Responsible Research and Innovation between “new governance” and fundamental rights

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Introduction: Governing technologies under uncertainty conditions[1]

Academic literature and public debates alike have increasingly acknowledged the pervasiveness of uncertainty in science, technology and their governance. Uncertainty is no longer viewed as a residual area of ignorance and risk to be gradually reduced by way of increasing expert knowledge and enhancing technological control. On the contrary, uncertainty is viewed as the unavoidable consequence of the interaction of technology with its environment, that is, of technology's ecological nature (Luhmann 1993). As an effect of these limitations of our experimental knowledge, the introduction of new technologies in society becomes a form of "societal experimentation" (e.g. van de Poel 2009; Felt and Wynne 2007), and risks and possible developments can be detected only after technologies have been introduced in and have displayed their impacts on society. Notions like "manufactured risk" (Giddens 1999) or "secondary consequences" (Beck 1992) were introduced to interpret this paradoxical relationship between increased contingency and the unprecedented knowledge about and control of social life and the physical world, characterizing new and emerging technologies. Indeed, the increased manipulative knowledge of nature and society produces uncertainty rather than reducing it (Coeckelbergh 2012).

The boundaries of science and policy, knowledge and values are redesigned by this radical uncertainty. Accepting that nature and society are co-produced (Jasanoff 2006; Pellizzoni 2010) implies the acknowledgement that the reception of scientific knowledge, technology developments and their consequences "is never, and never can be, a purely intellectual process, about reception of knowledge per se. People experience these in the form of material and social relationships, interactions and interests, and thus they logically define and judge the risk, the risk information, or the scientific knowledge as part and parcel of that 'social package'" (Wynne 1992: pp. 281–282). Knowledge and technology, therefore, implicitly incorporate models, worldviews and societal patterns (Wynne 1992), and, therefore, uncertain knowledge comes with embattled consent where the governance of new technologies is concerned (Douglas and Wildavsky 1983: p. 6).

In this chapter, we argue that responsible research and innovation (RRI) can be an effective answer to this twofold uncertainty, so that responsiveness and the normative steering of research and innovation acquire more importance over risk individuation and management. Our hypothesis is that the models of governance currently in place and the governance framework that is outlined in the literature and policy documents on RRI may be suitable to address the uncertainty challenges, if some conditions are met, such as the ability of these models to properly include the reference to normative dimensions, among which fundamental rights are the edge, and to implement a certain idea of responsibility.

The following sections will first examine the diffusion of soft regulation as an answer to the twofold uncertainty described above, which is addressed by leveraging the knowledge pool possessed by the regulatees and by integrating the divergence of values and interests through cooperation and flexibility. After presenting some examples of soft regulatory initiatives from nanotechnologies, the chapter frames these regulatory developments in the context of the New Governance approach. A second part of the chapter briefly presents RRI in the broader context of the evolution of responsibility paradigms. By referring to their characterization in terms of time orientation (prospective, retrospective) and active/passive attitude to responsibility, three paradigms (fault, risk and precaution) are distinguished. Then, RRI is presented as a proactive, participative, multidimensional approach to responsibility in the governance of STI that is founded on the mutual commitments of societal actors, thus constituting a distinct paradigm on its own. Drawing on these remarks, the meaning and relevance of fundamental rights in RRI is assessed. Far from being a constraint on innovation and on the public debate of its trajectories, fundamental rights are viewed as a catalyst of normative orientation *and* public participation. The conclusions observe how the reference to fundamental rights makes RRI a more comprehensive approach when compared with New Governance, as it internalizes the problem of the normative anchoring of decisions and of the consistency among different kinds of normative elements. Eventually, it is noticed that the potential of fundamental rights to successfully combine normative orientation with openness and flexibility in RRI is conditioned by the capacity to design a governance framework that can ensure the complementarity between hard and soft regulation, legal norms and voluntary commitments.

Soft regulation: General remarks and examples from nanotechnology

The notion of "soft regulation" refers to a broad range of regulatory instruments such as guidelines and recommendations, resolutions, declarations, codes of practice and conduct. Soft regulation is a set of explicit rules which have either a non-binding character or are utterly voluntary (Fredriksson et al. 2012; Skjærseth et al. 2006). While they are acknowledged as having legal relevance, soft norms lack the formal binding effects and clearly top-down delineated enforcement mechanisms that are typical of traditional "command and control" regulatory approaches (Shaffer and Pollack 2013). Definitions like "non-legislative modes of policy-making" (Hérriet, in Fredriksson et al. 2012: p. 53) or even "quasi-legal instruments" (Koutalakis et al. 2010: p. 330) have been introduced to capture this characteristic nature of soft norms. As Dorbeck-Jung and Shelley-Egan notice (2013: p. 56), soft regulation describes a shift "from direct intervention ('rowing') to indirect intervention ('steering') in terms of enabling, motivating and pressing the regulated parties to regulate and to comply with self-regulation".

The prominence of soft regulation has increased as a consequence of three intersecting processes (Arnaldi 2014). First, globalization fundamentally reshaped the general context in which soft regulation has established its significance. These changes challenged the previously uncontested role of the State in setting domestic and international regulations, through command-and-control mechanisms and the forms of international public law (Ferrarese 2000).

Second, soft regulation represents a tool that regulators have for leveraging the information advantages of those actors who are (or are being) regulated. In emerging technological fields that are characterized by a high degree of uncertainty, regulators have insufficient resources or information to define mandatory rules (Dorbeck-Jung and Shelley-Egan 2013). The effective regulation of these areas often requires "frequently changing cognitive and material resources for effective regulation, which state actors often do not have and lie with industry as the primary rule target. This is particularly the case in highly technical areas where the state depends on individual producers for crucial regulatory information related to product characteristics and production processes" (Koutalakis et al. 2010: p. 334). Third, uncertainty drives regulatory decision-making towards "a more political direction" (Falkner and Jaspers 2012). Regulatory choices become more "political", insofar as they require "the weighing up of sometimes competing values, such as technology promotion versus harm prevention. Scientific risk assessment criteria alone cannot guide regulators and policy-makers in such situations. Instead, a wider range of factors enters the calculations that inform regulatory action, from political ideology and societal risk attitudes to national or sectorial economic interests" (Falkner and Jaspers 2012). In this context, soft regulation is used to improve the legitimacy and sustainability of regulatory decisions when "there is the need to build a participated consensus on legal and political decisions" (Pariotti 2011: p. 516) and there is "little space for different and conflicting interests to be articulated" (Garsten and Jacobsson 2011: p. 422).

The coexistence and the combination with hard law create "hybrid" regulatory frameworks (Heyvaert 2009: pp. 649–650). "This happens when, for instance, a voluntary good practice code is used as a benchmark for compliance with a 'hard law' prescription" (Heyvaert 2009: p. 650) or, on the contrary, when soft regulatory instruments refer to hard law provisions. On the international level, soft regulatory processes are seen to combine inter-governmental, shared-sovereignty aims and non-governmental, civil society values (Hickey et al. 2006: p. 298).

In the nanotechnology field, soft regulatory solutions have been widely implemented and have been regarded with particular interest as a tool for the international harmonization and coordination of regulatory frameworks (Bowman and Hodge 2007; Marchant et al. 2009; see Table 7.1 for some examples based on the level of the regulatory initiatives and the type of initiator).[2] The European Commission's Code of Conduct for responsible nanosciences and nanotechnologies (European Commission 2008), the "Voluntary Reporting Scheme for Engineered Nanoscale Materials" of the UK Department of Environment, Food and Rural Affairs (DEFRA 2008a, 2008b), the voluntary "stewardship program" for nanoscale materials under the Toxic Substances Control Act (TSCA) of the US Environmental Protection Agency (EPA n.d.), the Responsible Nanocode (NIA, n.d.), the codes of conduct and assessment frameworks developed by companies like DuPont and BASF (DuPont 2012; BASF, n.d.) or broader initiatives like ResponsibleCare© for the chemical industry (Heinemann and Schäfer 2009, ICCA 2006) are all examples of initiatives fostering the cooperative and voluntary commitment of a variety of social actors, beyond mere legislative and regulatory compliance[3].

Soft regulation and "New Governance"

This evolution in regulation has been seen as a part and consequence of the emergence of the so-called "New Governance" model. The New Governance, which is also referred to as "distributed governance" (MASIS 2009), "constructive governance" (Ozolina 2009) or "democratic experimentalism" (Szyszcak 2006), is the model of governance that inspires, for example, the "open method of coordination" among member States about the EU goals for social policies (and social rights) (cf. Trubeck and Trubeck 2007: pp. 12–16, for an illustration and a comparison with the Classic Community Method). It rests on tools such as guidelines, periodic reporting, multilateral surveillance, exchange of best practices and social dialogue. As it relies on local deliberation and stakeholder participation, it was meant to provide an answer to the democratic deficit in EU (Kohler-Koch and Rittberger 2006). As such, it is rightly inscribed in the broader shift towards distributed, soft regulatory frameworks that we described in the previous section of this chapter. Indeed, it does not rely solely on experts' deliberation within European regulatory agencies or committees, but "enables stakeholders to participate directly in decision-making processes" (Eberlein and Kerwer 2004: p. 133).

As is widely acknowledged, the turn to governance in policy-making and in regulation (Braithwaite, Coglianese and Levi-Faur, 2007) implies the following main elements: (1) a shift in situation in which "the government is a relationship of negotiation and cooperation with private actors" so that (Chowdhury and Wessel 2012: p. 345) (2) rule/norm making, rule implementation and rule enforcement activities are dispersed "across different administrative levels both within and beyond nation state" (Chowdhury and Wessel 2012: p. 346) and (3) a central ordering of regulation is lacking. In this framework, the "New Governance model" introduces a special concern for public engagement and participation as one of its essential features.

It can be said that the New Governance model integrates principle-based regulation and outcome-oriented regulation as an alternative to rule-based regulation. It has a set of specific features, like participation and power-sharing, integration of different levels of governance, diversity and decentralization and expansion of the space for stakeholders' deliberation. Furthermore, its features of flexibility and revisability make it experimental and tentative in nature, so that regulation can adapt to distinctive economic, environmental, social and administrative conditions that cannot be regulated through uniformly binding legislative requirements (Scott and Trubeck 2002; Pariotti 2011), thus reducing transaction costs of regulators and regulatees (Koutalakis et al. 2010: p. 330).

In general, this model is not immune from criticism and, again, nanotechnology represents a significant example. Maynard and Rejeski (2009) contest the effectiveness of voluntary reporting of nanomaterials by industry and support the adoption of mandatory measures. Marchant and Abbott (2013) point to the inconsistent and limited implementation of the existing international soft regulation initiatives for nanotechnology and of their impacts. Stokes (2013) notes that regulators prefer more conventional command-and-control methods of regulation in dealing with considerable uncertainties. For instance, important stakeholders such as the European Trade Unions Confederations (ETUC) and political bodies such as the European Parliament have asked for stricter and more specific provisions, especially by applying the existing chemical or cosmetics regulations (ETUC 2008; 2010; European Parliament 2009; Ponce del Castillo 2013; Ruggiu 2013) to nanotechnologies. In the US, the EPA undertook a step in a similar direction, proposing in 2013 a mandatory reporting programme under the TSCA for several nanomaterials (EPA, n.d.).

Indeed, the crucial challenge of "New Governance" arrangements is to strike a balance between flexibility and efficacy, in terms of the behavioral orientation of the (self)-regulated parties. As the examples above show, the critique of soft regulation tends to prefer binding, rule-based regulation over the outcome-based approach that is typical of soft regulatory instruments, which measures performance against regulatory goals rather than against rule compliance.

As stated in the introduction, we maintain that this complementarity is just the kind of result that is pursued by the idea of RRI. In order to support this position, we characterize RRI in the context of the diversity and historical evolution of the notion of responsibility. This argument is preliminary to discussing the interplay of the New Governance and fundamental rights *vis a vis* the realization of RRI.

Responsible research and innovation as a new paradigm of responsibility?

RRI aims at introducing responsibility into research and innovation processes at an early stage, by involving those who are concerned with their consequences in the framing of the innovation activities and in the definition of their aims and scopes. In this perspective, innovation and research activities might be characterized as "responsible" according to the ways they are performed in a broad societal perspective (van den Hoven et al. 2013), more than under the perspective of liability or compensation for damages, as well as under the traditional risk management approach.

As RRI claims to be a new approach to responsibility in science and innovation, the issue of whether it has new features or whether it is yet another version of responsibility paradigms we already know has to be addressed. In particular, it should be questioned whether RRI distinguishes significantly from the Precautionary Principle (PP) or not, as the inner logic of the PP is also that of anticipating responsibility in scientific and technological innovation activities.

The idea of precaution stems from the new context of scientific uncertainty highlighted above (see section 1), to which neither the preventive approach of risk management could provide acceptable answers, nor the fault paradigm would help in making innovation processes more responsible. Instead, it frames responsibility in terms of a duty of anticipating the undesirable outcomes of techno-scientific activities through value-centered decisions in a context of epistemic uncertainty. The PP is based on the idea of a *preventive exercise* of responsibility rather than on its subsequent ascription (be it via fault or risk management mechanisms): within this logic, the focus of responsibility is on anticipating the potentially harmful outcomes by framing responsibility in terms of value-balance within a context-based decision. Indeed, precaution operates precisely where adequate guarantees against undesirable harmful consequences of scientific innovation cannot be provided by applying the general rules and standards of risk management, so that the criteria for a responsible management of innovation have to be set case by case. So it could be told that the PP operates a sort of a re-ethicization of the responsibility idea, not because it introduces new figures of liability (nor new criteria of risk assessment), but rather because it shapes legal responsibility in a way similar to an ethical judgment in situation (Papaux 2006; Gorgoni 2010), as it asks (and prompts) for decision-making in a context where the causal link between potentially harmful activities and the possible threats (be it for the human health or for the environment) is not certain, marking a major epistemic break with the epistemology underpinning typical risk management techniques (Osimani 2013).

Under this perspective, RRI shares the same epistemology with the PP, but it declines it in a different way, as the lack of scientific certainty about potential harms not only should no longer constitute an obstacle for taking *preventive* actions (like in the PP), but rather it gives way to a *proactive* appraisal of a situation characterized by both *cognitive uncertainty* and some degree of *values indeterminacy*. What, therefore, specifically characterizes RRI as an approach distinct from the PP is, at least in principle, the *integration of responsibility within the innovation process itself.* In other words, what makes RRI different from the PP is not its inner logic (that of anticipation) or its underlying epistemology (as they both refer to decisions in a context of uncertainty), but rather its contexts and conditions of application. Indeed, the PP has been invoked as a safeguard against the undesirable outcomes of innovation activities, serving as a tool for correcting its path, either by inverting, diverting or blocking it (Callon, Lascoumes and Barthe, 2009). Nevertheless, the PP remains linked to a context in which positions are confronted in an adversarial logic, while RRI aims at changing the context in which precaution intervenes, by shifting to a cooperative logic when decisions about the innovation trajectories are concerned. Indeed, RRI promotes a logic of *responsibilization*, which has been broadly characterized as "predisposing actors to assume responsibility for their action" (Dorbeck-Jung, Shelley-Egan 2013), but which – in RRI perspective – could and should be more explicitly characterized in terms that predispose societal actors to voluntarily assume an early and shared responsibility for the research and innovation processes by overcoming the perspective of the pure abiding by duties or complying with rules.

For an RRI idea to represent something new, it is necessary giving value to these features and taking out the consequences implied on those premises, which contain strong claims in terms of principles but which may convert into nothing but a rhetorical appeal if they are not given credit and their consequences taken into account and fully developed.

The novel features of RRI within existing responsibility models

In order to develop the features distinguishing RRI from other approaches highlighted above, it is necessary to frame it within the context of the existing responsibility approaches. Instead of detailing the different meanings of responsibility, as others have done (e.g. Davis 2012; van de Poel 2011; Vincent 2011; Gorgoni 2011; Ricoeur 2000; Hart 1968), we propose to take into account and examine the deep semantics underpinning the different meanings of responsibility, which can be basically structured on the combinations between two different modes (passive and active) and two temporal directions (retrospective and prospective). We could maintain that different meanings of responsibility are built on the combinations of these modes and these time orientations. In the following pages, we will first characterize each of those modes, and then we will analyse their combinations.

As for the first polarity highlighted, that between passive and active modes, the passive pole of responsibility corresponds to one of its most common understandings, i.e. that of a sanction intended in a broad sense, as synonymous of holding someone responsible for something (typically the legal imputation of liability), while the active pole of responsibility is also linked to another common understanding of responsibility, the idea of "acting responsibly", in the sense of assuming one's own responsibilities (self-ascription of responsibility), whether in terms of specific duties or in terms of a relation of care for something or somebody. The passive and the active modalities of responsibility are not mutually exclusive so that it is possible to highlight some oscillations of the meaning of responsibility between those poles, which sometimes may be conflicting with each other.

Indeed, if we shift from the passive towards the active modes, responsibility can be equally understood in terms of 1) the *obligation* to bear the consequences of an action (liability, which is essentially passive); 2) the *capacity* to act, taking into account one's duties (combining the passive pole of obligation and the active pole of capacity); and 3) the *capacity* to act, taking into account the resulting consequences, even without necessarily referring to some pre-established duties (which could be termed as a self-ascription of responsibility). Characterized in this latter sense, the idea of responsibility has to be intended in terms of *responsiveness* more than in terms of *reaction*. Responsiveness expresses the idea of a *response* to somebody's appeal (Pellizzoni 2004: p. 557), thus characterizing the active pole of responsibility in very different terms than the passive one.

As for the second polarity highlighted above, the distinction between the active and the passive modalities of responsibility entails, in its turn, some distinctions regarding the time orientation of responsibility, namely the retrospective (backward-looking) (Bovens 1998) and the prospective (forward-looking) one (Cane 2002; Gorgoni 2008). Retrospective responsibility is essentially linked to the idea of an ex-post imputation of responsibility, and so to the ideas of sanction (*liability*), compensation (*damage*) or justification (*accountability*), which do shape the idea of responsibility, essentially in terms of a *reaction* to a certain state of affairs. Responsibility, in this case, is essentially backward-looking, i.e. past-oriented, and therefore can be characterized as retrospective in that its key moment is the *ex post* evaluation of a situation and the subsequent judgement in terms of the imputation of the consequences.

On the other side, prospective responsibility is essentially linked to the idea of acting responsibly, both in the sense of complying with the duties associated to someone role, but also with the broader idea of *(pro)actively* assuming responsibilities, even when the contents of duties and tasks are not or cannot be established in advance. These features make the idea of prospective responsibility more complex than that of a duty (with which it nevertheless tends to be identified in the legal field), characterizing the idea of responsibility as prospective in that responsibility is not a *reaction to* a certain state of affairs, but rather a *projection over* it.

Drawing on this discussion, the different models of responsibility can be framed as combinations between the two semantic poles and the two time dimensions highlighted above. When examining the historical evolution of the idea of responsibility, following the suggestions of François Ewald (2001), it is possible to point out three main paradigms of responsibility (which can be clearly distinguished only at the theoretical and historical level, but whose different logics nevertheless are coexisting, overlapping and sometimes competing at the practical level), namely: 1) the paradigm of *fault*, corresponding to the traditional moral and legal idea of responsibility as a reaction to a certain state of affairs, and which is essentially *retrospective* (e.g. Hart 1968); 2) the paradigm of *risk*, which aims at guaranteeing the compensation for the damages rather than the sanction of the fault, by disconnecting indemnification from liability (Beck 1992); and 3) the paradigm of *safety*, which is linked to the idea of *precaution* as a reaction to the residual situation of uncertainty that cannot be domesticated by means of risk calculation. Indeed, the two former paradigms of responsibility are seriously challenged by the evolution of science and innovation, as they both presuppose either an identifiable author (fault) or the possibility of relying on statistical data (risk).

Compared with those paradigms, RRI presents some distinctive features that we should briefly analyze. Despite the differences in definitions between various authors dealing with the subject (von Schomberg 2013; Owen 2014; van den Hoven et al. 2013; Forsberg et al. 2015), we take RRI as a single idea as, in our opinion, the literature on RRI shares some common understanding of responsibility, namely (in no particular order) 1) the orientation towards future of responsibility, advocating for a *prospective* idea of responsibility as a mean of steering the innovation processes according to societal values and needs; 2) the focus on proaction, as RRI is intended to be mainly a *driving factor* of innovation process more than a constraint, engaging responsibility beyond the strict boundaries of what is legally due; 3) the framing of responsibility as a *collective and participative* process: not only is responsibility thought as being shared across different actors, each of which has different roles and powers along the innovation process, but it is also seen as a result of a collaborative process between the innovators and society as a whole; and d) the crucial role of *voluntary instruments*: RRI both promotes and implies collaborative dynamics instead of typical dispute-settlement mechanisms (be it at the judicial level or not), encouraging the creation of (commonly agreed) voluntary standards and procedures. So, ultimately, according to the RRI idea, responsibility should be organized through norms both adaptive (flexible) to the technological development and committed to broader societal goals such as environmental, social and economic sustainability, the goal being to promote proactive interventions in order to avoid or reduce any potential or even unforeseeable risk in cases of scientific uncertainty.

If we give credit to its ambitions, and only if we do so, then RRI can perhaps be considered as a new paradigm of responsibility, combining in a new way the elements of other responsibility paradigms (see Table 7.2 for an unavoidably simplified comparison) as it aims at *steering the innovation process from the inside* towards societal goals rather than coping with its (actual or anticipated) unwanted and unintended externalities, by integrating responsibility within the innovation process itself. Despite the (at least partial) indeterminacy of societal goals and values on which this approach is based, we maintain that a distinctive feature of RRI is its normative commitment to the protection of fundamental rights (Arnaldi, Gorgoni and Pariotti 2016), which sets it aside from regulatory approaches based on deregulation in a purely market-driven logic (Arnaldi and Gorgoni 2016).

RRI and fundamental rights[3]

The nature of RRI as a conceptual and policy approach aimed at actors' reciprocal responsibilization defines a space for innovative forms of governance centred on the adoption and the practical implementation of (self-) regulatory instruments such as codes of conduct, guidelines, technical standards, reporting and audits. As we have seen, these types of regulatory instruments and their incorporation into hybrid regulatory schemes correspond to the features that are key to the New Governance model, like participation and power sharing; integration of different levels of governance, diversity and decentralization; and expansion of the space for stakeholders' deliberation.

Yet, RRI directly addresses the question of defining the ultimate purposes of science, technology and innovation by affirming the need to guarantee some essential features in order to be a truly innovative and alternative approach to research and innovation governance (as indicated by the switch from the logic of "science *and* society" to that of "science *in* society", marking their reciprocal integration rather than their separation).

Under this perspective, it is therefore clear that RRI brings some strong normative requirements in order to be both a coherent and innovative way of dealing with responsibility issues of the research and innovation process.

While a significant part of the literature considers the definition of the ultimate purposes of science, technology and innovation as the result of (normative) deliberations emerging from the spontaneous interplay between science and society (Owen et al. 2013), the literature that is most close to the EU policy environment from which the notion of RRI originated seems to include more explicitly fundamental rights as the source of orientation of research and innovation (von Schomberg 2013; Ozolina et al. 2009: p. 3).

In our view, this latter approach is better suited for configuring RRI as a more comprehensive new approach to the governance of responsibility, as it introduces some explicit "normative anchor points" which are in line with the democratic guarantees that ultimately characterize the RRI idea.

Indeed, in one of its most cited definitions, RRI is framed as "a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)" (Von Schomberg 2013: p. 50; 2014: p. 39). In this view, we agree on affirming that ethical acceptability in the EU context "refers to a mandatory compliance with the fundamental values of the EU Charter on fundamental rights" (von Schomberg 2013: p. 40). Moreover, social desirability "captures the relevant, and more specific normative anchor points of the treaty on the European Union" (von Schomberg 2013: p. 40). Under this view, competitiveness, scientific progress, fundamental rights and environmental protection can be taken as the normative anchor points of EU research and innovation policies and, therefore, it seems reasonable that they play a role as the normative "building-blocks" of a governance framework for Research and Innovation activities.

Indeed, RRI comprehensively combines and integrates various earlier approaches and methods, as "technology assessment and foresight, application of the precautionary principle, normative/ethical principles to design technology, innovation governance and stakeholder involvement and public engagement" in both deliberation and regulation (von Schomberg 2013: p. 41). RRI complements this interest in the design and implementation of governance frameworks, understood as sets of concrete processes and mechanisms, with the warranty of compliance with normative requirements. On the other hand, however, the definition of RRI we have cited emphasizes the integrated presence of multiple dimensions within the notion of RRI, like the ethical, political, social and legal ones.

When these governance approaches are discussed, stressing the reference to fundamental rights could be regarded as a way to rigidly set values and goals, even regardless of public debate and public opinion development. From this point of view, fundamental rights could be considered as normative constraints defined in a top-down way, limiting the scope and influence of public involvement. However, this representation of fundamental rights in general and of their specific role in RRI is indeed debatable. Human rights are usually seen from two opposite perspectives and both of them should be rejected. According to a first view, human rights are abstract ideals, which easily can be reduced to rhetorical appeals. According to a different one, human rights are expressed by norms and, because of that, they have a closed and compelling meaning that concerns solely the relationships between citizens and their governments or judicial courts. In this understanding, fundamental rights have no relation to public opinion.

Fundamental rights can, on the contrary, be thought of as claims that are justified by strong moral reasons and supported by legal norms, suitable for regulating both the (vertical) relations between the government and the citizens and, often, the (horizontal) relations among citizens themselves and, in general, among private actors. However, it is important to note that the legal norms supporting such claims are often structurally vague, because they have to apply to as high a number of cases as possible.

In science, technology and innovation many private actors actively self-regulate and possess information and knowledge crucial to regulation, so regulation needs to reflect such a diffuse and shared nature of responsibility. As a consequence, the contents of fundamental rights should emerge in a bottom-up fashion through a diffused meaning-making process which could, and often does, also contribute to shaping self-regulatory tools.

Indeed, human rights do affect the regulation of innovation in several ways. First, on a judicial level, by referring to the sources on fundamental rights in the EU, the judicial stance contributes to the definition of the content of rights. Second, on a policy level, the protection and promotion of rights might act as a driver for policy-making. Third, the reference to human rights plays a role also on a horizontal level, between private actors, such as, for instance, when the most diverse organizations adopt and implement social responsibility instruments (codes of conduct, self-regulation).

Therefore, it is possible to maintain that fundamental rights are a basic reference for a normative governance model and that, nevertheless, the development and implementation of such a model should and can come to terms with different values and with different interpretations of the rights themselves, in particular within the European context where "human rights can help in strengthening both the legislation needed for regulating the present market and the soft instruments needed for steering research and for fostering the stakeholders' participation without sacrificing the coherence of the regulatory response" (Ruggiu 2013: p. 201).

When understood in this way, human rights might gain a central space in RRI as they could represent the "normative anchor points" for defining ethical acceptability, thus shaping what has been regarded as the main feature of a specific European approach to the ethical and regulatory challenges of innovation (Ozolina et al. 2009: p. 27). As we already mentioned, normative-flavored definitions of RRI explicitly link the ethical acceptability of research and innovation and compliance with the EU charter on fundamental rights, besides a general reference to safety as a paramount criterion for assessing technology and innovation (van den Hoven et al. 2013: p. 58). Moreover, innovation is expected to take into account the societal needs embodied in the Treaty on European Union, as sustainable development, equality and quality of life (van den Hoven et al. 2013: p. 58). Yet, fundamental rights and societal needs are seen as explicitly and mutually linked goals of a comprehensive normative framework for the governance of science, technology and innovation. Nevertheless, despite their strong embedding within the EU Treaty and the EU Charter of Fundamental Rights, it has to be recognized that some ambiguities can exist among the "normative anchor points" themselves, as conflicting interpretations, uses or applications might rise around them, and this is the reason why RRI frameworks should give room to contestation as an unavoidable feature to be taken into account (e.g. see Res-AgorA Project, Responsibility Navigator: http://responsibility-navigator.eu/).

To sum up, two remarks here are in order to justify an integrated view of fundamental rights and governance. First, considering fundamental rights as essential elements of a governance framework does not imply any closure to public involvement, as it does not mean that both the normative standards to be complied with and the goals to be pursued are already fully set in a top-down manner. Far from it: once listed, fundamental rights have to be filled with contents and have to be detailed with regard to specific domains, contexts and cases. In this open-ended process of interpretation and application of principles, societal values and norms can find (and usually do find) a way of expression. Within this perspective, they can rather be seen as being "a public normative practice" (Beitz 2009: p. 170), as long as their content is not established once and for all in the law-making process, but it has to be shaped also in a bottom-up manner by several relevant actors during the application stage, such as judges, but also private actors creating and promoting tools of self-regulation. Second, fundamental rights are not simply constraints for innovation that aim at reducing or avoiding its undesirable or negative consequences by warranting the respect of human health, dignity, privacy etc. Rather, they also concern the shaping of policies, so that rights are not only respected and protected, but also promoted by way of proactive initiatives: "we should allow fundamental rights to work in a truly proactive fashion, and this is possible only in a rights based model, a system where (legal issues on) human rights are not an accident on the route of governance, but are integrated into all its phases from the outset" (Ruggiu 2015: p. 233). When their meaning is understood in this way, the reference to fundamental rights adds a significant dimension to governance frameworks aimed at encouraging proactive policies, as they imply and require the contribution of stakeholders and, in general, of the citizens in determining their content and the concrete goals to be pursued within the innovation process.

Conclusion

RRI can be deemed as a governance approach integrating fundamental rights with voluntary regulatory mechanisms and instruments typical of the New Governance model. The efficacy of this approach is based on just such an integrative nature, i.e. on the combination of principle-based and outcome-oriented regulation. We emphasized fundamental rights as the main "building blocks" of principle-based regulation and, more in general, of this framework.

The combination of fundamental rights with soft and hybrid regulatory instruments that are typical of New Governance seems particularly apt to cope with the situation to which RRI is called to answer. As we have said in the introduction, we might see the orientation provided by the RRI approach as "a joint product of knowledge about the future and consent about the most desired prospects", in a situation that can be properly characterized as uncertain in terms of knowledge and contested in terms of consent (Douglas and Wildavsky 1983: pp. 5–6). In the context of RRI, the reference to fundamental rights could be seen, therefore, as an important component in the constellation of elements determining the ethical acceptability of innovation and techno-scientific developments. This is the main reason for maintaining that, in the field of the governance of innovation, RRI tends to be a more comprehensive approach than the New Governance itself. In RRI, the reference to fundamental rights is one of the elements to be taken into consideration when assessing the ethical acceptability of innovation. This situation reflects the RRI focus on actors' *responsibilization* and the appeal to their capacity of committing to some goals beyond what is strictly mandated by the law: "Responsibilization – namely expecting and assuming the reflexive moral capacities of various social actors – is the practical link that connects the ideal-typical scheme of governance to actual practices on the ground. Responsibility – in contrast to mere compliance with rules – presupposes one's care for one's duties and one's un-coerced application of certain values as a root motivation for action" (Shamir 2008, p. 7).

Our discussion suggests that the potential of fundamental rights to successfully combine a stable normative orientation with openness and flexibility in RRI should be considered with regard to how this commitment to fundamental rights can be properly adjusted into decentred and bottom-up-shaped regulation. In other words, it is a matter of how the basic requirements of constitutional state can be preserved in the multilevel and manifold regulation that characterizes the New Governance approach. Indeed, when assessing the coherence and suitability of soft regulation according to the framework of RRI, the relationship between the New Governance approach and the (multilevel) constitutional dimension of the EU needs to be addressed. In general, the relationships between the typical tools of New Governance have been differently identified as characterized by complementarity, rivalry or transformation (i.e. the transformation of legal regulation due to the influence of governance frameworks) (Trubek and Trubek 2007: pp. 6–13). The success of referring to fundamental rights as a solution to provide "normative anchor points" for RRI requires a careful examination of the legal and regulatory framework in which STI activities are framed in the EU and, at the same time, a deliberate effort to construe a governance framework designed to ensure the complementarity between hard and soft regulation, legal norms and voluntary commitments.

RRI would be yet another recast of purely market-based approaches promoting an "'economized' language of responsibility" (Shamir 2008) instead of a "responsible" approach in the broader sense claimed by RRI (Arnaldi and Gorgoni 2016) if it is not backed by strong normative commitments towards the basic democratic values expressed by constitutionalism and the rule of law, which do represent a fundamental, specifically European, ethical-political and also legal legacy.

References

1. Arnaldi S. (2014). '¿Qué tan suave debería ser la regulación nano? Identidades sociales y opiniones de los stakeholders italianos', *Mundo Nano. Revista Interdisciplinaria en Nanociencias y Nanotecnología*, 7(13), pp. 6–27.
2. Arnaldi, S., Ferrari, A., Magaudda, P. and Marin F. (2014). Nanotechnologies and the quest for responsibility. In Arnaldi, S., Ferrari, A., Magaudda, P., Marin, F. (Eds.), *Responsibility in Nanotechnology Development*. Dordrecht: Springer, pp. 1–18.
3. Arnaldi S., Gorgoni G. and Pariotti, E. (2016). *Responsible Research and Innovation as a governance paradigm: What is new?* In: Lindner R., Kuhlmann, S., Randles, S., Bedsted, B., Gorgoni, G., Griessler, E., Loconto, A. and Mejlgaard, N. (Eds.), *Navigating Towards Shared Responsibility in Research and Innovation. Approach, Process and Results of the Res-AGorA Project*. Karlsruhe: Fraunhofer ISI, pp. 23–29. ISBN: 978-3-00-051709-9.
4. Arnaldi, S. and Gorgoni, G. (2016). Turning the tide or surfing the wave? Responsible Research and Innovation, fundamental rights and neoliberal virtues. *Life Sciences, Society and Policy*, 6, pp. 1–19. DOI : 10.1186/s40504-016-0038-2.
5. Arnaldi, S. (2017). Changing Me Softly: Making Sense of Soft Regulation and Compliance in the Italian Nanotechnology Sector. NanoEthics 11(1), pp. 3–16. https://doi.org/10.1007/.
6. BASF. (n.d.). *Nanotechnology code of conduct*. Available from: http://www.basf.com/group/corporate/nanotechnology/en/microsites/nanotechnology/safety/code-of-conduct. [accessed 30 December 2013].

7. Beck, U. (1992). *Risk Society: Towards a New Modernity*. London: Sage Publications.

8. Beitz, C. (2009). *The Idea of Human Rights*. Oxford: Oxford University Press.

9. Bovens, M. (1998). *The Quest for Responsibility. Accountability and Citizenship in Complex Organisations*. Cambridge: Cambridge University Press.

10. Bowman, D. M. and Hodge, G. A. (2007). Governing nanotechnology without government? *Science and Public Policy*, 35(7), pp. 475–487.

11. Braithwaite, J., Coglianese, C. and Levi-Faur D. (2007). Can regulation and governance make a difference. *Regulation and Governance*, 1, pp. 1–7.

12. Callon, M., Lascoumes, P. and Barthe, Y. (2009). *Acting in an Uncertain World. An Essay on Technical Democracy.* Cambridge (MA):MIT Press.

13. Cane, P. (2002). *Responsibility in Law and Morality*. Oxford: Hart Publishing.

14. Chowdhury, N. and Wessel, R. A. (2012). Conceptualising multilevel regulation on the EU: A legal translation of multilevel governance? *European Law Journal*, 18(3), pp. 335–357.

15. Coeckelbergh, M. (2012). Moral responsibility, technology, and experiences of the tragic: From Kierkegaard to offshore engineering. *Science and Engineering Ethics*, 18(1), pp. 35–48.

16. Davis, M. (2012). Ain't no one here but us social forces: Constructing the professional responsibility of engineers. *Science and Engineering Ethics*, 18 (1), pp. 13–34.

17. DEFRA – Department of Environment, Food and Rural Affairs. (2008a). *The Voluntary Reporting Scheme*. Available from: http://archive.defra.gov.uk/environment/quality/nanotech/documents/ vrs-nanoscale.pdf. [accessed 30 December 2013].

18. DEFRA – Department of Environment, Food and Rural Affairs. (2008b). *A supplementary guide for the UK Voluntary Reporting Scheme*. Available from: http://archive.defra.gov.uk/environment/quality/nanotech/documents/nano-hazards.pdf. [accessed 30 December 2013].

19. Dorbeck-Jung, B. and Shelley-Egan, C. (2013). Meta-regulation and nanotechnologies: The challenge of responsibilisation within the European Commission's code of conduct for responsible nanosciences and nanotechnologies research. *Nanoethics*, 7(1), pp. 55–68.

20. Douglas, M. and Wildavsky, A. B. (1983). *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers*. Berkeley: University of California Press.

21. DuPont. (2012). *DuPont Position Statement on Nanotechnology*. Available from: http://www.dupont.com/corporate-functions/news-and-events/insights/articles/position-statements/articles/nanotechnology.html. [accessed 30 December 2013].

22. Eberlein, B. and Kerwer, D. (2004). New governance in the European Union: A theoretical perspective. *Journal of Common Market Studies*, 42(1), pp. 121–142.

23. EPA – Environmental Protection Agency. (n.d.). *Control of Nanoscale Materials under the Toxic Substances Control Act*. Available from: http://www.epa.gov/oppt/nano/. [accessed 30 December 2013].

24. EPA – Environmental Protection Agency. (n.d.). *Nanoscale Materials Stewardship Program*. Available from: http://epa.gov/oppt/nano/stewardship.htm. [accessed 30 December 2013].

25. European Commission. (2008). *Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, 1st Revision: Analysis of results from the Public Consultation of the Public Consultation*. Available from: http://ec.europa.eu/research/consultations/nano-code/consultation_en.htm. [accessed 30 December 2013].

26. Ewald, F. (2001). Philosophie politique du principe de precaution. In: Ewald F., Gollier C., and de Sadeleer N. (Eds.), *Le principe de precaution*. PUF: Paris, pp. 29–44.

27. 26. Falkner, R. and Jaspers, N. (2012). Regulating nanotechnologies: Risk, uncertainty and the global governance gap. *Global Environmental Politics*, 12(1), pp. 30–55.

28. Ferrarese, M. R. (2000). *Le istituzioni della globalizzazione*. Bologna: Il Mulino.

29. Forsberg, E. M., Quaglio, G. L., O'Kane, H., Karapiperis, T., Van Woensel, L. and Arnaldi, S. (2015). Assessment of science and technologies: Advising for and with responsibility. *Technology in Society*, 42, pp. 21–27.

30. Fredriksson, M., Blomqvist, P. and Winblad, U. (2012). Conflict and compliance in Swedish health care governance: Soft law in the shadow of hierarchy. *Scandinavian Political Studies*, 35(1), pp. 48–70.

31. Garsten, C. and Jacobsson, K. (2011). Post-political regulation: Soft power and post-political visions in global governance. *Critical Sociology*, 39(3), pp. 421–438.

32. Gorgoni, G. (2008). La responsabilité comme projet. Réflexions sur une responsabilité juridique "prospective". In: Eberhard (Ed.), *Traduire nos responsabilités planétaires, recomposer nos paysages juridiques*. Bruxelles: Bruylant, pp. 131–146, ISBN/ISSN: 9782802726548.

33. Gorgoni, G. (2010). (Pre)caution improvisation area. Improvisation and responsibility in the practice of the precautionary principle. *Critical Studies In Improvisation*, 6(1), (*Lex Non Scripta, Ars Non Scripta: Law, Justice, and Improvisation)*, ISSN : 1712-0624, online [http://www.criticalimprov.com].

34. Gorgoni, G. (2011). Modelli di responsabilità e regolazione delle nanotecnologie nel diritto comunitario. Dal principio di precauzione ai codici di condotta. In: Guerra, G., Muratorio, A., Pariotti, E., Piccinni, M. and Ruggiu, D. (Eds.), *Forme di responsabilità, regolazione e nanotecnologie.* Bologna: Il Mulino, pp. 371–395.

35. Hart, H. L. A. (1968). *Punishment and Responsibility*. Oxford: Oxford University Press.

36. Heinemann, M. Schäfer, H. (2009). Guidance for handling and use of nanomaterials at the workplace. *Human and Experimental Toxicology*, 28(6–7), pp. 407–411.

37. Heyvaert, V. (2009). Levelling down, levelling up, and governing across: Three responses to hybridization in international law. *The European Journal of International Law*, 20(3), pp. 647–674.

38. Hickey, G. M., Innes, J. L., Kozak, R. A., Bull, G. Q. and Vertinsky, I. (2006). Monitoring and information reporting for sustainable forest management: An inter-jurisdictional comparison of soft law standards. *Forest Policy and Economics*, 9(4), pp. 297–315.

39. ICCA – International Council of Chemical Associations. (2006). *Responsible Care® Global Charter in English*. Available from: http://www.icca-chem.org/ICCADocs/09_RCGC_EN_Feb2006.pdf. [accessed 30 December 2013].

40. ISO – International Organization for Standardization. (n.d.) ISO/TC 229 Nanotechnologies. Available from: http://www.iso.org/iso/iso_technical_committee?commid=381983. [accessed 30 December 2013].

41. Jachtenfuchs, M. (1995). Theoretical perspectives on European governance. *European Law Journal*, 1(2), pp. 115–133.

42. Jasanoff, S. (2006). Ordering knowledge, ordering society. In: *States of Knowledge: The Co-Production of Science and the Social Order*. New York: Routledge, pp. 13–45.

43. Kohler-Koch, B. and Rittberger, B. (2006). The 'governance turn' in EU Studies. *Journal of Common Market Studies*, 44, pp. 27–49.

44. Koutalakis, C., Buzogany A. and Börzel, T. A. (2010). When soft regulation is not enough: The integrated pollution prevention and control directive of the European Union. *Regulation and Governance*, 4(3), pp. 329–344.

45. Luhmann, N. (1993). *Risk: A Sociological Theory*. New Bruswick: Transaction Publishers.

46. Marchant, G. E. and Abbott, K. W. (2013). International harmonization of nanotechnology governance through 'soft law' approaches. *Nanotechnology Law and Business*, 9(4), pp. 393–410.

47. Marchant, G. E., Sylvester, D. J., Abbott, K. W. and Danforth, T. L. (2009). International harmonization of regulation of nanomedicine. *Studies in Ethics, Law*, and *Technology*, 3(3), art. no. 6.

48. MASIS – Monitoring Activities of Science in Society in Europe Experts Group. (2009). *Challenging Futures of Science in Society. Emerging Trends and Cutting-Edge Issues*. European Commission, Directorate-General for Research, Luxembourg.

49. Maynard, A. and Rejeski, D. (2009). Too small to overlook. *Nature*, 460(7252), p. 174.

50. Osimani, B. (2013). An epistemic analysis of the precautionary principle. *Dilemata*, 11, pp. 149–167.

51. Owen R., Stilgoe, J., Macnaghten, P., Fisher, E., Gorman, M. and Guston, D. H. (2013). A framework for responsible innovation. In: Owen, R., Heintz, M. and Bessant, J. (Eds.), *Responsible Innovation. Managing the Responsible Emergence of Science and Innovation in Society*. Hoboken (NJ): John Wiley & Sons, pp. 27–50.

52. Owen, R. (2014). *Responsible Research and Innovation: Options for research and innovation policy in the EU*. Available from: https://ec.europa.eu/research/innovation-union/pdf/expert-groups/Responsible_Research_and_Innovation.pdf [accessed 2 February 2015].

53. Ozolina, Z., Mitcham, C. and Stilgoe, J. (2009). *Global Governance of Science, Report of the Expert Group on Global Governance of Science to the Science, Economy and Society Directorate*. Brussels: Directorate-General for Research, European Commission.

54. Papaux, A. (2006). *Introduction à la philosophie du "droit en situation". De la codification légaliste au droit prudentiel*. Paris/Zurich/Bruxelles: L.G.D.J./Schulthess/Bruylant.

55. Pariotti, E. (2011). Normatività giuridica e governance delle tecnologie emergent. In: Guerra, G., Muratorio, A. Pariotti, E., Piccinni, M. and Ruggiu, D. (Eds.), *Forme di responsabilità, regolazione e nanotecnologie.* Bologna: Il Mulino, pp. 509–549.

56. Pellizzoni, L. (2010). Environmental knowledge and deliberative democracy. In: Gross, M. and Heinrichs, H. (Eds.), *Environmental Sociology*. Amsterdam: Springer, pp. 159–182. doi:10.1007/978-90-481-8730-0_10.

57. Pellizzoni, L. (2004). Responsibility and environmental governance. *Environmental Politics*, 13(3), pp. 541–565.

58. Peters, A., Pagotto, I. (2006). Soft law as a new mode of governance: A legal perspective. *Report of the project NEWGOV New Modes of Governance. Integrated Project. Priority 7 – Citizens and Governance in the Knowledge-Based Society*, 04, D11, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1668531andrec=1andsrcabs=1876508andalg=1andpos=1. [accessed 28 August 2013].

59. Felt, U. and Wynne, B. (2007). *Taking European Knowledge Society Seriously. Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research*. Brussels: European Commission.

60. Ponce Del Castillo, A. M. (2013). 'The European and member states' approaches to regulating nanomaterials: Two levels of governance. *NanoEthics*, 7(3), pp. 189–199.

61. Ricoeur, P. (2000). *The Just*. Chicago: Chicago University Press.

62. Ruggiu, D. (2013). Temporal perspectives of the nanotechnological challenge to regulation: How human rights can contribute to the present and future of nanotechnologies. *NanoEthics*, 7(3), pp. 201–215.

63. Ruggiu, D. (2015). Anchoring European governance: Two versions of responsible research and innovation and EU fundamental rights as 'normative anchor Points'. *NanoEthics*, vol. 9, pp. 217–235.

64. Scott, J. E. and Trubeck, D. M. (2002). Mind the gap: Law and new approaches to governance in the European Union. *European Law Journal*, 8(1), pp. 1–18.

65. Shaffer, G. and Pollack, M. A. (2013). Hard and soft law. In : J.L. Dunoff and Pollack, M.A. (Eds.) *Interdisciplinary Perspectives on International Law and International Relations*. New York: Cambridge University Press, pp. 197–222.

66. Shamir, R. (2008). The age of responsibilization: On market-embedded morality. *Economy and Society*, 37(1), pp. 1–19. Doi:10.1080/03085140701760833.

67. Skjærseth, J. B., Stokke, O. S. and Wettestad, J. (2006). Soft law, hard law, and effective implementation of international environmental norms. *Global Environmental Politics*, 6(3), pp. 104–120.

68. Stokes, E. (2013). Demand for command: Responding to technological risks and scientific uncertainties. *Medical Law Review*, 21(1), pp. 11–38.

69. Szyszcak, E. (2006). Experimental governance: The open method of coordination. *European Law Journal*, 12(4), pp. 486–502.

70. Trubek, D. M. and Trubek, L. G. (2007). New governance and legal regulation: Complementarity, rivalry, and transformation. *Legal Studies Research Paper Series*, University of Wisconsin Law School, Paper No. 1047.

71. van de Poel, I. (2009). The introduction of nanotechnology as a societal experiment. In: Arnaldi, S., Lorenzet, A. and Russo, F. (Eds.), *Technoscience in Progress. Managing the Uncertainty of Nanotechnology*. Amsterdam: IOS Press, pp. 129–142.

72. van de Poel, I. (2011). The relation between forward-looking and backward-looking responsibility. In: Vincent, N. A., van de Poel I., van den Hove I. (Eds.), *Moral Responsibility: Beyond Free Will and Determinism*. Dordrecht: Springer, pp. 37–52.

73. van den Hoven, J., Jacob, K., Nielsen, L., Roure, F., Rudze, L., Stilgoe, J., et al. (2013). *Options for strengthening responsible research and innovation: Report of the Expert Group on the State of Art in Europe on Responsible Research and Innovation*. Available from: http://ec.europa.eu/ research/science-society/document_library/pdf_06/options-for-strengthening_en.pdf. [accessed 2 February 2015].

74. Vincent, N. A. (2011). *A Structured Taxonomy of Responsibility Concepts*. In: Vincent N. A., van de Poel I. and van den Hoven, J. (Eds.), *Moral Responsibility: Beyond Free Will and Determinism*. Dordrecht: Springer, pp. 15–35.

75. Von Schomberg, R. (2010). *Organising Collective Responsibility: On Precaution, Codes of Conduct and Understanding Public Debate*. In: Fiedeler U. et al. (Eds.), *Understanding Nanotechnology*. Heidelberg: AKA Verlag, pp. 61-70.

76. Von Schomberg, R. (2013). A vision of responsible innovation. In: Owen, R., Heintz, M. and Bessant, J. (Eds.), *Responsible Innovation. Managing the Responsible Emergence of Science and Innovation in Society*. Hoboken (NJ): John Wiley & Sons, pp. 51–73.

77. Wynne, B. (1992). Misunderstood misunderstanding. Social identities and public uptake of science. *Public Understanding of Science*, 1(3), pp. 281–304.

7.1Table 7.1 Examples of soft regulatory initiatives

Tab. 1- Soft regulatory initiatives: somexample			
	Level of initiative		
Initiator		National/subnational	International/supranational
	Public	Voluntary Reporting Scheme for Engineered Nanoscale Materials (UK) EPA Nanoscale Materials Stewardship Program	OECD Working Party on Nanotechnology European Commission Code of Conduct
	Private	Responsible Nanocode	ISO TC 229 Responsible Care

Source: Arnaldi (2014)

7.2Table 7.2 RRI and the evolution of responsibility paradigms (adapted from Arnaldi and Gorgoni 2016)

Paradigm	**Criterion of ascription**	**Mean of realization**	**Target**	**Dimension**	**Orientation in time**	**Responsibility dimensions**	**Regulating mechanism**
Fault	Liability	Sanction	Negative outcomes	Individual	Retrospective	Liability-responsibility	Hard law
Risk	Damage	Compensation	Negative outcomes	Systemic	Prospective/retrospective	Causality-responsibility	Hard law
Safety	Uncertainty	Expertise	Negative outcomes	Collective	Prospective/anticipative (or preventive)	Capacity-responsibility	Hard law/soft law
RRI	Responsiveness	Participation	Negative and positive outcomes	Collaborative	Prospective/proactive	Virtue-responsibility	Self-regulation/soft law/hard law

1 All the authors outlined the structure of the chapter. S. Arnaldi wrote sections 1, and 2; G. Gorgoni wrote section 4, and 5; E. Pariotti wrote sections 3, and 6; all authors wrote section 7. All authors have read and approved the manuscript. The materials and arguments of this chapter are based on several publications in which the Authors have discussed the links between responsibilization and soft regulation, as well as between RRI and fundamental rights (Arnaldi, Gorgoni, Pariotti 2016; Arnaldi and Gorgoni 2016; Arnaldi 2017).

2 For further details about these and other initiatives, see Arnaldi (2014); Arnaldi et al. (2014).

3 For the purposes of this chapter we do not differentiate between “Fundamental Rights” and “Human Rights”, although it is both possible and relevant to do it from a legal point of view, as they have a different legal status. The consequences of the distinction for an RRI framework are explained by Ruggiu (2015: p. 232).References