Chapter 2

Governance: A Theoretical Framework

2.1 Introduction

2.1 With the increasing importance of science and technology for the growth of the economies of the most industrialized countries, we can observe a progressive shift from modes of government that are still state-centric, based on a 'top-down legislative approach' that attempts to regulate the behaviour of people and institutions in detailed and compartmentalized ways, to modes of governance characterized by the diffusion of actors (public and private) who contribute to steer processes of economic, financial and technoscientific development through the creation of self-regulating and self-coordinated ecosystems (Roco, 2006, p. 3). Since the desired and unintended effects of technoscientific progress cross the boundaries of each single nation (Beck, 1986) and the globalized dimension of the market also involves latest results of science and technology,[1] it is a fact that the rise of emerging technologies cannot

[1] For example, nanotechnologies are used in a wide number of commercial products that reach store shelves worldwide. We can think of OLED technology (organic light-emitting diode) that is used in television screens, computer monitors, mobile phones, and gaming consoles. Silver nanospheres are used in sportswear, toys, toothpastes, air conditioning systems, and washing machines. Titanium dioxide

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be restricted to a given territory or region. The rapid development of technological innovation and the increasing size and power of transnational corporations are leading to the globalization of production and market systems boosted by pressures for further trade liberalization (Lyall and Tait, 2005, p. 8). In this context, the spread of emerging technologies has become a transnational phenomenon which needs forms of governing able to encompass: the action of several nations, the coordinating function of non-state organizations at regional, national, supranational level, the increasing importance of the role of firms and corporations in the evolution of a given scientific and technological sector. In this framework traditional arrangements of governing appear obsolete and clearly insufficient to coordinate a multitude of actors that can individually influence the trajectories of a single technological field. In this context, where no institution appears able to control the others, power is pulverized among a multitude of subjects (the State, non-state actors, private actors, both profit and non-profit entities) giving rise to phenomena of the progressive de-personalization of forms of governing, a blurring between public and private sectors, and the building of self-organizing networks (Stoke, 1998). Here governing and government are conceptually separated and tend to have a per se existence in the theoretical framework. In particular, the concept of governance seems even more capable of interpreting the novelties of this paradigm change in political theory.

This shift witnesses the progressive separation and independence of rules governing science and technology from the subjects regulating them, and the increasing presence of supranational and non-state actors (the EU, EGE, US OTA, WTO, WMA, the Council of Europe, transnational corporations, etc.) in the international landscape. What counts is the act of governing as the result of the interaction of a plurality of forces and institutions, not the law-

nanoparticles are widely used in cosmetics. Carbon nanotubes are used in some sport articles (e.g. bicycles), nanoparticles are also used in food and ingredients. In addition to the given scientific uncertainty concerning the risks of new technologies, this wide diffusion gives rise to the phenomenon of the spread of risks among people, connected to a sort of pulverization of responsibilities that are distributed among a multitude of unaware persons (workers, users, consumers, and simply unaware people in the case of mere human exposure) (Beck, 1986).

making subject itself (the government, the EU, etc.), that is considered as only one of the multiple actors of governance. Therefore, the essence of governance is that it focuses on mechanisms of governing which do not resort to traditional sanctions or the classic concept of authority (Stoke, 1998). The concept of governance refers to the creation of an order that cannot be externally imposed but is the result of the interaction of a multiplicity of governing forms and actors influencing one another (Kooiman and Van Vliet, 1993), p. 64). Thus governance (i.e. the act of governing) no longer stems from governments as such, but is the outcome of the intersection of multileveled and multi-subjective dimensions and structures (local, regional and supranational, public and private) (Stoke, 1998; Salter and Jones, 2002, p. 810; Pariotti and Ruggiu, 2012). Thus, this chapter intends to present the theoretical framework concerning the concept of governance necessary to understand current trajectories of governance, at European level in particular.

2.2 Governance and Meta-governance

2.2.1 There are several definitions of governance,[2] depending often on the ambit in which they were originated. It has been defined as a 'change in the meaning of government, referring to a new process of governing; or a changed condition of ordered rule; or the new method by which society is governed' (Rhodes, 1996, pp. 652–653); or as 'the development of governing styles in which boundaries between and within public and private sectors have become blurred' (Lyall and Tait, 2005, p. 4). These definitions underline some relevant aspects, but they lack the regulatory dimension[3] which pervades the concept of governance at its base

[2] For example, the Commission's White Paper on Governance defines it as 'rules, processes and behaviour that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence'. European Commission (2001) *European Governance: a White Paper*, 25.7.2001, COM(2001) 428 final, p. 8, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf. Accessed 19.5.2012.

[3] In this work, by 'regulation' I intend a regulatory landscape of norms of hard and soft law which concur to regulate any aspect of social life with different degrees of legal

and is at the centre of this book insofar as it interacts with human rights law. The fact that the phenomenon of governance gives rise to forms of governing distributed among several subjects and deprived of a centre able to control and regulate everything, does not remove the fact that governance belongs to the normative dimension since it is characterized by the intersection of several flows of norms at different levels (international law, EU law, statutory law, judge made law, hard and soft law, ethical advice, technical norms), with different sources of production (the UN, UNESCO, the Council of Europe, the EU, national governments, national and supranational courts, ethical advisory boards, transnational corporations, etc.) and with different degrees of normativity (legal, ethical or technical norms). In this sense by governance I mean the network of processes with reticular character, diffuse among public and private actors both at national and supranational level, made up of norms of soft[4] and hard law, as well as ethical and technical norms, somehow coordinated and aimed at solving conflicts and making decisions in a particular technological, economic, or financial field (Ruggiu, 2012b, p. 156; Ruggiu, 2013a, p. 104).

With the crisis of the State-centric model of societal governing where just one actor, the State, has centralized the monopoly of all legal sources, the rise of governance has led not only to a multiplication of the sources of law and law-making subjects (Ferrarese, 2012, p. 124ff.), but also to the integration of further normative sources (ethical, technical) with those of law. In this sense, governance is broader than regulation since it encompasses the full range of research and innovation policies that together constitute broad structures for governing science (Roco, 2006, p. 3; Kearnes and Rip, 2009, p. 3). Thus regulation should be

normativity. Law has diverse degrees of normativity. There is a continuum between hard and soft law and possibly between other qualities of the law. (Peters, Pagotto, 2006, p. 8; Peters, 2001, p. 23). In this regard, regulation loses any state-centric connotation typical of hard law instruments and includes the activity of several actors both public and private.

[4] I intend the term 'soft law' as referring to guidelines, declarations or recommendations containing principles and standards, or voluntary measures (self-regulation tools, voluntary codes of conduct, third-party certification systems) not supported by formal legal sanctions, that can nevertheless have legal effects (Pariott and Ruggiu, 2012).

deemed as a one of a number of 'tools of governance' set up in the context of the overall governance of emerging technologies, which serves to interconnect technoscientific development and civil society (Eberlein and Kerwer, 2004, p. 131).

The rise of governance in scientific literature has made several profiles belonging to the complexity of the concept apparent.

First of all, this perspective is partially built on the challenge of the legal/constitutional tradition that dominated political theory up to the 1950s (Stoke, 1998, p. 19). The traditional model of power is built around a dominant agent, of a public nature, providing all services for a given community. In this framework power is legitimated through formal criteria of power delegation. In a context where there is no agent dominating others, in which, therefore, the mere interaction of a multitude of agents is relevant, the criteria of legitimation are deeply changed and, instead of (power conferring) rules, they rest on the effective provision of services, mobilizing resources and promoting cooperation, and on the capacity of agents to produce norms able to be followed by the other forces. In other words, accountability generates the legitimation of the action of different agents. In the governance framework, legitimation is able to produce accountability that determines the relationships of power among different actors and who is the recipient of regulation (Pariotti, 2011).

Another aspect of governance is the new modulation of responsibility relations in which the State takes a step back, while responsibilities are increasingly distributed into the private sectors on a voluntary base (Stoke, 1998, p. 21). There is a shift in the balance between the State and civil society, meaning that private forces increasingly accompany public ones. Within the framework of international relations, States are only one of the number of actors at play. Now several different agents act in the horizon of international relations. International and supranational organizations such as the WTO or the EU are even more important. Non-state actors, such as Greenpeace, ETC group, the International Life Science Institute (ILSI), which represents several industry members, or the Organisation for Economic Co-operation and Development (OECD), can influence policies of States and even policies of more complex political organizations such as the EU. Transnational corporations

acting across several countries are able to determine the success or failure of policy choices. Third-party certification systems such as the ISO underline the role of corporations in the success of a given regulatory direction with regard to a particular technological ambit. In this instance, the effectiveness of regulation succeeds only if there is a spontaneous assumption of responsibility by the enterprises that play a leading role in the framework of international governance. In this sense, making stakeholders responsible can be crucial (Dorbeck-Jung and Shelley-Egan, 2013). In this context even the individual with the power of his/her internationally recognized rights (i.e. human rights) can affect directions of the governance of emerging technologies (Pariotti, 2007, 2013; Ruggiu, 2015). For example, in 2011, the patentability of isolated and purified neural progenitor cells for the treatment of neural defects (stem cells) was greatly limited by a decision of the CJEU (Ruggiu, 2013a; 2015).[5] Thus, contextually, national and supranational courts can also substantially affect choices of governance (Ruggiu, 2015). The rising landscape is one in which responsibilities are increasingly assumed by private actors and the role of the State is re-sized, even though it is far from disappearing or becoming secondary in this theoretical framework. In this context the concept of responsibility as such needs to be thoroughly redefined (von Schomberg, 2010; Owen et al., 2013; Ruggiu, 2015).

If in the current landscape of global governance there is no longer a single organization which dominates the others, one that can dominate a particular process of exchange (Stoke, 1998, p. 22). In this framework, governing is an interactive process since no single actor (public or private) has the monopoly of knowledge, the exclusive possession of all resources and the capability to tackle problems unilaterally (Lyall, Tait, 2005, p. 4). As has been rightly noted, it is a kind of 'invisible hand' of Adam Smith which guides 'the co-ordination of independent initiatives to a maximum advancement of science' (Polanyi, 1962). In this regard there is the need to create forms of systemic coordination among different agents through forms of information and knowledge exchange,

[5] Judgement of the Court of Justice (Grand Chamber), *Oliver Brüstle v. Greenpeace eV* (Case C-34/10) 18 October 2011, not yet published.

styles of partnership, and modes of joint-working able to generate self-regulating networks. A shift from the subject of governing to the quality of the relationship among the different subjects has been determined. It is the interactivity of relations that counts in a framework in which forms of cooperation are crucial in order to realize common purposes and goals. Systemic coordination leads to 'games *about* rules' instead of 'games *under* rules', meaning that regulation is the result of the interaction of several actors and not only the means by which collective action is steered and guided. In this context many consequences are produced, some desired and some unintended, but not all unintended consequences are undesired per se. In this sense, governance is a form of governing characterized by a degree of uncertainty and therefore it is suitable for steering fields, such as that of emerging technologies, dominated by a state of uncertainty with regard to risks, potentials, definitions, classifications, metrology, the applicability of existing norms and the production of new ones (Kearnes and Rip, 2009; von Schomberg, 2011).

Under this perspective governance implies the creation of autonomous and self-regulating networks of actors (Stoke, 1998, p. 23). This leads to the formation of a sort of 'regime' in which actors and institutions gain the capacity to blend and integrate resources, skills and purposes in a spontaneous and (lightly) coordinated long-term coalition. In a world where uncertainty in problem-solving processes increases due to the augmented complexity and the unavoidable diversity of life situations, a uniform solution is simply not possible (Scott and Trubek, 2002, p. 5ff.). Instead of adopting classical forms of government, various institutional arrangements are created to enable actors to cooperate over resources which are finite and to which they have open access. In certain contexts, self-organized systems of control among different actors can be more effective than regulations imposed by the government. The processes of integration among different levels of governance can be vertical or horizontal (Lyall, Tait, 2005, p. 10). The vertical ones act through the delegation of responsibilities from higher to lower levels and set up objectives within a clearly hierarchical mechanism. These integration systems often imply top-down control with some form of sanctions imposed. The horizontal ones take place across

department boundaries in order to amalgamate policies of different institutions in a coordinated ecosystem. These institutional structures (e.g. interdisciplinary research in academia) are important but can be non- decisive with regard to the effectiveness of integration. The 'impact of effective horizontal integration is a loosening of control and the introduction of greater complexity into policy implementation processes' (ibid., p. 11). This gives rise to the problem of the accountability of these self-organized systems since, to a certain degree, they are driven by the self-interests of the members of the group. Thus if this systemic cooperation has to work, it needs to show it can realize common objectives and purposes in order to gain the trust of the other forces and participants. In this context, accountability is the main form of legitimation among the multitude of actors acting in the landscape of supranational governance. In a dimension where effectiveness is the main feature of the system, the ability to be followed by the other agents and to be recognized as accountable is the principal quality of all participants (Pariotti, 2011).

Finally, instead of traditional powers of governing aimed at commanding and using their own authority, new tools and techniques able to steer and orient the behaviour of agents have been created (Stoke, 1998, p. 24). Governance first identifies the main stakeholders and then develops the effective links among the most relevant parts. Thus it influences and guides relationships in order to reach the desired outcomes. In this sense, often public authorities are only led to redefine their role in this framework. Finally, it involves different sub-systems with a view to making them reflect and act through mechanisms of effective coordination aimed at reducing unintended effects. Old fashion command-control tools have lost their centrality in the international governance landscape, as well as their attractiveness. New softer forms of norms able to guide human behaviour have been developed. Forms of soft law such as guidelines, declarations, recommendations containing principles and standards or voluntary measures such as codes of conduct or third-party certification systems not supported by any legal sanction that can nevertheless have legal effect are spreading (Pariotti, 2011; Pariotti, Ruggiu, 2012). Furthermore, new forms of norms without any legal force such as ethical advice or technical

standards have become even more important in this landscape. In this regard, governance appears as the result of the interaction of a number of norms only some of which are endowed with a legal nature, and it shows the capability of different modes of normativity to reach objectives increasingly relevant for the community. In this context human rights appear as a form in equilibrium among several expressions of normativity since they are referred to both in hard law documents of international law (such as the Council of Europe ECHR), and in soft law instruments (such as the Oviedo Convention), and even in ethical advice as principles of a merely ethical nature (e.g. the opinions of EGE, guidelines, codes of conduct, etc.). This fact makes them a suitable tool of governance able to act as the cornerstone of different dimensions of governance by giving them the necessary coherence (Ruggiu, 2013a, 2013b, 2015).

2.2.2 In literature, scholars increasingly distinguish the concept of governance from that of meta-governance. By meta-governance we mean that level constituted by organizations, structures and processes that produce (the conditions of) governance (Jessop, 2003) through the arrangement of normative tools (of a legal, ethical or technical nature) (Ruggiu, 2013a, p. 104). In this sense governance can be dissociated into its basic elements (such as codes of conduct, consultation processes, guidelines, ethical committees, research laboratories, research programmes, etc.) which can be studied at a more analytical level with a view to recomposing them within a clearer perspective. At the meta-governance level, relations among organizations and governance structures are basically characterized by heterarchy instead of a kind of framing of a hierarchical type. This fact deprives processes of governance of a centre which can determine all the relations of the system by giving a merely eccentric and diffuse character. In this regard governance appears *de facto* to be distributed among several subjects and, thus, to be effective, any model of governance should be able to involve a wide range of stakeholders (Pariotti and Ruggiu, 2012; Ruggiu, 2013a). The analytical study of these structures, organizations and institutions within the wide conceptual framework of governance aims to clarify their role, functions and individual contribution to governance in a given field. Consider the role of transnational

corporations, or the action of NGOs within worldwide governance, or, again, the increasing importance of organs without legislative power but absolutely central in Europe, such as ethical committees, especially at the Community level.

These governance structures and processes can be further analysed with regard to their external elements. In this context we can distinguish formalized structures and processes producing governance from informal ones (Ruggiu, 2013a, p. 105). Those of the first type encompass soft and hard law instruments such as EU directives, recommendations, self-regulatory tools including codes of conduct, third-party certification systems that can have nevertheless legal effects and, in this regard, we can also include in this class human rights. Those of the second type can be, for example, reports and opinions of ethical advisory boards such as the EGE, internal documents of corporations without any legal effect, or acts of NGOs, or, again, scientific results of academic networks inasmuch as they can influence policy-making processes in some way. In other words, through the respect for formal procedures and norms of competence the structures and processes of governance produce in the first instance legal norms with binding force (hard law norms) or legal norms without binding force but able to have some legal effect (soft law norms); in the second case they produce norms (moral, technical, etc.) without any legal effect but able to influence decision-making and law-making processes (e.g. official reports, opinions at the EU level). It is clear that it is easier to analyse the behaviour of formalized structures and processes since the reference to the parameters of their existence, such as legal norms, are more easily identifiable than informal ones are. But since the separation of legal norms from other types of norms is not so definite, it is often (though not always) possible to follow the numerous intersections of norms of different type that governance produces. For example, corporations often resort to forms of self-regulation such as codes of conduct that are public and, once adopted, can have legal effects in any case. In this way they can be studied from a legal perspective. For example, ethical advisory boards such as the EGE act under a constellation of norms which constitute their legal basis, they are then subject to changes of remit, which influence the scope of their opinions and finally they produce a shift in regulation that can be

detected. In this regard, the life of both formalized and informal structures of governance can be analysed and compared.

In sum, governance is the result of the intersection of several different plans and dimensions, normatively organized, with different degrees of formalization (often blurred), giving rise to a normative landscape in which norms of a given kind coexist with norms of a different type without a clear-cut separation, but within a process of stratification.

2.3 The 'New Turn of Governance'

2.3.1 The rise and consolidation of the concept of governance has occurred with the 'New Governance turn', when new forms of soft arrangements were developed within the EU. Modes of governance can be called new when their function of steering is characterized by (i) informality meant as non-typicality (they mainly use old tools in a non-typical fashion) (ii) weak hierarchic relations (public institutions maintains a coordinating role in this model) (iii) the presence of private actors that are systematically involved in policy formulation and (iv) the anticipatory nature (they adopt tools aimed at anticipating risks and triggering voluntary behaviour of stakeholders) (Peters and Pagotto, 2006; Scott and Trubek, 2002; Lyall, and Tait, 2005; Eberlein and Kerwer, 2004). It can be seen as a recipe to use old tools in a novel way (Smismans, 2008). 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, 2002, p. 2). The increasing state of uncertainty in solving problems that appear even more complex and irreducibly diverse may simply not allow a uniform solution according to traditional modes of governing (Scott and Trubek, 2002, p. 5ff.). In

these instances new forms of governance can better tackle issues generated by the increasing complexity, diversity and uncertainty of policy-making contexts by bringing together actors from various levels of governments (localities, subnational regions, national or European) in modes that facilitate dialogue and coordination among several levels of government by privileging, when it is feasible, the lowest possible level in order to extend deliberation among stakeholders and provide some degree of democratic legitimation according to a flexible, revisable, experimental approach which is also able to produce knowledge. New governance is thus characterized by being multilevel and decentralized since it gives rise to mechanisms which leave final policy-making not to the highest level but to the lowest possible one. These mechanisms often have a participatory nature by privileging distributed forms of problem solving aimed at implementing their legitimation (Eberlein and Kerwer, 2004, p. 122). They rely on less formal rules and open-ended standards, flexible and revisable guidelines and other forms of soft law able to adapt to diversity, tolerate alternative approaches, experiment problem-solving processes and create new knowledge by exchanging results, benchmarking performance and sharing best practices. In other words, even in the new governance framework, law does still 'play a role, but more as procedural framework than as a "policy instrument"' (ibid., 131).

To understand the concept of 'new governance' we need to refer to another (and counterpoised) governance model: the classic 'Community Method' (CCM). This model mainly follows command-and-control style and traditional forms of regulation. Here, at the EU level, the exclusive right to legislative initiative belongs to the European Commission, while the legislative and budgetary powers are the competence of the Council of Ministers and the European Parliament. In this context, qualified majority voting is identified by the European Commission as an essential requirement for ensuring the effectiveness of this method, and the Luxembourg Court (CJEU) as the central organ in guaranteeing respect for of the rule of law.[6]

[6] European Commission (2001) *European Governance: a White Paper*, 25.7.2001, COM (2001) 428 final, p. 8, available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0428en01.pdf. Accessed 19 May 2012.

In this regard, the CCM tends to give rise to binding legislative and executive acts at the EU level by imposing uniform rules for all member States (Scott and Trubek, 2002, p. 6). The main problem of this model is the lack of flexibility and the incapacity to quickly adapt to the fast course of the technoscientific development. Its regulatory structures are exposed to fast processes of obsolescence.

New governance can be identified in several categories of tool that can be used to implement the effectiveness of classic forms of governing. Some of them are also present in traditional forms of governance. For example, an initial flexibility was also established in the CCM with comitology. In this sense, the CCM itself contains the seeds of the rising method of new governance. Comitology is not distinguished by the character of norms which it produces but by the institutional structure which produce them. The novelty of the new governance method consists in the implementation of committees in the decision-making processes in order to facilitate the executive functions of both the Council and the Commission (ibid., p. 3).

Another instance of new governance consists in the great range of actors involved in the decision-making processes. In this regard the White Paper on European Governance emphasizes the Community aim of enhancing the participation of civil society throughout the 'policy-chain'.[7] In scientifically controverted issues there is an increasing demand 'for greater public involvement in assessing the costs and benefits' (Jasanoff, 2003, p. 236). This need has been slowly acquired at the institutional levels of the EU. The adoption of the new governance method (NGM) within the classic Community structures of the CCM occurred with regard to environmental protection in which the flexibility in setting norms accompanied the 'market proceduralization' of Community law.[8] This happened in the case Consultative Forum on Sustainable Development, for example.[9]

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[7] Ibidem, 10.

[8] On the limits of this proceduralization of the Community market in the environmental field with regard to the right to a healthy environment see Ruggiu (2012a).

[9] This body is no longer extant. See Commission decision of 26 September 2001 repealing decision 97/150/EC *on the setting-up of a European Consultative Forum on Sustainable Development*.

A third category of new governance emerges from the partnership existing in the context of Community structural funding allocation through Community multi-annual programmes (e.g. FP6, FP7, Horizon, 2020). These partnership committees, in which the European Commission, member States, social and economic bodies and other expressions of civil society at local and regional level are represented, have great power in selecting research projects. In this instance we have the establishment of a case of multilevel and multi-actor governance which leads to inedited forms of governance.

Another instance of NGM is the figure of social dialogue established with the Maastricht Treaty which allows, in particular, the officially recognized representatives of employees and employers to enter into voluntary agreements that will subsequently be enacted as directives by the Council (Scott and Trubek, 2002, p. 4; Peters and Pagotto, 2006, p. 19).

A fifth category of new governance which deeply characterizes the model is the Open Method of Coordination (OMC) that has been developed with regard to the European Employment Strategy (Scott and Trubek, 2002; Peters and Pagotto, 2006; Pariotti, 2011). The OMC has been used since the European Council of Lisbon. Within the OMC member States agree on a set of policy goals but remain free to pursue them in the national context as regards the appropriate means and measures to be adopted. Mere cooperation is thus a less intrusive strategy than harmonization of national law and legislation. Its legal basis can be found in the provisions of the Article of the Treaty on the Functioning of the European Union (TFEU) ex-Article 99 TEC (member States' economic policies as a matter of common concern) and in Article TFEU ex-Article 128 TEC (member States' employment policies taking into account Council guidelines) (Peters and Pagotto, 2006). Related to the OMC is the concept of 'Environmental Policy Integration' (Art. 11 TFEU, ex-Article 6 TEC) which aims to horizontally integrate policy objectives of the different member States within the implementation of other areas of Community policy.

2.3.2 In the ambit of emerging technologies, with regard to nanotechnologies for example, the NGM is shaping the governance landscape (Kearnes and Rip, 2009, 16; Rip, 2002). In this framework,

emerging approaches to the governance and regulation of science and technology arise at both European and national levels, leading to forms of negotiation of regulation and standard setting on a supranational level in the ISO and OECD through the use of voluntary, principle-based forms of soft law (Kearnes and Rip, 2009; Mandel, 2009; Marchant et al., 2008). In this context we can observe the proliferation of non-state initiatives and the development of forms of voluntary regulation through codes of conduct, recommendations, guidelines, certification systems, as well as comitology and agency networking accompanying the emergence of a discourse on responsible technological development (Kearnes and Rip, 2009, p. 4). At both national and EU level new approaches to science and technology issues able to engage private actors are rising (Kurath et al., 2014). Through codes of conduct, for example, the regulator pursues the goal of setting rules that govern the adoption and the development of forms of self-regulation among the principal stakeholders (e.g. Ruggiu, 2014). These forms of regulation of processes of self-regulation are also known as a case of 'meta-regulation'[10] and are aimed at implementing the participatory nature of regulatory processes (Parker, 2009; Coglianese and Mendeson, 2010). In the Community ambit a good example of an inclusive process developed by the European Commission is the Code of conduct for responsible nanosciences and nanotechnologies research (EC CoC)[11] (Dorbeck-Jung and Shelley-Egan, 2013; Ruggiu, 2014). It could be also deemed as a case of 'meta-regulation in action'. The EC CoC was anticipated and followed by two consultation processes, one

[10] By the term 'meta-regulation' we mean the mere descriptive fact of the State regulating its own regulation as a consequence of policies applying transparency, efficiency and market competition to itself. Meta-regulation can also entail any other form of regulation (whether by tools of State law or other mechanisms) that regulates any other forms of regulation. In this regard it may include legal regulation of self-regulation (Peters and Pagotto, 2006, pp. 6–7).

[11] European Commission (2008) Commission recommendation of 7/2/2008 *on a code of conduct for responsible nanoscience and nanotechnology research*, C (2008) 424 final, available at http://ec.europa.eu/research/consultations/pdf/nano-consultation_en.pdf. Accessed 18 February 2015. On this see Chapter 3 in Part I.

held in 2007[12] and the other in 2009/2010[13] (Ruggiu, 2014). In the consultation paper for a European Code of conduct for responsible nanosciences and nanotechnologies research (2007) the Commission emphasized that it was part of an 'ambition to promote a balanced diffusion of information on nanosciences and nanotechnologies' and that the code 'would offer those following it recognition of a responsible approach towards nanosciences and nanotechnologies research, making their action more visible at the European level' (European Commission, 2007, p. 2). In this context the aim of the Community authorities was to involve member States, industry, universities, research organizations, research funding organizations and other parties to take concrete actions for the safe use of nanotechnologies. As expressly declared by the Commission: 'Good governance of nanosciences and nanotechnologies implies an open and transparent dialogue addressing possible risks and realistic expectations'. A second consultation process involving 304 European and international experts held in 2009/2010 aimed to implement the adoption of the EC CoC (Meili et al., 2011).

As shown above, new governance is a label which encompasses both mere departures from the CCM and new forms of governing. From the analysis provided above some characteristics of the concept clearly emerge (Scott and Trubek, 2002, p. 5ff.). These are: inclusion, heterarchy, flexibility and adaptability.

(i) Different approaches use new modes for fostering public participation by parts of civil society in policy-making processes. In this way policy-making becomes a process of mutual problem-solving among stakeholders.[14] New governance processes tend to encourage the participation of affected actors, instead of

[12] http://ec.europa.eu/research/science-society/document_library/pdf_06/consultation-nano-sinapse-feedback_en.pdf. Accessed 28 September 2017.

[13] http://ec.europa.eu/research/consultations/nano-code/results_en.pdf. Accessed 28 September 2017.

[14] Limits and shortcomings of the participatory approach are expressed by Simismans (2008). In particular, in the face of some questions, such as the case of emerging technologies, which implies the use of expertise and much technical knowledge, participatory arrangements are severely limited so that, even after the establishment of participatory paths, only experts can concur in defining the set of rules in those fields.

involving merely representative actors (de Búrca and Scott, p. 3). In this context public authorities do not disappear but maintain coordination competences by fostering inclusion and ensuring the preconditions of public engagement. In this regard transparency is a means of information sharing and learning. The social dialogue seems to respond to problems of democratic deficit. This often implies the delegation of problem-solving competences to the recipients themselves of Community norms (Scott and Trubek, 2002, p. 8).

(ii) The NGM tends to develop forms of coordination and integration of the diverse actors at play with multilevel arrangements able to integrate several dimensions such as localities, subnational, national and European regions according to modes that facilitate dialogue among parties. Thus, rather than hierarchically operating through the structure of the authority of central government, NGM fosters the emergence of infrastructures of governance that ensure coordination or exchange among constituent parts (de Búrca and Scott, p. 3). While traditional approaches to law look for hierarchy and put courts at the centre of systems of accountability, the NGM searches for heterarchy and often looks outside courts to find the real accountability of governance processes and structures (Scott and Trubek, 2002, p. 8). Here heterarchy means the abandon of hierarchical relations based on command-and-control logic in order to foster voluntary behaviour of stakeholder. Thus in this framework the coordination by public institutions is still strategic. For this reason, the regulation (hard and soft law) is still a means to reach to goal of obtaining the voluntary cooperation of stakeholders.

This model relies on the assumption that diversity and decentralization are values worthy of being pursued inasmuch as it ensures effectiveness of the system. In this regard it privileges forms of power delegation in favour of the lowest level possible when it is feasible. This fact relies on the subsidiarity principle according to which decisions should preferably remain at national level by amplifying the trend to accept diversity, allow flexibility and encourage decentralized experimentation. While a traditional

conception of law searches a unitary and ultimate source of authority, the NGM looks for the fragmentation and dispersion of authority and is based upon fluid systems of power sharing (Scott and Trubek, 2002, p. 8).

In this context deliberation processes (e.g. consultations) are conceived for extending participation to stakeholders. In this way the capability for problem solving can be ameliorated and processes are endowed with a certain degree of democratic legitimation (Pariotti, 2011). In this regard, several mechanisms are designed for implementing cooperation among member States instead of increasing uniformity at Community law level.

(iii) This approach implies the flexibility and revisability of decision-making processes. A certain degree of elasticity in decisions, strategies and standards is essential to promote cooperation between the different parties involved in the legislative process. This implies abandoning forms of governance which rely on formal standards and hard legislations in favour of forms of soft law and interaction between different dimensions of normativity (ethical, technical, etc.). While a traditional conception of law relies on a clear distinction between law making on the one hand, and rule application and implementation on the other, the NGM tends to privilege indeterminate and flexible rules as more suited to meeting the challenges of modernity (Scott and Trubek, 2002, p. 8).

The NGM is characterized by strong forms of experimentalism (tentative governance) which tend to create knowledge by fostering informal modes of information exchange, benchmarking performance, and sharing best practices, which rely on multilateral surveillance instead of rigid forms of control among the parties involved. While the traditional conception of law underlines the linkage with existing knowledge, the NGM is a continuous process of generating new knowledge and data with a view to preparing new solutions and needed (albeit abrupt) changes of direction (ibid., p. 9). In emerging technologies field, some talk of 'tentative governance' meaning that these forms of governance develop according to a case-by-case logic (Stoke and Bowman, 2012)

and encompass 'provisional, flexible, revisable, dynamic and open approaches that include experimentation, learning, reflexivity, and reversibility' (Kuhlmann et al., 2012).

We must not think that the NGM implies surpassing classic modes of regulation completely. In this context the traditional forms of regulation remain in the background, though they do not disappear (Scott and Trubek, 2002; Eberlein and Kerwer, 2004; Smismans, 2008). It is true that not only old instruments, such as agency and comitology, concur with new forms of governance (consultations processes, social dialogue), but traditional forms of regulation can pursue the goals of fostering public participation and flexibility within the new governance paradigm. In this regard, a hybrid dimension of governance, mixing new and classic patterns, has been reached at the EU level in the field of nanotechnologies.[15]

(iv) Finally, the NGM is characterized by adaptability. The complexity, which needs to be governed, causes great uncertainty regulatory, ethical, scientific. In this context the regulator does not have any prefixed recipe. If the aim of adapting previous regulatory structures. In a given field which is rapidly developing, there are most chances to control at early stage, with far fewer costs but too little information to decide how to act or not to act (Kearnes and Rip, 2009, p. 99). In this framework a too anticipated regulation risks of stopping opportunities of development especially in the field of emerging technologies where some unknown and unforeseen risks are often integral part of innovation (Owen et al., 2013). In this context scholars and policymakers prefer to rely on existing regulation and eventually adopt new rules when risks become apparent (Stoke and Bowman, 2012). This is the reason why in the meanwhile some flexible tools can better cope with challenges of rising fields that are just at their infancy. Yet, to apply previous legislations on novel fields of innovation is quite problematic since they could not foresee risks and harms that can be known only today.

[15] See Chapter 3 of Part I on European governance of emerging technologies.

A sub-specie of the new governance model is that of the self-governance. It can be deemed as a variation of the NGM since it stresses only some features and partially diverges from new governance paradigm. It is characterized by (i) autarkic nature, (ii) deep spontaneity, (iii) surrogatory character, (iv) flexibility and (v) provisory nature. Governance in this context tends to be a complex process of co-governance that involves a number of private subjects (sometimes also public authorities) through a redistribution of tasks and the establishment of distributed poles of self-government (Sørensen and Triantafillou, 2009). In self-governance stakeholders spontaneously take the initiative in order to arrange by themselves a flexible governance framework. Stakeholders take the initiative without any inputs stemming from public authorities. It is a spontaneous initiative. Thus, like NGM it tends to enlarge the participation. In this sense it is a form of self-organization in a given field where the initiative is taken by a given group of stakeholders where public institutions are only a part and play a peripheral role. It uses flexible and not legally binding tools in order to self-arrange a minimal governance framework. This process of self-coordination tends to develop through the adoption of self-regulatory instruments, forms of voluntary cooperation, shared programming and participated negotiation among different parts (ibid.). Differently from new governance patterns self-governance arrangements do not try to adapt any existing regulatory framework. It mainly develops when a technological field is at its infancy and public institutions do not provide any structure in this field yet. In this sense, in front of the inertia of public institutions self-governance aims at substituting the public sector in providing a regulatory framework. From this perspective it testifies the increasing importance of the private sector. The risk here is of being only a partial representation of the interest at stake. It is destined to be replaced by an institutional governance arrangement. 'Community self-governance provides a realistic and potentially powerful complement or alternative to regulation, legislation, treaties and other interventions by outside entities. [. . .] While self-governance tends to be less stringent than legislation and cannot change existing laws or institutions, it also offers significant advantages. First, self-governance is the

right thing to do [. . . since] biologists need to "take responsibility" for "preventing potential misuses of their work." Second, almost always faster than other methods. Third, it derives from consent and is therefore frequently more elegant than externally imposed solutions. Finally, it is inherently international. This can be a crucial advantage in a world where science and commerce routinely span national boundaries' (Maurer et al., 2006, p. 4). The advantages of this should be greater efficacy, a greater efficiency and a greater democratization of the process (Sørensen and Triantafillou, 2009). Like the NGM, self-governance aims at providing efficacy to governance structures and at filling the lack of legitimation of the action of governance.

In face of the novelty of the NGM several attitudes stemming from the new governance model have been adopted by the CJEU. In one instance NGM has been clearly recognized by the Community jurisprudence. In *Stanley and Metson*[16] the Luxembourg Court recognized that the Nitrates Directive could be applied by member States in different ways since it does not intend to seek uniformity in national laws, but rather to get them to create the measures needed for ensuring protection against pollution by granting them wide discretion in identifying the waters covered by the Directive. Thus the Court acknowledged that the Directive pursued the objective through the instrument of social dialogue, but according to modes identified by the NGM. In this regard it assessed the capability to represent the several parties involved and the concept of 'collective representativity'. In this framework the participation of any party becomes essential in configuring this representativity (Scott and Trubek, 2002, p. 13).

The NGM has been endorsed also by EU institutions. According to the White Paper on Governance, five principles underpin good governance. In fact, in the Commission's view, the EU should implement its ability to pursue openness, participation, accountability,

[16]Judgement of the Court of Justice (Fifth Chamber), *The Queen v Secretary of State for the Environment and Ministry of Agriculture, Fisheries and Food, ex parte H.A. Standley and Others and D.G.D. Metson and Others*, of 29 April 1999 (Case C-293/97) [1999] *ECR I-2603*.

effectiveness and coherence.[17] First of all, Community institutions should work in a more open fashion. Thus, they, together with member States, must communicate what they do and the decisions that they take in an accessible language. Then, the relevance and quality of EU policy effectiveness depends on the implementation of a participatory path able to engage a broad part of civil society in decision-making processes. In this regard central governments must follow an inclusive approach when they implement EU policies. Thus, each Community institution must explain its role in legislative and executive processes and take responsibility for what it does. This process of the development of accountability must be taken at every level by member States too, therefore. Policies must be effective and timely, delivering what is needed, a clear array of objectives, an evaluation of their future impact and past experiences. Finally, all EU policies must be coherent and easily understood. In this framework we can clearly see the influence of new forms of governing on trajectories of EU policies.

2.4 The Theoretical Framework of the Relationship between Law and 'New Governance'

2.4.1 The rise of the NGM can be an opportunity for rethinking the relationship between law, as well as those recent expressions of law such as human rights, and the emerging processes of governance at the European level. The 'new governance turn' with its bag of flexibility, revisability, decentralization and new participatory approaches tends to strongly distinguish itself from law.

There is scepticism in the research community on the capability of the regulation of interpreting the new paths of modern times. In this sense some criticized the capability of regulation in general, and human rights in particular, to cope with the fast course of innovation with its bag of unforeseen risks and unpredictable harms, especially

[17] European Commission (2001) *European Governance: a White Paper*, 25.7.2001, COM (2001) 428 final, p. 10, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri= CELEX:52001DC0428&rid= 2. Accessed 29 September 2017.

in the face of emerging technologies (Groves, 2015). For example, to justify resort to governance arrangements, Mihail Roco (2006, p. 13) stated that '[b]eyond very simple principles, no single set of rules of ethical behaviour is universally accepted'. In this context human rights could maintain only a residual role. For instance, René von Schomberg (2013) who defends a version of governance which entails EU fundamental rights, argues that within the EU framework human rights can be reflected in Community international policies by demonstrating European Union solidarity with the poorest on earth. Governance structures, especially in their novel form, tend to put in question the adequacy of traditional expression of law to cope with rapid changes triggered by innovation that need to found policy decisions on large consent. For example, some addressed a tendential inconsistency between tools of public engagement and those prefixed goals such as individual rights (Heydelbrand, 2003, p. 234). If processes of participation aim at identifying purposes and values of innovation, the value of the democratic participation, according to which the society decides what are its priorities, need to be preserved. In this context individual rights could alter the prioritization established by the majority in the face of technoscientific progress. According to some no decision even by a Constitutional court could subvert what people have democratically decided through processes of participation (Waldron, 1999, p. 94). In this framework the relationship between governance and regulation appears problematic. Thus, it is worthwhile asking whether these two phenomena (i.e. law and the NGM) represent two forms of a compatible or antagonist existence, and in this contest how rights can be structured in the face of new governance.

With a view to answering this question, it is useful to articulate the conceptual framework of this controversial relationship.

The relationship between law and new governance has been variously interpreted in literature (de Búrca and Scott, 2006). These different interpretations must not be deemed as necessarily alternative, but, to some degree, complementary since they variously contribute to an understanding of the controversial relationship between law, especially constitutional law with its bag of individual rights protected at national and supranational levels, and new rising forms of governance.

2.4.2 In this theoretical landscape we can identify three theses: the 'gap thesis' (with its sub-thesis), the 'hybridity thesis' (with a further three articulations), and the 'transformation thesis'.

According to the 'gap thesis' there is a hiatus between formal law and the practice of new governance (ibid., p. 4ff.). In this view, formal law is broadly blind to new governance trends and, in turn, governance tools are completely extraneous to law. In fact, legal texts, including constitutional ones, cancel the relevance and presence of new forms of governing. In this regard, law either cannot not keep pace with the developments of new governance or ignores them as they do not conform to its requirements, presuppositions and structures. We can address two distinct tendencies within the 'gap thesis'. One argues that law is resistant to the new governance phenomenon and in this regard it should be deemed as impermeable to these new trends. The other argues that law is facing a reduction of its capacity. The 'resistance argument' holds that law is an obstacle or an impediment to new governance. It would not only be blind to this trend, but it would also tend to inhibit this experimentation (Trubeck, 2006; Lobel, 2006; Sturm, 2006). The argument of 'law reduced capacity' is instead preoccupied not with what law does, but with what it can no longer do. The mismatch between its fundamental premises and those of new governance would put in peril the law's capacity to steer and inform normative directions of policy and to ensure the accountability of diverse actors in governance. Evidence of this blindness could be deemed the non-ratification of the EU Constitution due to the prevalence of new forms of governance that privilege the involvement of civil society (Kilipatrick, 2006).

The 'hybridity thesis' deals with the issue of the relationship between law and governance in a more optimistic and constructive fashion, viewing them as mutually interrelated and mutually sustaining (de Búrca and Scott, 2006, p. 6ff.). Each sphere potentially shares its own strong points by mitigating its own shortcomings. This thesis has both a descriptive and a normative version. According to some, the hybridity of law and new governance is a transitory phenomenon towards the complete embrace of new governance styles. According to others, it is a long-term phenomenon and not simply a passing stage.

In this framework the role of soft forms of regulation comes into consideration. The simultaneous and mutually interdependent resort to hard and soft law is the main characteristic of EU governance. Within the context of the development of new trends of governance soft law is variously interpreted. According to some, soft law is the second-best choice, less effective and alternative to hard law (Kilpatrick, 2006). According to others, it is less a tool for directly constraining and more a transformative tool able to change behaviour (Trubeck, Cottrell and Nance, 2006).

De Búrca and Scott (2006) draw three versions of the 'hybridity thesis': the 'baseline or fundamental normative hybridity', 'functional/developmental hybridity', and 'default hybridity or governance in the shadow of law'.

According to the 'baseline or fundamental normative hybridity' the framework of traditional legal tools still plays a relevant, if not prevalent, role (ibid., p. 7ff.). In this framework, constitutional norms and established rights that remain binding and justiciable appear essential. While new governance arrangements can serve to enhance the efficaciousness of hard law instruments, this normative dimension of constitutional rights represents the bottom-line below which the experimentation of new governance cannot take place. In this context we can also consider human rights, meaning that they are a sort of 'forbidden field' over which governance can never go.

With 'instrumental/developmental hybridity' the use of new governance tools represents a means for developing or applying the existing legal norms (ibid., p. 8ff.). These instruments serve for the elaboration and continuous transformation of the old legal ones. In this regard, the EU context could be deemed as a clear example of this version of the hybrid relationship between law and the new processes of governance (Scott and Holder, 2006). Accordingly, the Union would combine new governance tools within binding framework directives which are binding with regard to their aim, while they leave discretion with regard to the choice of the best measures needed for their implementation. Thus new governance tools would serve for the implementation of traditional Community tools. In the experience of the 'instrumental or developmental hybridity' new governance arrangements would be considered as means for the applying, elaborating and ensuring respect for legal

and constitutional rights, for both new rights, such as social rights, and old ones, such as classic civil and political rights (de Búrca, 2006; Strum, 2006; Harvey, 2006). In this context some propose making the fundamental rights of the EU the beginning of an internal transformation of Union policies on emerging technologies (von Schomberg, 2011, 2013). Indeed, EU fundamental rights, together with other Union goals, are established in the treaties or in acts having the same force as treaties (i.e. the EU Charter) and can work within the EU governance as 'normative anchor points' by steering and guiding the choices of Community authorities in a proactive and anticipatory style, even influencing in advance research funding decisions and deciding which research projects are to be funded (von Schomberg, 2013).[18]

The thesis of 'default hybridity' or 'governance in the shadow of law' argues that legal norms represent a form of 'default penalty' applicable only when new governance tools fail to conform to stakeholders' behaviour (de Búrca and Scott, 2006, p. 9). Indeed, an earlier use of penalty defaults produces compliance in underregulated areas in which law encounters difficulties of enforcement. This leads to forms of regulation that are voluntary instead of mandatory. The increasing importance and influence of transnational or multinational corporations is an instance where mechanisms of command-and-control can enter into crisis. In this context, the use of mandatory rules is no longer useful especially if these corporations operate abroad. Furthermore, even inside national borders, instead of complying with statutory rules, great corporations are able to avoid the application of rules and to influence law-making processes. For these reasons resort to voluntary forms of regulation can produce interesting outcomes. This case is well exemplified in the environmental governance of the US, where the threat of federal intervention can induce States to elaborate clean air implementation plans (Karkkainen, 2006; Lobel, 2006).

The 'transformation thesis' argues that new governance implies a reshaping of the concept of law by abandoning a more formalistic

[18] On this see Chapter 3 of Part I on RRI.

and positivistic conception of law (de Búrca and Scott, 2006, p. 9 ff.). We need to rethink structures and forms of law according to new trajectories of social, economic and, above all, technological governance. The basic premises, normative presuppositions and functions of law thus need to be rethought in the light of emerging new practices and of public law in particular (Simon, 2006; Pariotti, 2011). 'Law, as a social phenomenon, is necessarily shaped and informed by the practices and characteristics of new governance, and new governance both generates and operates within the context of a normative order of law' (de Búrca and Scott, 2006, p. 9).

The rise of human rights in the national dimension through judicial practices which necessarily transcend the boundaries of each single State re-propose the question of the relationship between rights and new developments of governance with special regard to the European context. Notwithstanding the efforts of the scientific community, this relation still remains controversial. By paraphrasing de Búrca and Scott (2006), these new forms could either attempt an instrumental use of legal norms and human rights law practices or they could remain untouched by higher practices of European human rights law, or they could stand in the face of human rights law in an antagonistic manner by eroding one another's ambit of existence.

2.5 Soft Law: Nature, Justification, Functions, and the Issue of Its Legitimation

2.5.1 With the openness of law to soft forms of regulation we are in the territory of new governance. As acknowledged by Peters and Pagotto (2006, p. 4) 'both in international law and on the EU-level, governance by means of soft law is not new at all'. By 'soft law' we mean any set of norms and mechanisms that, even if not binding or enforced by virtue of a formal legal sanction or mechanism, have legally relevant effects (Pariotti and Ruggiu, 2012, p. 157 nt. 2; Ferrarese, 2010, p. 36). The resort to novel types of acts by political authorities represents a means to overcome the lack of formal

law-making capacity (Peters and Pagotto, 2006, p. 5). The increasing climate of uncertainty and the complexity of global contexts suggest adopting less demanding and more flexible regulatory instruments. Furthermore, when there are concerns about the possibility of non-compliance the use of non-binding tools can be a more prudent strategy of regulation. Finally, the absence of legal sanctions makes resort to soft law more rapid and simpler than the conclusion of a binding treaty (ibid., p. 24). With regard to States, it is easier to adopt obligations stemming from soft law norms since they do not threaten the States' sovereign identity. With regard to enterprises, which are more sensitive to egoistic interests such as profit, makes it is easier to adopt these obligations since they need to augment their credibility in the business sphere, by adopting self-regulatory codes and thus assuming the image of an 'ethical enterprise' (Ferrarese, 2010, p. 40).

The rise of soft law in legal culture implies the abandoning of a binary view of law, according to which either it is law or it is non-law but *tertium non datur*, for a 'graduated conception of normativity', according to which 'there is no bright line between hard and soft law. Legal texts can be harder or softer' (Peters and Pagotto, 2006, p. 12; Peters, 2011, p. 23). The binary law view of Kelsenian origin holds that recognizing the status of law as non-binding ultimately obscures the meaning of law and undermines its normative power. It erodes the normative power of the international legal order as a whole. Notwithstanding the clear advantage of providing simple dichotomic structures, the first danger of this conceptualization can be an oversimplification. Instead, the graduated normativity view provides a quantitative interpretation of reality that appears more realistic and closer to the real evolution of international standards. In fact, reality leads us to a normative continuum where norms can be harder or softer but not simply black or white. Starting from a typological conception of law we can understand that there is a plurality of types of law, but we must also acknowledge that conceptual categories are merely indicative and only the practice of law can tell us whether we are facing law or non-law phenomena. A characteristic of graduated normativity is the distinction between rules, principles, and standards that

nowadays scholars[19] increasingly acknowledge (Peters and Pagotto, 2006, p. 9). This variety of typological norms better explains the continuum of norms inside the law and the contemporary presence of differences and similarities among different realms of normativity (legal, ethical, technical and so forth).

2.5.2 In the perspective of regulation theory, resort to soft regulation has been justified in two ways: either with the 'reflexive regulation theory' or with the 'responsive regulation theory' (Pariotti, 2011). The first considers the law as the centre of a process through which individuals, organizations, and other social entities give rise to forms of spontaneous cooperation using the means of soft law (Teubner, 1983). According to the latter, law is a means to express and spread social values, and soft regulation can be a tool for helping to pursue this objective effectively (Ayres and Braithwaite, 1992; Marchant et al., 2008; Bowman and Hodge, 2006).

In the view of 'reflexive regulation theory', instead of pursuing the outcomes of social processes through the means of regulatory responsibility, reflexive law restricts itself to the installation, correction, and redefinition of democratic self-regulatory mechanisms (Teubner, 1983, p. 255). In this context, legal structures can reinterpret themselves in the light of external needs and demands that are selectively filtered through regulatory processes and adapted in accordance with a logic of normative development (ibid., p. 249). In this context the use of voluntary forms of arrangements is not only strategic, but the only way of realizing the 'self-reference of legal structures' by providing forms of integration and coordination of each sub-sphere within the same systemic environment (ibid., p. 274). In other words, law is only the medium for achieving the self-reflexivity of all sub-systems (politics, science, economy, moral and law) in functionally differentiated societies, thus performing a merely integrative function (ibid., p. 275).

In the perspective of 'responsive regulation theory', law has a motivational goal. Here '[p]ublic regulation can promote private

[19] In particular, this distinction is acknowledged by scholars of legal hermeneutics (Dworkin, 1977; Esser, 1971; Zaccaria, 1990; Pastore, 2003). On the distinction between rules/principles see also Alexy (2002).

market governance through the enlightened delegation of regulatory functions' (Ayres and Braithwaite, 1992, p. 4). As regulation responds to industry conduct, to how industry is effectively making private regulation work, law attempts to make market private actors responsible through the delegation of normative functions that should be deemed as neither wholesale nor unconditioned but motivated by given social values. In this regard, private actors are maximizers or at least satisfiers of some social values (ibid., p. 79). This flexible approach can be illustrated by the construction of an 'enforcement pyramid' which depicts the spectrum of all possible sanctions, from persuasion and warnings at the base, up through civil, licensure, and criminal penalties at the apex (Marchant et al., 2008, p. 51). This picture captures the range of regulatory strategies available, from self-regulation at the base, through supervised or enforced self-regulation and other forms of interaction among public and private actors, to standard forms of command-and-control arrangements with a range of different penalties provided for. 'The threat of regulatory intervention both deters non-compliance by potential defectors and encourages all firms to develop an attitude of social responsibility' (ibid., p. 52). Thus, according to 'responsive law theory', self-regulation is the means for expressing and implementing responsibility in all key actors. Recently an 'incremental version' of the 'responsive regulation theory' has been developed in the field of nanotechnologies. According to this version the different regulatory layers of the pyramid have to be seen through time, thus considering different regulatory strategies as sequentially ordered, beginning with softer and decentralized measures able to gain greater information, then using less flexible and more intrusive means according to a command-and-control style (ibid., pp. 52–53).

2.5.3 We can identify three functions in soft regulation: pre-law, plus-law, and para-law functions.

Soft law instruments can have a pre-law function when they are adopted with a view to the elaboration and preparation of future international treaties or Community legislation (Peters and Pagotto, 2006, p. 22; Peters, 2011, p. 34). When binding rules are unavailable or inopportune for other reasons, soft law may give an impulse to

legislative processes, phenomena of building mutual confidence, and further political negotiation. The first legal effect produced by the adoption of soft law is that the subject involved is removed from the *domain reserve* of the State (de-nationalizing effect). Therefore, *ultra vires* soft law can pave the way for a formal extension of competences of the organization concerned. A second significant effect is that the promulgation of soft law declarations and conclusions can be indicative of an existing *opinion iuris* in the direction of those instruments (promoting effect). A further pre-law effect, on the other hand, could be the creation of legal uncertainty. In this regard both Article 263(3) TFEU and the European Parliament warned against the abuse of pre-legislative instruments (Peters, 2011, p. 35).

Soft law instruments can have a plus-law function within 'mixed regimes' of hard and soft law by complementing hard regulation. In this regard it is generally accepted that soft law makes hard law concrete and guides the interpretation of it (Peters and Pagotto, 2006, p. 23). Thus in the interpretation of hard legislation norms the CJEU can take into account soft texts to clarify the meaning of a general concept or some hard legislation provisions (Peters, 2011, p. 36).[20] Moreover national judges are also obliged to take into account soft law texts such as recommendations in their interpretation.[21]

Lastly, soft law regulation can constitute a surrogate of hard law. In situations where the only alternative to the resort to soft law is anarchy, soft law is more than the second-best solution (Peters, 2011, p. 37). In these instances, a soft solution can help to overcome deadlocks in the relations between States when the efforts of hard law have failed (or might fail). Powerful States might prefer recourse to soft law to retain their freedom of action while showing a cooperative attitude at the same time. Weaker States can adopt soft law instruments as the best they can politically achieve. But soft law can be the only legal instruments possible (ibid., pp. 14–18). Indeed, in international law there is a category of subjects

[20] Judgement of the Court of Justice, *The Queen v the Licensing Authority*, *established by Medicines Act 1968, (acting by The Medicines Control Agency) ex parte Generics (UK) Ltd and Others*, of 3 December 1998 (Case C-368/96) *ECR I-7967*, para. 12.

[21] Judgement of the Court of Justice, *Salvatore Grimaldi v. Fonds des maladies profesionelles*, of 13 December 1989 (Case C-322/88) *ECR I-4407*, para. 18.

such as transnational enterprises which are not endowed with legal subjectivity (Pariotti, 2007, 2013). In this case the only way to impose legal obligations, such as those concerning human rights, can, when they act abroad, be resort to soft law. In this regard, in the field of nanotechnologies we have observed the phenomenon of the 'proliferation of codes of conduct' especially among large corporations (Kernes and Rip, 2009).

2.5.4 The spread of soft instruments among private actors has led to a sort of 'privatization of law', namely to the diffusion of private or semi-private soft law such as self-regulation and co-regulation (Peters, 2011, p. 41). This phenomenon raises problems of both effectiveness and legitimation which appear to be mutually interconnected. Excessive standardization can lead to the phenomenon of over-regulation. Moreover, unlike the case of private exchanges and private law, the base of legitimation of standard setting does not rest on private autonomy and non-state actors' consent as standards have a general scope. In fact, unlike the contract sphere, standards address and bind not only the authors of these norms, but also third–parties. In these instances, non-state actors not only regulate themselves and their future behaviour, but also others who have not participated in the processes of standard setting. Thus consent is only a partial basis of its legitimation (ibid.).

Indeed, a further basis of legitimation could be the delegation by governments or by the European Union when member States or Community authorities have delegated the standard-setting powers to private actors. Since States have the overall legitimacy and authority to produce norms, acts of delegation can provide private actors with the legitimacy lacking in standard-setting processes. In highly complex global contexts governments lack both knowledge and the capacity to regulate issues that transcend state boundaries. In this framework business actors can offer their expertise to improve standard-setting processes and at the same time concur to design norms in a more suitable fashion according to their primary interests. In this regard, at the global level 'power appears diffuse among public and private nets which, due to their structure, ways of functioning, aims, and lack of international law subjectivity', tend to elude national and international rules, such as human rights

(Pariotti and Ruggiu, 2012, p. 162). In these contexts, traditional tools of regulation can be useless or largely ineffective. Self-regulation can set constraints and standards to relevant subjects' behaviour by acting from the inside of the enterprise organization. Furthermore, it can also involve relevant private actors whose expertise may be taken advantage of when setting the rules (i.e. researchers, research centres, funding organizations). Since, in the globalized world decisional processes are increasingly decentralized and *de facto* involve non-state actors, the main criterion of the legitimacy of regulation is not given by its connection to the idea of representation as its ability to foster accountability. In other words, possibilities to improve compliance with norms of soft law and their effectiveness depend on the fact that firms' behaviour goes along with other actors' expectations. In this sense, accountability can increase only in the presence of adequate accountability practices that foster information exchange, transparency, and the justifiability of an enterprise's choices in the face of other stakeholders. In this context the voluntary resort to forms of undue regulation can be a means to consolidate stakeholders' trust. Only the acknowledgement and the assumption of responsibility for actions, decisions and an enterprise's policies can strengthen the network of relations among all actors and create a climate of confidence for supporting compliance with norms of both hard and soft regulation. In this regard soft norms all fall within the path of accountability practices since the lack of acknowledgement of one's own accountability leads to the failure of the compliance mechanisms provided. Thus, in the end, accountability is to be deemed as the source of soft law legitimation (ibid.).

2.6 Soft Law and Corporate Social Responsibility

2.6.1 According to Parker (2009, p. 207) the idea of Corporate Social Responsibility (CSR) hides an inner paradox since it tries to include compliance with business' legal responsibilities, but goes 'beyond compliance' to encompass the economic, ethical and discretionary expectations of civil society. Indeed, society needs the production of certain goods and services that are not yet on

the market, the adoption by enterprises of additional forms of behaviour that are not necessarily codified into legal texts, even when members of society do not have a clear-cut message on those forms of behaviour, but nonetheless they want them to be followed by business. In these instances, CSR tends to build a sort of 'compliance beyond compliance'. While regulation works by holding people legally accountable to meet thresholds set up by legal standards through forms of liability, CSR 'internalizes standards by building them into self-conceptions, motivations and habits' of the organization, thus extending the responsibility of the business enterprise (ibid., p. 213).

Since technological innovation became a successful business strategy, the rise of emerging technologies has gone hand in hand with the development of the market, and many high-technological products have reached the store shelves. The case of nanotechnologies is in this sense emblematic. While nanotechnological research promises to revolutionize our life, by providing new cures for cancer, solving the global food scarcity, enhancing human performance, giving rise to even more wearable technologies, nanotechnologies invade our shops at every corner. Nanotechnologies are currently used in OLED technology (organic light-emitting diode) that gives rise to a multitude of high-tech products in our houses, such as television screens, computers monitors, mobile phones and gaming consoles. Yet, nanotechnologies are also largely used in cosmetics, such as face and hand creams, toothpastes, in food packaging, toys, sportswear, and so forth. Thus, although some hold that mass personalization and distribution has substituted forms of mass production, such as in the case of nanomedicine (Roco, 2006), mass production processes still represent the main landing place of emerging technologies in the global market. The problem, however, is that many people often do not know it yet (Throne-Host and Strandbakken, 2009).

The large diffusion of emerging technologies in goods used in our everyday lives underlines the relevance of firms and corporations, mainly those of a transnational size, within the global governance framework. We must not forget that the globalization of the market gives these multi- and transnational corporations, which are without any subjectivity in international law, the chance to avoid compliance

with international obligations set up for the protection of human rights (Pariotti, 2007). Due to their dimension, transnational corporations can exert a quasi-political power (Pariotti, 2013, p. 140). In fact, they can influence the goals and the agenda of both politics and regulation. Then, when transnational corporations dislocate part of their production abroad, they can influence the policy choices of their host countries. They can, in any case, directly produce rules through acts of self-regulation. In sum, they can shape policies, rules and even ideas (ibid.). Moreover, since the economic context has become global, normative differences between several legal orders can encourage the 'lex and fora shopping phenomena' among enterprises which have the resources to do business in a plurality of countries and choose the best regulatory conditions in which to develop it (ibid., p. 140). When transnational corporations act abroad, outside their home State borders, they can become opaque to international law and elude the State's control.

2.6.2 Both international and national laws have relevant limits in imposing the State's responsibility for human rights violations when private actors are at stake (ibid., p. 147). Due to their structural features, human rights are able to reach the State's responsibility (their 'vertical effect'), but they tend to evaporate when non-state actors such as transnational corporations are at play. In these instances, in order to strengthen their 'horizontal effect' among private actors, self-regulation is suitable and the paradigm of CSR arises (Pariotti, 2007, 2013; Pariotti and Ruggiu, 2012).

With regard to the possibilities of protecting human rights when non-state actors are at stake, three theories structure the relationship between responsibility and international personality in different ways (Pariotti, 2013, pp. 142–143). The first conception refuses to acknowledge any legal personality to entities different from States and thus to attribute business enterprises with any responsibility for breaches of human rights. The second theory, though it does not tackle the question whether they have any personality or not, holds that it is possible to ascribe the responsibility for human rights violation to firms. The third theory, finally, tends to attribute transnational corporations with partial international subjectivity with regard to the duty to abstain from human rights violations

(Weschka, 2006, p. 659) and the possibility of considering them responsible for human rights breaches.

International law has developed several instruments to strengthen the protection of human rights when transnational corporations' behaviour runs the risk of leading to violations (the so-called 'horizontal effect' of human rights). Here we can mention several International Labour Organization (ILO) initiatives such as the Tripartite Declaration on Fundamental Principles Concerning Multinational Enterprises and Social Policy[22] of 1977, which addresses governments, workers' and enterprises' organizations and transnational corporations by offering detailed guidelines especially with regard to human rights; the Declaration on Fundamental Principles and Rights at Work[23] of 1998 which encompasses all four core labour standards, namely freedom of association and the rights to collective bargaining, the effective abolition of child labour and the elimination of discrimination in employment and occupation (Weschka, 2006, pp. 645–646). We must also mention the Organization for the Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises.[24] Finally the International Chamber of Commerce (ICC) Business Charter for Sustainable Development[25] addresses enterprises with a view to steering their behaviour according to principles which are not merely based on business (Pariotti, 2013, p. 145).

[22] ILO (1977) *Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy*, adopted by the Governing Body of the International Labour Office at its 204th Session (Geneva, November 1977) as amended at its 279th Session (Geneva, November 2000), (2002) 41 ILM, 186–201, at 186–187, http://www.ilo.org/wcmsp5/groups/public/—ed_emp/—emp_ent/—multi/documents/publication/wcms_094386.pdf. Accessed 2 September 2013.

[23] ILO (1998) *ILO Declaration on Fundamental Principles and Rights at Work*, 86th Session, Geneva, June 1998, http://www.ilo.org/public/english/standards/relm/ilc/ilc86/com-dtxt.htm. Accessed 2 September 2013.

[24] Organisation for Economic Co-operation and Development (1976) *The OECD Guidelines for Multinational Enterprises. 2011 Edition* OECD Publishing, 2011, http://www.oecd.org/daf/inv/mne/48004323.pdf. Accessed 2 September 2013.

[25] International Chamber of Commerce (ICC) (1991) *Business Charter for Sustainable Development: Principles for Environmental Management, Year 2000 Edition*, Second World Industry Conference April 1991, ICC, Rotterdam, http://www.iccwbo.org/Advocacy-Codes-and-Rules/Document-centre/2000/ICC-business-charter-for-sustainable-development-(2000)-(EN/FR/ES)/. Accessed 2 September 2013.

At the UN level it is worthwhile mentioning the Global Compact and the UN-Norms. The Global Compact[26] is a governance framework, an initiative of the ex-UN-Secretary General Kofi Annan, of a voluntary nature, 'open to business, which strives to promote ten principles through a variety of instruments, such as dialogue, learning and projects' (Weschka, 2006, p. 650), covering the areas of human rights, labour rights, the environment and corruption. In 2004 it was endowed with a sanction mechanism based fundamentally on public criticism, whose aim is to lead towards greater accountability of business enterprises. In August 2003 the UN-Sub Commission on the Promotion and Protection of Human Rights adopted the UN Norms on the Responsibilities of Transnational Corporation and other Business Enterprises (UN-Norms)[27] which provides a comprehensive set of global business standards including a broader range of human rights, then those protected by other instruments and bearing the UN *imprimatur* (ibid., p. 654). The UN-Norms directly envisage provisions of their implementation in the text itself (ibid., p. 655). The document encountered significant opposition from the business sector and thus the Commission on Human Rights ultimately determined in 2004 that it had no legal standing (i.e. it was annulled). Finally it was substituted in 2005 by the Protect, Respect and Remedy Framework on Transnational Corporation and Human Rights[28] also known as Ruggie's principles (from John Gerard Ruggie, the author of the guiding principles), recently endorsed in 2011 by the UN Human Rights Council.

None of these instruments are binding and rest on merely voluntary bases.

The rise of forms of self-regulation is at the base of the development of the CSR paradigm in business ethics. According

[26] UN Global Compact Homepage, http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html. Accessed 4 September 2013.

[27] ONU (2003, 13 August) *UN Norms on the Responsibilities of Transnational Corporation and other Business Enterprises with regard to Human Rights*, Document E/CN.4/Sub.2/2003/38/Rev.2 (26 August 2003), http://www1.umn.edu/humanrts/links/norms-Aug2003.html. Accessed 4 September 2013.

[28] ONU (2011) *Protect, Respect and Remedy Framework on Transnational Corporation and Human Rights-Guiding Principles*, http://www.business-humanrights.org/media/documents/ruggie/ruggie-guiding-principles-21-mar-2011.pdf. Accessed 4 September 2013.

to CSR business enterprise does not only hold obligations of an economic origin (i.e. making profits), nor exclusively legal obligations (to workers, suppliers, costumers) stemming from binding rules, but also kinds of moral and social obligations to all stakeholders variously affected by its activity (Pariotti, 2013, p. 145). Voluntary tools (such as codes of conduct, the promotion of social projects having value for a given community where the firm itself acts, third-party certification systems) can extend the scope of an enterprise's responsibility. The rationale of these voluntary tools rests on the progressive involvement of stakeholders in order to build an alliance among all different interests. In this sense CSR is 'a set of vague, discretionary and non-enforceable corporate responses to social expectations' (Parker, 2009, p. 208).

Within stakeholder theory, the term 'stakeholder' means either who has an interest or an eligible claim to the firm; any group or individual who can affect, or can be affected by, the firm's interests; or, finally, any group or individual whose level of well-being can be affected by decisions concerning the firm's action or inaction (Pariotti, 2013, p. 145). Thus business enterprise not only has to limit negative externalities and to respect legal rules such as those on human or fundamental rights, but also to pursue social development and community well-being (ibid., p. 146). In this context mere respect for the law is no longer enough. The reason for this is that respect for the law cannot prevent some interests that are increasingly acknowledged at the international law level, in particular human rights, from being affected by the enterprise's business both within the State borders and abroad. Thus the activity of transnational corporations is even more the target of increasing expectations of civil society and the international community (Parker, 2009, p. 2). This is the background against which a new form of responsibility in equilibrium between legal and ethical spheres is being created.

Scholars usually distinguish between internal stakeholders such as workers, suppliers, customers and creditors, and external stakeholders, such as the environment and the community (Pariotti, 2013, p. 145). Thus, according to the CSR paradigm the duties of business enterprise become larger by including not also those who have a relevant interest in the firm's activity such as stockholders

and shareholders (i.e. the owners and investors), but also other categories belonging to civil society (ibid.). In this framework three dimensions emerge within the enterprise's activity which form a 'triple bottom line', namely profit, persons, and the environment in its broad sense.

2.6.3 The main instrument to develop forms of CSR is the code of conduct. Codes of conduct are increasingly used in the field of emerging technologies, especially with regard to nanotechnologies (Kearnes and Rip, 2009; Kurath et al., 2015). Thus we have observed the rise of several ethical codes on nanotechnologies: the Responsible NanoCode by the Royal Society, Insight Investment and Nanotechnology Industries Association; the 'Code of Conduct: Nanotechnology' developed by BASF[29] which addresses the responsibility of the organization to its employees, customers, supplies and other stakeholders, such as future generations; the Nanocare Initiative launched by a group of chemical companies[30]; the European Commission's Code of conduct for nanosciences and nanotechnologies research[31] which is a case of meta-regulation (Dorbeck-Jung and Shelley-Egan, 2013; Ruggiu, 2014); the 'Nano Risk Framework to Aid in Responsible Development of Nanotechnology' developed by the joint work of DuPont and the (US) Environmental Defense; and the 'Code of Conduct: Nanotechnologies' developed by the Swiss retailers association IG DHS (Kearnes and Rip, 2009, p. 15). In these instances, the lack of legal sanctions is reinforced by a synergic relationship between public and private actors that partially reinforce each other.

First of all, we need to distinguish between the code of conduct and the code of ethics (Arrigo, 2006). The first is *ruled-based*, that is, a set of rules aimed at driving the conduct of recipients in order to solve each problem of the enterprise's existence (such as harassment in the workplace, mobbing, safety etc.). The latter is

[29] http://www.basf.com/group/corporate/nanotechnology/en/microsites/nanotechnology/safety/code-of-conduct. Accessed 9 September 2013.

[30] http://www.nanopartikel.info/cms. Accessed 9 September 2013.

[31] European Commission (2008) Commission recommendation of 7 February 2008 *on a code of conduct for responsible nanosciences and nanotechnologies research* C(2008) 424 final, http://ec.europa.eu/research/participants/data/ref/fp7/89918/nanocode-recommendation_en.pdf. Accessed 19 February 2015.

value-based, that is, a set of principles (such as the protection of the environment, health, non-discrimination), without specifying how these values should be concretized (ibid., p. 93).

The code of conduct is usually made up of a formulation of the mission of the organizations that will adopt it, namely what their goal is, why they exist and why stakeholders should have relations with them; an assessment of the means deemed suitable to reach the organization's goal; finally, an explanation of the reason why to adopt the code (D'orazio, 2011, p. 474). Its aim is to make all stakeholders, the business enterprise *in primis*, accountable for their actions, thus acting according to a responsibilization rationale, i.e. the progressive distribution of responsibilities (Ruggiu, 2014).

When, through the means of meta-regulation which regulate the development of self-regulation, '[l]aw attempts to constitute corporate "consciences" getting companies "to do what they should do"' beyond mere compliance with legal norm, it seeks to hold business accountable for taking their responsibility seriously (Parker, 2009, p. 208). Meta-regulation must be aimed clearly at values or policy goals (e.g. respect for human and fundamental rights) for which business enterprise can take responsibility. Then, meta-regulation must be aimed at making sure these social values such as individual rights are built into the practices and organizational structure of the corporation. Finally, it must recognize that the main goals of the organization are still pursued within the responsibility framework of the enterprise. In this regard, the tool of the code of conduct can contribute to meeting the enterprise's main goals of producing particular goods and services, providing a return to its investors, and providing paid employment to its workers and managers within the framework of established values. In this way these values become an integral part of business practices and entrepreneurial structure (ibid., pp. 215–217). Thus, in this conceptual framework, codes of conduct may present a way to foster the accountability of business enterprises effectively.

A variety of models structure the balance of interests which are about the enterprise's business (D'orazio, 2011, p. 474). In particular, we can count the 'company codes' or 'industry associations' codes' where the corporation's interests are at the centre of all relations and only primary stakeholders (i.e. those

groups without whose participation the corporation cannot exist) are concerned. There are also 'multi-stakeholder codes' where there is an alliance among all stakeholders in a joint partnership, and the interests of the business enterprise are just some among others. 'Multi-stakeholder codes' represent the last generation of ethical codes and better express the potentiality of new forms of governance as regards human rights (Pariotti and Ruggiu, 2012). In this framework stakeholders are bearers of mutual rights and duties and are equally involved in the business of the enterprise. Here the firm's interest is not at the apex of the whole process but one of the interests at stake. This framework can be deemed as the more suitable to pursue the aim of protecting human rights within the business ambit. Here also individual rights are assumed as a legitimate source of the final arrangement of the business enterprise. Basically 'multi-stakeholders codes' are based on the idea of 'stakeholder democracy' (Matten and Crane, 2005), which stresses the openness of businesses to the social system as a source of the legitimation of self-regulation. A case of a multi-stakeholder code in the field of nanotechnologies can be deemed the Responsible NanoCode by the Royal Society, Insight Investment and Nanotechnology Industries Association (D'orazio, 2011, p. 476ff.; Pariotti and Ruggiu, 2012) or the Commission code of conduct on nanotechnologies research (Ruggiu, 2014).

As said, the multi-stakeholder perspective can better cover those interests expressed by human rights. Since right to health, workers' and consumers' rights, right to a healthy environment are all at the same time human rights and interests affected by business, they need to be accordingly represented in the life of the enterprise (Pariotti and Ruggiu, 2012). This also corresponds to an interest of the enterprise itself. In this sense, the early care of these interests can be a precise strategy of corporations. As publicly recognized, '[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 Holiday, p. B2). As the recent worldwide scandal of Volkswagen taught, trust is a good which is difficult to gain, but it is more difficult to maintain. This is true also in technoscientific field. 'Though the opportunities for a technology may be literally endless, these opportunities cannot be achieved if

a technology is not developed in a secure manner that maintains public confidence' (Mendel, 2009, p. 2). In this context, human rights are not only a 'negative externality' of business in technoscientific field, since they can, where violated, lead to adverse decision of national and supranational courts, by representing an instance of system failure (von Schomberg, 2013, p. 61ff.; Ruggiu, 2015, p. 229ff.). If they are considered from the outset within the CSR paradigm, they can thus proactively transform the life of business enterprises in depth. In this regard, beyond traditional mechanisms of regulation that are also provided for human rights, soft law tools, such as codes of conduct, guidelines or certification systems can be a further way of implementation in the business sphere: the necessary complement of their legal dimension. In other words, legal constraints stemming from the protection of human rights lead also to assume a proactive attitude in governance frameworks by adopting coherent tools of soft law and implementing them in the sphere of CRS.

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