), thus running the risk of endangering some individual rights (information, health, the environment). In some sectors, which are strategic for the economies of European countries, attention may even appear to be excessive (e.g. nanoelectronics, nanomedicine), representing a restraint for growth. In this regard, the ethics framework provided by research funding framework programmes does seem to affect policy choices in an incoherent manner at the EU level.
3. Some measures have been slow to appear, such as those on the definition of nanomaterial (2011), or those on labelling in cosmetics and food (2009, 2011), which could have been adopted much earlier, or the re-modulation of the legislation on chemicals (2012) and that on safety at the workplace (2009), which was already foreseeable in the 2000s. Finally, although the EU recognized that nanomaterials are all different, thus making general regulation problematic, no specific measure has been adopted until now, despite the fact that potential uses are emerging from scientific research and this cannot but imply unnecessary risks for individual rights. For example, although toxicological studies on carbon nanotubes have been known in the scientific community since 2005, no measure has been taken into account on their use at the workplace, even in order to address or foster good practices. But a similar argument could be made with regard to other materials (e.g. silver nanoparticles). The anticipatory dimension of the current model is thus somewhat questionable, particularly as regards human rights. Indeed we could ask whether the adoption of some upstream criteria at the earliest stage could have led to a more coherent, homogeneous and timely approach to nanotechnologies. The resources of human rights could have played a more proactive role within EU policies, by creating coherence for the whole system and thus avoiding sudden changes in regulatory direction (Ruggiu, 2013a; 2013c; 2015).

7. CONCLUSIONS

The regulatory framework, which is emerging at the EU level, is actually a hybrid using new governance tools as a bellows in preparation for the adoption of instruments of a sectoral nature. According to a case-by-case approach this model has shifted from an initial preference for soft forms of governance based upon a view that the existing regulatory framework was adequate, to a model of governance, which is slowly replacing its sectoral legislation with new forms of legislation. Following this slow process of consolidation I argue that this model lacks consistency since it is exposed to abrupt changes of direction. It lacks homogeneity since it pays excessive attention to some key sectors (nanoelectronics, nanomedicine) negatively affecting European growth, while other sectors are given little attention (novel food, chemicals, workplace), thus opening up to possible and further future shifts. It lacks the needed coherence since it risks shifting from an underestimation of the cases where nanotechnologies imply risks to humans, to an irrational over-evaluation of existing risks accompanying undeniable benefits (e.g. nanomedicine) [23] . In other words, this model, so exposed to evaluations according to a case-by-case rationale, has a weak anticipatory dimension, which leads it to face risks just and when they appear depending only on the incremental process of scientific knowledge. Thus the model seems to respond to them with belated solutions. Conversely, the implementation of some upstream criteria such as human rights would allow specific instances that need more attention as regards individual rights to be addressed in a timely fashion (and which could be considered as possible future legal cases), thus avoiding belated and expensive measures, which takes the form of tools of a hard law nature [24] . Human rights, instead, can also provide solutions of a soft law nature by fostering forms of Corporate Social Responsibility focused on specific situations (individual health, information, the environmental protection etc.), by treating use of traditional legislative measure as exceptional (Pariotti and Ruggiu, 2012). This would allow the system to develop solutions inspired by the new governance framework. It would create coherence and relative stability on the basis of a set of upstream rights that can be found today in most European societies, and would also ensure flexibility in dealing with the challenges of emerging technologies (Ruggiu, 2012; 2013a; 2013c; 2015).

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REFERENCES

Aitken, R A, Bassan, A, Friedrichs, S, Hankin, S M, Hansen, S F, Holmqvist, J, Peters, S A K, Poland, C A and Tran, C L (2011), Specific Advice on Exposure Assessment and Hazards/Risk Characterisation for Nanomaterials under REACH (RIP-oN 3) - Final Project Report, RCN/ RIP-oN 3/FPR/1/FINAL, 07 July 2011, European Commission, http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf . (accessed on 1 March 2015).

Arrigo, E (2006), "Code of Conduct and Corporate Governance", *Symphonya. Emerging Issues in Management*, Vol. 1, pp. 93-109, http://symphonya.unimib.it/article/view/2006.1.07arrigo/8776. (accessed on 18 February 2015).

Barr, A and Wilson R (2014), "Google's Newest Search: Cancer Cells", *The Wall Street Journal*, Oct. 29, 2014, http://www.wsj.com/articles/google-designing-nanoparticles-to-patrol-human-body-for-disease-1414515602 . (accessed on 6 March 2015).

Beck, U (1986), *Risikogesellschaft. Auf Weg in eine andere Moderne*, Frankfurt am Main: Suhrkamp; (2000), *La società del rischio. Verso una seconda modernità*, Trans. W Privitera, C Sandelli, G C Brioschi and M Mascarino, Roma: Carocci.

Berger, M (01.07.2013), "An Overview of the European Union's Nanotechnology Project", *Nanowerk*, http://www.nanowerk.com/spotlight/spotid=31109.php. (accessed on 7 March 2015).

Bowman D M, van Calster G and Friedrichs, S (2010), "Nanomaterials and Regulation on Cosmetics", *Nature Nanotechnology,* Vol. 5, No. 2, p. 92.

Coglianese, C and Mendelson, E (2010), "Meta-regulation and Self-regulation", in: Baldwin, R, Cave, M and Lodge, M (eds) *The Oxford Handbook on Regulation*, Oxford: Oxford University Press, pp. 146 168.

Cooper, RG (1990) "Stage Gate Systems: a New Tool for Managing New Products", *Business Horizons,* Vol. 33, No.3, pp. 44-54.

Cosmetics Europe, (2011), *Colipa Guidelines on Cosmetic Products. Compliance with Regulation 1222/2009 on Cosmetics products*,https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=84 . (accessed on 27 March 2015).

Cosmetics Europe, (2012), Roles and Responsibilities Along the Supply Chain : A Practical Guide. Compliance with Regulation 1222/2009 on Cosmetics products, https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=89. (accessed on 27 March 2015).

de Búrca, G and Scott J (2006) "Introduction: New Governance, Law and Constitutionalism", in: De Burca G and Scott J (eds) *Law and New Governance in the EU and the US,* Oxford: Hart Publishing, pp. 1-12.

Dorbeck-Jung, B and Shelley-Egan, C (2013), "Meta-regulation and Nanotechnologies: the Challenge of Responsibilisation within the European Commission's Code of Conduct for Responsible Nanosciences and Nanotechnologies Research", *Nanoethics,* Vol. 7, No. 1, pp. 55-68.

Eberlein, B and Kerwer, D (2004), "New Governance in the European Union: A Theoretical Perspective", *Journal of Common Market Studies*, Vol. 42, No. 1, pp. 121-142.

European Commission (2004), Commission communication of 12/05/2004 *Towards a European Strategy for Nanotechnology*, COM(2004) 338 final, Luxembourg: Commission of the European Communities, http://ec.europa.eu/research/industrial_technologies/pdf/nanotechnology_communication_en.pdf. (accessed on 23 February 2015).

European Commission, (2005), Commission communication of 07/06/2005 *Nanosciences and Nanotechnologies. An Action Plan 2005-2009,* COM(2005) 423 final, Brussels: European Commission, http://ec.europa.eu/research/industrial_technologies/pdf/nano_action_plan_en.pdf . (accessed on 23 February 2015).

European Commission, (2007a), Commission communication of 19/07/2007 "Towards a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research and Nanotechnologies Research" Consultation Paper, Brussels: European Commission, https://ec.europa.eu/research/industrial_technologies/pdf/policy/nano_com_en_new.pdf. (accessed on 24 February 2015).

European Commission, (2007b), "*Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*"- *Detailed Analysis of Results from the Consultation*. Brussels: European Commission, http://ec.europa.eu/research/science-society/document_library/pdf_06/consultation-nano-sinapse-feedback_en.pdf . (accessed on 24 February 2015).

European Commission, (2008a), Commission recommendation of 07/02/2008 *on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research*, C(2008) 424 final. Brussels: European Commission. http://ec.europa.eu/research/participants/data/ref/fp7/89918/nanocode-recommendation_en.pdf . (accessed on 23 February 2015).

European Commission, (2008b), Commission communication of 17/06/2008 *on Regulatory Aspects of Nanomaterials*, COM(2008) 366 final, Brussels: European Commission, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:en:PDF . (accessed on 1 March 2015).

European Commission, (2010), Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research: 1st Revision. Analysis of Results from the Public Consultation, http://ec.europa.eu/research/consultations/nano-code/results_en.pdf. (accessed on 24 February 2015).

European Commission, (2011), Recommendation of the European Commission of the 18 October 2011 *on the Definition of Nanomaterial*, 2011/696/EU, 2011, *Official Journal of the European Union*, L275/38, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011H0696&from=EN . (accessed on 29 February 2015).

European Commission, (2012a), Commission Staff Working Paper *on Types and Uses of Nanomaterials, Including Safety Aspects*, SWD(2012) 288 final, 3.10.2012, Brussels: European Commission, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF . (accessed on 1 March 2015).

European Commission, (2012b), Proposal of 26/09/2012 for a Regulation of the European Parliament and of the Council *on Medical Devices,* and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM(2012) 542 final, Brussels: European Commission, http://ec.europa.eu/health/medical-devices/files/revision_docs/proposal_2012_542_en.pdf. (accessed on 3 March 2015).

European Commission, (2012c), Commission communication of 3/10/2012 *Second Regulatory Review on Nanomaterial*, COM (2012) 572 final. Brussels: European Commission, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN . (accessed on 20 February 2015).

European Commission, (2013), *Nanotechnology: The Invisible Giant Taking Europe's Future Challenges*, Luxembourg: Publications Office of the European Union, http://bookshop.europa.eu/en/nanotechnology-pbKI3013325/downloads/KI-30-13-325-EN-C/KI3013325ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAlMEUUsWb0000Gho_fC38;sid=Fn1fd9slL9Zfeor1JQnB0LkAtL4jJ5ZGCA8=?FileName=KI3013325ENC_002.pdf&SKU=KI3013325ENC_PDF&CatalogueNumber=KI-30-13-325-EN-C . (accessed on 7 March 2015).

European Medicines Agency (EMA) (2006), *Reflection Paper on Nanotechnology-Based Medicinal Products for Human Use*, EMA/CHMP/79769/2006, London: European Medicines Agency,http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/01/WC500069728.pdf . (accessed on 9 April 2015).

EFSA Scientific Committee, (EFSA) (2011), "Scientific Opinion on Guidance on the Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain", *EFSA Journal 2011*, Vol. 9, No. 5: 2140, pp. 1-36.

European Food Safety Authority (EFSA) (2015), "Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed for 2014", *EFSA supporting publication 2014*, EN-762, pp. 1-11.

European Group on Ethics in Science and New Technologies, (EGE) (2007), *Opinion on the Ethical Aspects of Nanomedicine - Opinion N. 21 - 17 January 2007*, Luxemburg: Publications Office of the European Union, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0428&rid=2. (accessed on 18 February 2015).

European Parliament, (2006), Parliament resolution of 28/09/2006 *Nanosciences and Nanotechnologies. An Action Plan 2005-2009,* (2006/2004 (INI)), Strasbourg: European Parliament, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT%2BTA%2BP6-TA-2006-0392%2B0%2BDOC%2BXML%2BV0//EN . (accessed on 23 February 2015).

European Parliament, (2009), Parliament resolution of 24/04/2009 *on Regulatory Aspects of Nanomaterials* (2008/2208(INI)), Brussels: European Parliament, http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P6-TA-2009-0328+0+DOC+PDF+V0//EN . (accessed on 23 29 February 2015).

European Parliament, (2012), Resolution of the European Parliament of 19 January *2012 on the Council's Position at First Reading with a View to the Adoption of a Regulation of the European Parliament and of the Council, Concerning the Making Available on the Market and Use of Biocidal Products*(05032/2/2011 - C7-0251/2011-2009/0076 (COD)), P7_TA-PROV(2012)0010.

European Union, (2006), Decision (EC) No 1982/2006 of the European Parliament and of the Council of 18/12/2006 *Concerning the Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007-2013)*,*Official Journal of the European Union*, L412/1, 30.12.2006. http://cordis.europa.eu/documents/documentlibrary/90798681EN6.pdf. (accessed on 11 March 2015).

European Union, (2008), Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on Classification, Labelling and Packaging (CLP) of Hazardous Substances and Mixtures*, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, *Official Journal of the European Union*, L353/1, 31.12.2008.

European Union (2009). Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 *on Cosmetics Products*,*Official Journal of the European Union*, L349/59.

European Union, (2011), Regulation (EC) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 *on the Provision of Food Information to Consumers*, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive

90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004,*Official Journal of the European Union*, L304/18.

European Union, (2011), Directive 2011/65/EU of the European Parliament and of the Council of 08/06/2011*on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment*, *Official Journal of the European Union*, L174/88, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0065&from=EN. (accessed on 26 February 2015).

European Union, (2012a), Regulation (EU) No. 528/2012 of the European Parliament and the Council of 22/05/2012 *Concerning the Making Available on the Market and Use of Biocidal Products*, *Official Journal of the European Union*, L167/1, 27/06/2012, pp. 1-123, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=EN . (accessed on 20 February 2015).

European Union, (2012b), Directive 2012/19/EU of the European Parliament and the Council of 04/07/2012 *on Waste Electrical and Electronic Equipment (WEEE)*, *Official Journal of the European Union*, L197/38, 24/07/2012, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN . (accessed on 14 March 2015).

European Union, (2013), Regulation (EU) No. 1291/2013 of the European Parliament and the Council of 11/12/2013*Establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)*, *Official Journal of European Union*, L347/104, 20/12/2013, http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf. (accessed on 11 March 2015).

European Union, (2014), Regulation (EU) No. 334/2014 Amending Regulation (EU) No. 528/2012 of the European Parliament and the Council of 22/05/2012 *Concerning the Making Available on the Market and Use of Biocidal Products*, *Official Journal of the European Union*, L103, 05/04/2014, pp. 22-32.

Ferrarese, M R (2010), *La governance tra politica e diritto*, Bologna: Il Mulino.

Grande, E. (2001), "The Erosion of State Capacity and the European Innovation Policy Dilemma. A Comparison of German and EU Information Technology Policies", *Research Policy*, Vol. 30, pp. 905-921.

Grobe, A, Kreimberger, N and Funda, O (2011), *NanoCode WP2 Synthesis Report on Stakeholder Consultations*, March 2011.

Hafner, A, Lovric, J, Lakos, G P and Pepic, I (2014), "Nanotherapeutics in the EU: An Overview of the Current State and Future Directions",*International Journal of Nanomedicine*, Vol. 9, pp. 1005-1023.

Hankin, S M, Peters, S A K, Poland, C A, Foss Hansen, S, Holmqvist, J, Ross, B L, Varet, J and Aitken, R J (2011), *Specific Advice on Fulfilling Information Requirements and Exposure Assessment for Nanomaterials under REACH (RIPoN 2) - Final Project Report*, RCN/ RIP-oN

2/FPR/1/FINAL, 01 July 2011, European Commission, http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf . (accessed on 2 March 2015).

Journeay, W S and Goldman, R H (2014), "Occupational Handling of Nickel Nanoparticles: A Case Report", *American Journal of Industrial Medicine*, Vol. 57, No. 9, pp. 1073-1076.

Kagan, V E, Konduru N V, Feng, W, Allen, B L, Conroy J, Volkov Y., Vlasova, I I, Belikova N A, Yanamala N, Kapralov A, Tyurina Y Y, Shi, J, Kisin E R, Murray A R, Franks J, Stolz, D, Gou, P, Klein-Seetharaman, J, Fadeel, B, Star, A and Shvedova A A (2010), "Carbon Nanotubes Degraded by Neutrophil Myeloperoxidase Induce Less Pulmonary Inflammation", *Nature Nanotechnology*, Vol. 5, pp. 354-359.

Kearnes, M B and Rip, A (2009), "The Emerging Governance Landscape of Nanotechnology", in: Gammel, S, Lösch, S and Nordmann, A (eds)*Jenseits Von Regulierung: Zum politischen Umgang Mit Der Nanotechnologie*, Berlin: Akademische Verlagsgesellschaft, pp. 97-121.

Kooiman, J and Van Vliet, M (1993), "Governance and Public Management", in: Eliassen, K and Kooiman, J (eds), *Manging Public Organizations* (2 ndedn), London: Sage.

Kjølberg, K L and Strand, R (2011), "Conversations About Responsible Nanoresearch", *Nanoethics*, Vol. 5, No. 1, pp. 99-113.

Krupp, F and Holliday, C (2005), "Let's Get Nanotech Right", *Wall Street Journal*, Tuesday, June 14, 2005, Management Supplement, p. B2.

Kuhlbus, Th A J, Asbach, Ch, Fissan, H, Göhler and Stintz M (2011), "Nanoparticle Exposure at Nanotechnology Workplaces: A Review", *Particle and Fiber Toxicology*, Vol. 8, No. 22. http://www.particleandfibretoxicology.com/content/pdf/1743-8977-8-22.pdf. (accessed on 12 March 2015).

Kurath, M, Nentwich, M, Fleischer, T and Eisenberger, I (2014), "Cultures and Strategies in the Regulation of Nanotechnology in Germany, Austria, Switzerland and the European Union", *Nanoethics*, Vol. 8, No. 2, pp. 121-140.

Lyall, C and Tait, J (2005), "Shifting Policy Debates and the Implications for Governance", in Lyall, C and Tait, J (eds) *New Modes of Governance. Developing an Integrated Policy Approach to Science, Technology, Risk and the Environment*, Adelshot: Ashgate, pp. 1-17.

Mandel, G N (2009), "Regulating Emerging Technologies. Legal Studies Research Paper Series, Research Paper N. 2009-18, 04-08-2009", *Innovation & Technology*, Vol. 1, p. 75. http://ssrn.com/abstract=1355674. (accessed on 20 February 2015).

Mandel, G N (2013) "Emerging Technology Governance", in: Marchant, G E, Abbott, K W and Allenby, B (eds) *Innovative Governance Models for Emerging Technologies*, Cheltenham (UK), Northampton, MA. (USA): Edward Elgar, pp. 44-62.

Mantovani, A, Porcari, A, and Azzolini, A (2010), NanoCode WP1 Synthesis Report on code of Conduct, Voluntary Measures and Practices Towards a Responsible Development of N&N, September 2010.

Marchant, G E, Sylvester, D J and Abbott, K W (2008), "Risk Management Principles for Nanotechnology", *Nanoethics,* Vol. **2**, No. 1, pp. 43-60.

Marrani, D (2013), Nanotechnologies and Food in European Law, *Nanoethics*, Vol. 7, No. 3, pp. 177-188.

Meili, C, Widmer, M, Schwarzkopf, S, Mantovani, E and Porcari, A (2011), NanoCode MasterPlan: Issues and Options on the Path Forward with the European Commission Code of Conduct on Responsible N&N Research, November 2011.

Metha, M D (2004), "From Biotechnology to Nanotechnology: What Can We Learn from Earlier Technologies?", *Bulletin of Science and Technology*, Vol. 24, No. 1, pp. 34-39.

Murphy, T (ed), (2009), *New technologies and Human Rights*, Oxford: Oxford University Press.

Mwilu, S K, El Badawy, A M, Bradham, K, Nelson, C, Thomas, D, Scheckel, K G, Tolaymat, T, Ma, L and Rogers, K R (2013), "Changes in Silver Nanoparticles Exposed to Human Synthetic Stomach Fluid: Effects of Particle Size and Surface Chemistry", *Science of the Total Environment*, Vol. 447, pp. 90-98.

Owen, R (2014), *Responsible Research and Innovation: Options for Research and Innovation Policy in the EU,* European Research and Innovation Area Board (ERIAB), Foreword Visions on the European Research Area (VERA), http://ec.europa.eu/research/innovation-union/pdf/expert-groups/Responsible_Research_and_Innovation.pdf . (accessed on 7 March 2015).

Owen, R, Macnaghten, Phil and Stilgoe, J (2012), "Responsible Research and Innovation: Form Science in Society to Science for Society, with Society,*Science and Public Policy,* Vol. 39, pp. 751-760.

Owen, R, Stilgoe, J, Macnaghten, Phil, Gorman, M, Fisher, E and Guston, D (2013), "A Framework for Responsible Innovation", in: Owen, R, Bessant, J and Heintz M (eds) *Responsible Innovation*, London: John Wiley & Sons Ltd, pp. 27-50.

Pariotti, E (2011), "Normatività giuridica e *governance* delle tecnologie emergenti", in: Guerra, G, Muratorio, A, Pariotti, E, Piccinni, M and Ruggiu, D (eds), F*orme di responsabilità, regolazione e nanotecnologie,* Bologna: Il Mulino, pp. 509-549.

Pariotti, E and Ruggiu, D (2012), "Governing Nanotechnologies in Europe: Human Rights, Soft Law, and Corporate Social Responsibility", in: Van Lente, H, Coenen, C, Konrad, K, Krabbenborg, L, Milburn, C, Seifert, F, Thoreau, F and Zülsdorf, T (eds), *Little by Little. Expansions of Nanoscience and Emerging Technologies*, Heidelberg: IOS press/AKA, pp. 157-168.

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: Cambridge University Press, pp. 207-241.

Peters, A and Pagotto, I (2006). "Soft Law as a New Mode of Governance: a Legal Perspective", Report of the Project *NEWGOV New Modes of Governance. Integrated Project. Priority 7 - Citizens and Governance in the Knowledge-Based Society*, 04, D11, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1668531&rec=1&srcabs=1876508&alg=1&pos=1 . (accessed on 18 February 2015).

Poland C A, Duffin, R, Kinloch, I, Mynard, A, Wallace, W A C, Seaton, A, Stone, V, Brown, S, Mac Nee, W and Donaldson, K (2008), "Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-Like Pathogenicity in a Pilot Study", *Nature Nanotechnology*, Vol. 17, July 2008, pp. 423-428.

Rip, A (2002), *Coevolution of Science, Technology and Society. An Expert Review for the Bundesministrium Bildung und Forshung's Förderinitiative Politik, Wissenschaft und Gesellschaft (Science Policy Studies)* .
http://www.google.it/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=2&ved=0CEEQFjAB&url=http%3A%2F%2Fciteseerx.ist.psu.edu%2Fviewdoc%2Fdownload%3Fdoi%3D10.1.1.201.6112%26rep%3Drep1%26type%3Dpdf&ei=g7vKUfj0NoWpOrG5gbgP&usg=AFQjCNH9NKjk8E5pIoFqJsMVSPofWw-TLw&sig2=GjdoftjztHB-vqW160HMEA&bvm=bv.48340889,d.ZWU. (accessed on 20 February 2015).

Roco, M (2006), "Progress in Governance of Converging Technologies Integrated from the Nanoscale", *Annals of the New York Academy of Science,* Vol. 1093, pp.1-2.

Rhodes, R (1996) "The New Governance: Governing without Government", *Political Studies*, Vol. 44, pp. 652-667.

Ruggiu, D (2012), *Diritti e temporalità. I diritti umani nell'era delle tecnologie emergenti*, Bologna: Il Mulino.

Ruggiu, D (2013a), "Temporal Perspectives of the Nanotechnological Challenge to Regulation. How Human Rights Can Contribute to the Present and Future of Nanotechnologies", *Nanoethics*, Vol. 7, No. 3, pp. 201-215.

Ruggiu, D (2013b), "Dominating Non-Knowledge. Rights, Governance and Uncertain Times", Cosmopolis: Robotics and Public Issues, Vol. IX, No. 2, http://cosmopolis.globalist.it/Detail_News_Display?ID=68672&typeb=0&Dominating-Non-knowledge-Rights-Governance-and-Uncertain-Times .

Ruggiu, D (2013c), "A Rights-Based Model Of Governance: the Case of Human Enhancement and the Role of Ethics in Europe" in: Konrad, K, Coenen, Ch, Dijkstra, A, Milburn, C and van Lente, H (eds) *Shaping Emerging Technologies: Governance, Innovation, Discourse*, Berlin: IOS Press/AKA-Verlag, pp.103-115.

Ruggiu, D (2014), "Responsibilisation Phenomena: the EC Code of Conduct for Responsible Nanosciences and Nanotechnologies Research",*European Journal of Law and Technology*, Vol. 5, No. 3, pp. 1-16, http://ejlt.org/article/view/338.

Ruggiu, D (2015), "Anchoring European Governance: Two Versions of Responsible Research and Innovation and EU Fundamental Rights as 'Normative Anchor Points'", *Nanoethics* Vol. 9, No. 3, pp. 217-235.

Scientific Committee on Emerging and Newly Identified Health Risks, (SCENIHR) (2009), *Risk Assessment of Products of Nanotechnologies - Opinion of 19 January 2009 -*, Brussels: European Commission.

Scientific Committee on Emerging and Newly Identified Health Risks, (SCENIHR) (2014), *Nanosilver - Safety, Health and the Environment Effects and Role in Antimicrobial Resistance - Opinion of 10, 11 June 2014* - Luxembourg: European Commission.

Scientific Committee on Consumer Safety, (2012), *Guidance on the Safety Assessment on Nanomaterials in Cosmetics*, Brussels: European Commission.

Scott, J and Trubek, D M (2002) "Mind the Gap: Law and New Approaches to Governance in the European Union", *European Law Journal,* Vol. 8, No.1, pp. 1-18.

Shvedova, A A , Kisin, E R,Mercer R,Murray A R,Johnson, V J, Potapovich A I,Tyurina, Y Y,Gorelik, O,Arepalli, S,Schwegler-Berry, D,Hubbs, A F,Antonini, J,Evans, D E,Ku, B K,Ramsey, D,Maynard, A,Kagan, V E,Castranova, V and Baron, P (2005), "Unusual Inflammatory and Fibrogenic Pulmonary Responses to Single-Walled Carbon Nanotubes in Mice", *American Journal of Physiology Lung Cellular Molecular Physiology,* Vol. 289, No. 5, pp. L698-L708.

Smismans, S (2008), "New Modes of Governance and the Participatory Myth, *West European Politics*, Vol. 31, No. 5, pp. 874-895.

Song, Y, Xue, L and Xuqin, D, (2009), "Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma", *European Respiratory Journal*, Vol. 34, No. 3, pp. 1-31.

Sørensen, E and Triantafillou, P (2009) "Introduction", in: Sørensen E and Triantafillou P (eds) *The politics of self-governance*, Farnham: Ashgate, pp. 1-22.

Stoke, E and Bowman, D M (2012), "Looking Back to the Future of Regulating New Technologies: The Case of Nanotechnology and Synthetic Biology", *EJRR,* Vol. 2, pp. 235-241

Stoke, G (1998), "Governance as Theory: Five Propositions", *JSSJ,* Vol. 155, pp. 17-28.

Throne-Host, H and Rip, A (2011), "Complexity of Labelling of Nanoproducts on the Consumers Market, *European Journal of Law and Technology*,**2**(3).

Throne-Host, H. and Strandbakken, P. (2009). "'Nobody Told Me I Was a Nano-consumer': How Nanotechnologies Might Challenge the Notion of Consumer Rights", *Journal of Consumer Policy*, **32**(4), pp. 393-402.

van Calster, G (2006), "Regulating Nanotechnology in the European Union", *European Environmental Law Review*, August/September, pp. 238-247.

von Schonberg, R (2010), "Organising Public Responsibility: On Precaution, Code of Conduct and Understanding Public Debate", in: Fiedeler, U, Coenen, C, Davies, S R and Ferrari, A (eds) *Understanding Nanotechnology: Philosophy, Policy and Publics*, Amsterdam: Ios Press, pp. 61-70.

von Schonberg, R (2011), "Prospects for Technology Assessment in a Framework of Responsible Research and Innovation", in: Dusseldorp, M and Beecroft, R (eds) *Technikfolgen abschätzen lehren. Bildungspotenziale transdisziplinärer Methoden*, Wiesbaden: Vs Verlag, pp. 39-61.

von Schonberg, R (2013), "A Vision of Responsible Innovation", in: Owen, R, Heintz, M, Bessant, J (eds) *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, London: John Wiley.

Widmer, M, Meili, C, Mantovani E and Porcari, A (2010), *The FramingNano Governance Platform: A New Integrated Approach to the Responsible Development of Nanotechnologies*, February 2010.

Zhang, X, Sun, H, Zhang, Z, Niu, Q, Chen, Y and Crittenden J C (2007), "Enhanced Bioaccumulation of Cadmium in Carp in the Presence of Titanium Dioxide Nanoparticles", *Chemosphere*, Vol. 67, pp. 160-166.

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[2] Thus, according to SCENIHR: '[a]s there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case by case approach for the risk assessment of nanomaterials is recommended' (SCENIHR, 2009: 10).

[3] New governance has been defined as 'a construct which has been developed to explain a range of processes and practices that have a normative dimension but do not operate primarily or at all through the formal mechanism of traditional command-and-control legal institutions [...] [it] signals a shift away from monopoly of traditional politico-legal institutions, and implies either the involvement of actors other than classically governmental actors, or indeed the absence of any traditional framework of government, as is the case in the EU and in any trans-national context' (de Búrca and Scott, 2006: 2). Modes of governance

can be called new when their function of steering is characterized by i) informality, ii) the lack of hierarchy iii), and the presence of private actors who are systematically involved in policy formulation (Peters and Pagotto, 2006; Scott and Trubek, 2002; Lyall and Tait, 2005; Eberlein and Kerwer, 2004; Rhodes 1996; Pariotti, 2011). New governance implies either the involvement of actors other than classically governmental actors, or indeed the absence of any traditional framework of government, as is the case in the EU and in any trans-national context' (de Búrca and Scott, 2006: 2).

[4] With regard to carbon nanotube toxicology, it can be added that there is also a promising study in nanomedicine, which has identified an enzyme produced by some kinds of white blood cells (myeloperoxidase) that can biodegrade them by decomposing the carbon nanotubes into two innocuous elements, water and carbon dioxide (Kagan et al., 2010).

[5] There are also nanotechnological drugs used in anti-cancer therapy in nanomedicine (e.g. Myocet) that are commercialized within the EU (Hafner et al., 2014).

[6] The scanning tunnelling microscope used since 1981 to make matter visible at the atomic scale was firstly used for manipulating single atoms in 1989.

[7] Commission communication of 12/05/2004 *Towards a European Strategy for Nanotechnology*, COM(2004) 338 final. Luxembourg: Commission of the European Communitieshttps://ec.europa.eu/research/industrial_technologies/pdf/policy/nano_com_en_new.pdf.

[8] European Commission (2008) Recommendation *on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* C(2008) 424 final, available at http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf .

[9] Between 2010 and 2011 a survey held as a part of a EU funded FP7 project. Since it was also aimed at implementing the Commission code of conduct, it can be deemed as a part of responsibilisation phenomena triggered at the Community level (Meili et al., 2011).

[10] Even in the 2007 consultation some respondents pointed out that the 'issue of *liability* should be clarified' (European Commission, 2007b: 3 - italics mine).

[11] 'As long as risk assessment studies on long-term safety are not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided' (European Commission, 2008a: 9).

[12] 'N&N research organisations and researchers should launch and coordinate specific N&N research activities in order to gain a better understanding of fundamental biological processes involved in the toxicology and ecotoxicology of nano-objects man-made or naturally occurring. They should widely publicise, when duly validated, data and findings on their biological effects, be they positive, negative or null' (European Commission, 2008a: 10).

[13] In the second Commission consultation some pointed out the risk of the code being 'inapplicable considering the "present writing"' of 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, 2008a: 3 - italics mine). Yet, there was no specification on what these *ethical aspects* that need to be considered are. In this sense, the demand for an increased specificity and practicability' which emerged in all the surveys is quite understandable (Meili et al., 2011a: 23).

[14] 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'.

[15] It refers to opinions of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on definitions and risk assessment of nanomaterials (SCENIHR, 2009).

[16] On the limits of mandatory labelling see, for example, Throne-Host and Rip (2011).

[17] The commercialisation of medicines based on nanotechnologies came after the publication of a report by the EMA Committee for Medicinal Product for Human Use (CHMP) in 2006. See EMA (2006).

[18] See http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000345.jsp& . (accessed on 15 March 2015).

[19] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 *on Classification, Labelling and Packaging (CLP) of Hazardous Substances and Mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ,Official Journal of the European Union*, L353/1, 31.12.2008.

[20] See http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm . (accessed on 4 March 2015).

[21] A stage gate architecture is a framework where the whole process of decision-making is guided through the prevision of phases 'being subject to formal or informal approval at a decision "gate"' (Owen, 2014: 13).

[22] We have to consider in fact that, as regards nanotechnologies, the level of risk does not depend on the mere toxicological form of a given substance, but on the possibilities of it coming into contact (human exposure) with that potentially toxic substance (Kuhlbash, 2011: 11).

[23] In this instance a situation where risks are linked to therapeutic treatment cannot be compared to another where risks are only distributed among consumers.

[24] As clearly stated '[a]n early and open examination of potential risks of a new product or technology is not just good common sense- it's good business strategy' (Krupp and Holliday, 2005).