regulatory basis; or, finally, (iii) maintain the same regulatory framework under the same all-embracing definition, but start to draw some specific regulatory distinctions for synthetic biology. The risk of suddenly changing governance trajectory is implicit in any case-by-case approach, but we cannot exclude that the risks in the case of synthetic biology could be higher than in other technologies since, as expressly acknowledged, 'risk assessment criteria, methodology and risk management systems established for GMOs and pathogens provide a good basis for addressing potential risks' only for current and short-term developments of synthetic biology, namely until they are not diffuse into the market (SCENIHR, 2014, p. 19). In this sense, the proactive dimension of this model appears too fragile and it is unlikely to use the advantage given by the existing GMO regulation adequately.

3.5 The Rising Model of the *Responsible Research and Innovation*[105]

3.5.1 In a context where risks are distributed and responsibility is pulverized among a multitude of stakeholders, rules of innovation need to be rewritten. Today there is an increasing awareness that the success of innovation needs greater sharing of responsibility by all parties. In particular, in the field of the technoscientific progress.

First, this led to the spread of ELSI studies in order to strengthen the awareness of existing interconnections among disciplines put in question by emerging technologies. Since impacts of the technological development involve different fields, only the interdisciplinarity can cope with this new challenge.

This progressively paved the way to reshape governance processes in Europe.

The demand for the democratization of governance (Jasanoff, 2003) and the related demand for the democratization of ethics (Tallacchini, 2009) prepared the ground for the surge of the 'new governance' model in the field of emerging technologies and the provisory abandon of traditional tools of regulation (Kearnes and

[105] This paragraph retakes and slightly amends (Ruggiu, 2015a).

Rip, 2009; Widmer et al., 2010). In this framework, therefore, we can observe the spread of processes of responsibilization of all actors through the adoption of flexible tools aimed at fostering the participation to innovation (Dorbeck-Jung and Shelley-Egan, 2013). In this regard, soft forms of regulation, as well as spontaneous processes of self-regulation (i.e. self-governance), coexist in flexible frameworks which are fostered thanks to the usage of both old instruments, such as comitology, agency, networking, guidelines, ethical codes, and new ones, such as certification systems, social dialogue and consultations.

Within the European Union several examples of these flexible initiatives can be detected both in the field of nanotechnologies and in that of synthetic biology. These initiatives are thus aimed at: (i) implementing the process of responsibilization as natural support of research and innovation (Ruggiu, 2014b), (ii) at filling the gap of democratic legitimation of the unelected EU bodies, such as agencies (Trubeck et al., 2005, p. 16), and (iii) at preparing the passage to more traditional forms of regulation (Ruggiu, 2015b).

Now responsibility is the password for the advance in science and technology. And this outcome can be achieved only by anchoring governance on some key values at the centre of political communities. Today there is an increasing belief that the voluntary assumption of the responsibility is strictly connected to the ethical acceptability and the social desirability of research and innovation. Therefore, within the framework of the 'new governance' a novel paradigm of governance is rising in Europe.

This model, which is almost substituting 'new governance', is that of *Responsible Research and Innovation* (RRI).

'**Responsible Research and Innovation** (RRI) refers to the comprehensive approach of proceeding in research and innovation in ways that allow all stakeholders that are involved in the processes of research and innovation at an early stage (A) to obtain relevant knowledge on the consequences of the outcomes of their actions and on the range of options open to them and (B) to effectively evaluate both outcomes and options in terms of societal needs and moral values and (C) to use these considerations (under A and B) as functional requirements for design and development of new research, products and services' (van den Hoven et al., 2013, p. 3).

With RRI the incorporation of a number of strategic ethical values and societal inputs is deemed as the right way to transform the innovation process in a responsible action produced by the cooperation of all stakeholders. In this way innovation can feed the societal trust and stabilizes itself in a robust framework.

Within the research community there is the belief that only thanks to the support of key stakeholders for a responsible action of collective nature it is possible to successfully drive the innovation process and achieve outcomes that can be sharable within society. Trust is the non-eliminable ingredient of the recipe for the success of innovation. Today this belief is increasingly diffused within EU institutions. This is the reason why today the RRI paradigm already orients the EU practices in Europe, in particular in EU research framework programmes.

A clear example of this shift is Horizon 2020.

With Horizon 2020 research and innovation have 'been placed at the centre of the Europe 2020 strategy'.[106] Accordingly, Horizon 2020 seeks to develop this new model of governance within the European Union. According to EU authorities this model should boost for excellent science, a more competitive industry and a better society without compromising sustainability, ethical acceptability and a socially desirable framework.[107]

Notwithstanding this official endorsement, the RRI landscape appears to be quite multifaceted within the research community. This situation of epistemic disagreement can be also testified by the lack of a shared definition of RRI (Owen et al., 2013, p. 27). Notwithstanding this lack, or because of this, up to now at least two main tendencies characterize the RRI debate (Ruggiu, 2015a).

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[106] European Union (2013) Regulation (EU) No. 1291/2013 of the European Parliament and the Council of 11 December 2013 *Establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014–2020)*, of 20 December 2013, *Official Journal of European Union*, L347/104, http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/fp/h2020-eu-establact_en.pdf. Accessed 13 July 2015.

[107] In this institutional framework we need to mention that both the Lund Declaration (2009) and the Council conclusions on the social dimension of the European Research Area (2010) underline the importance of integrating societal needs and ethical concerns into the research and development (van den Hoven et al., 2013, p. 3).

One, which I call *socio-empirical*, emphasizes the role of public engagement since governance 'would need to be based on the principle of inclusiveness, involving all actors at early stage' (Owen et al., 2012, p. 752). In this way this participatory model should produce a shift from science in society to a science *for* society, *with* society (ibid.).[108] Here the values on which to anchor European governance are created through democratic processes. Innovation is the product of a collective action, therefore the society has to decide how it must be, by addressing the societal values that need to be put at the centre of innovation. Values are therefore the end of a process of negotiation over innovation.

The other, which I call *normative*, aims at anchoring the process of decision making on some prefixed normative filters, such some shared goals expressed at the EU treaties level, in order to produce the ethical acceptability, sustainability and social desirability (van den Hoven et al., 2013, p. 23). In other words, to be responsible, namely ethically acceptable, the EU values must steer research and innovation. Values therefore are the starting point of processes of research and innovation.

These two approaches are only two different tendencies within the RRI framework (Ruggiu, 2015a). They are two abstract potentialities. These two versions of the same theoretical model express only two extreme possibilities among the entire range of available opportunities opened up by RRI. Therefore, they do not exclude mixes and contaminations. And, as a matter of fact, in the reality we can count more contaminations between these models than the manifestation of their pure version.

3.5.2 As said, so far no shared definition emerged in the research community (Owen et al., 2012, p. 27). Nevertheless, the von Schomberg's definition of RRI is often recalled in the academic debate on RRI (e.g. (Owen, 2014), p. 6).

According to von Schomberg it should be defined as 'a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the

[108] This approach to RRI is also shared, among others, by Sutcliffe (2011), Blok, Lemmens (2014).

(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, 2011b, p. 54).

It is worth noting that this definition was substantially followed by the Experts Group on the State of the Art in Europe on Responsible Research Innovation, which lastly maintained all its main features (van den Hoven et al., 2013). Here the ethical acceptability is the starting point of the model and on this the participation can be built according.

On the other side, Owen and his colleagues (2013) proposed a shorter (and broader) definition of responsible innovation, which seems to stress only the participatory tendency of the model that is deemed to be, alone, productive of shared ethical values.

According to Macgnathen, Owen and Stilgoe, in fact, 'Responsible innovation is a collective commitment of care for the future through responsive stewardship of science and innovation in the present' (Owen et al., 2013, p. 36; Silgoe et al., 2013, 3). As it emerges from this definition public engagement, here, is the only means to reach ethical acceptability in accordance with a socio-empirical approach.

These two definitions well express the above-mentioned approaches to RRI: the *normative* and the *socio-empirical*.

In general, the RRI model is characterized by four basic features.[109] (i) RRI is a process able to *involve* actors, mainly private ones, which are distributed in the global sphere (Stilgoe et al., 2013, p. 4; Owen et al., 2013, p. 38). (ii) It aims at *anticipating* regulatory choices by voluntary or spontaneous behaviour of stakeholders, mainly researchers, innovators and research funders (Barben et al., 2008). In this regard some talk of 'RRI by design' (Owen, 2014, p. 11). (iii) It produces a shift of the focus from a risk-assessment

[109] While there is no shared definition, there is no agreement too on the main features of RRI. See e.g. van den Hoven et al. (2013, pp. 57–58); Owen et al. (2013, p. 38); Silgoe et al. (2013, pp. 3–5). In 2012 the Directorate-General for Research and Innovation of the European Commission has addressed six dimensions in the RRI framework (engagement, gender equality, science education, open access, ethics, governance). See http://ec.europa.eu/research/science-society/document_library/pdf_06/responsible-research-and-innovation-leaflet_en.pdf. Accessed 7 August 2015.

to the assessment of innovation processes since the model is aimed at considering also the *loss of innovation opportunities*. In this sense, it is crucial the anticipation of the impact assessment at an earliest stage in order to make the trade-off of both negative and *positive* impacts of a given emerging technology before it is too late (von Schomberg, 2013, p. 55; Stilgoe et al., 2013, p. 3). (iv) Finally, it is to mention the socially oriented character since *ethical acceptability*, sustainability and societal desirability are irrenunciable ingredients of innovation (van den Hoven, et al., 2013, p. 58).

The integration of these components should reach a better level of both reflexivity, by asking researchers to think about their ethical, political and social assumptions, roles, as well as responsibilities; and responsiveness, by opening up the process to inputs stemming from stakeholders in order to change its direction when it does not meet societal needs and is ethically contested (Owen et al., 2013, p. 38).

3.5.3 However, the two definitions mentioned above are able to encompass two different modes that can legitimately interpret the RRI style. The first, of fully normative nature, which articulates processes of co-responsibilization of stakeholders around a set of normative filters in order to foster ethical acceptability (e.g. von Schomberg 2011a, 2013; van den Hoven et al., 2013). The second, of socio-empirical nature, which focuses on interaction processes among different stakeholders aimed at developing participatory forms of co-responsibility in a given field of innovation, namely inclusion (e.g. Owen et al., 2012; Owen et al., 2013; Owen, 2014; Sutcliffe, 2011).

It worth noting that, while the normative version talks of 'Responsible Research and Innovation', the socio-empirical approach prefers to use the term of 'Responsible Innovation'. In this regard, these two approaches would differ one another also nominally. The difference though is also conceptual.

According to the first, in fact, both the stage of innovation and the design of the research are the target of the shaping action of normative filters.

According to the second, innovation is responsible because research practices autonomously develop themselves giving rise to

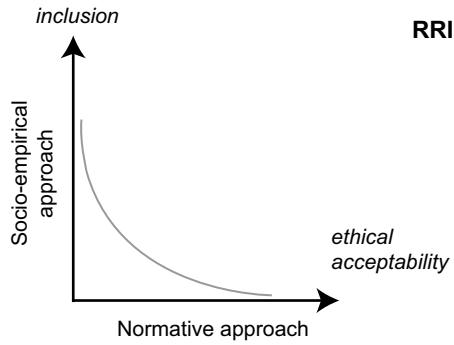

Figure 3.1 The normative approach tends to increase the ethical acceptability, while the socio-empirical approach tends to increase the level of inclusion. Within the RRI model the two approaches move in different directions.

responsible outcomes in the field of innovation. There is no need to shape practices from the external (top-down) because who take part to practices will transform them from the internal spontaneously, mutating their behaviour. And this will directly affect innovation (Groves, 2015).

The idea behind both approaches is that RRI can foster the surge of a responsible behaviour of a multitude of stakeholders by integrating the societal desirability of research and innovation and their ethical acceptability in flexible structures of governance. In this sense, they fully belong to the 'new governance' framework (Ruggiu, 2015a). In this conceptual framework participation plays in any event a crucial role. However, the relation between participation and ethical values is thought differently by these two approaches.

Notwithstanding both versions identify the same features and components of RRI (i.e. inclusiveness, anticipation, the focus on also positive impacts, the ethical acceptability), they differentiate each other for the different emphasis they put on some elements (i.e. normative anchor points, public engagement).

However, in this framework, by underlining exclusively the prescriptive nature of spontaneous responsible behaviour of stakeholders (i.e. they produce values), the socio-empirical approach tends thus to coincide with the current flexible, tentative and adaptive model of governance existing at EU level (Sutcliffe, 2011,

p. 5; Kearnes and Rip, 2009; Mandel, 2009). In this sense, it runs the risk of completely losing the novelty of the RRI model.

An example of this version can be deemed the consultation processes launched by the Commission in order to draft the code of conduct on nanotechnology research (Ruggiu, 2014b). In this context a number of sections of civil society including researchers, individuals, non-governmental organizations were involved through official consultations promoted at the EU level in order to identify principles of the code of conduct on nanoresearch.

Conversely, the normative approach means to create a responsible framework by anchoring policy choices on some principles of legal nature (van den Hoven et al., 2013, p. 23; Sutcliffe, 2011, p. 7), thus running the risk of stiffening governance processes.

Again, the case of the 2008 Commission code of conduct can be enlightening. In that occasion the final draft of the code on nanotechnology research was laid down on the basis of the EU objectives set out in the EU treaties that provided the basis for the subsequent consultations (Ruggiu, 2014b). In that case the institutional origin of 'normative anchor points' represented a difficulty to the communication process of values, which is strategic to rightly motivate stakeholders that will be requested to comply with rules stemming from those values. For example, consultation participants gave rise concerns on the vague reference to ethical principles and to responsibility for future generations, which was understood as legal liability and thus refused (European Commission, 2007b, p. 3). In this regard the socio-empirical version rightly points out that those values are better shared whether they are collectively addressed through the negotiation.

3.5.4 According to the socio-empirical version inclusion produces values, which have societal origin. Therefore, public engagement must be pursued to find values. The normative version, instead, thinks that pre-existing values produces inclusion. The ethical acceptability therefore is here the main value and this must be reached by identifying a set of ethical principles which are at the constitutional level.

Certainly, especially the socio-empirical version underlines the strategic role of public engagement of the parties at play (Sutcliffe,

2011, p. 3). Here, the starting point is the recognition of the limits existing in the idea of liability. The responsibility which is manifested through instruments of regulation is an important part of the responsible innovation 'but it has severe limitations' (Owen et al., 2013, p. 32). It expresses a *retrospective* logic unable to cope with challenges of the fast development of science and technology, which needs the ability of adapting choices and tools to the variability of scenarios. This capability is the resilience.

In this movable landscape neither actors, nor the society can wait for more data before commercializing a product. This fact creates a gap of responsibility since none can be deemed responsible for circumstances that cannot be foreseen and known at the stage of the action. Therefore, '[a]t the earlier stage of innovation we can have most of opportunities to shape and control innovation, with far fewer costs and vested interests; but it is precisely at these early stages that we have little or no evidence to make the case for control' (ibid., p. 34).

Against the precautionary principle, the risks of missed opportunities are the price of acting too early by regulating a field, which is rapidly growing up, but still unknown. In this framework it is better to rest on 'moral luck' since the moral responsibility is based on both what is known at the time of action and on what can be reasonably foreseen. The framework of responsible innovation must consider not only the products which would lead to a form of *retrospective responsibility*, but also the purposes of innovation which would pave the way to a form of *prospective responsibility* (ibid., p. 34). These purposes refer to what kind of future we want science and technology to face, to what challenges we want they cope with, and to what values we want they are anchored on (Owen, 2014, p. 3). In other words, this version of RRI 'asks how the targets for innovation can be identified in an ethical, inclusive, and equitable manner' (Owen et al., 2013, p. 35).

All societal actors, including researchers, policymakers and civil society, must be engaged in order to reach 'their joint participation in research and innovation, in accordance with the value of inclusiveness' which is expressly set out also in the Charter of fundamental rights of the European Union (Directorate-General for Research and Innovation of the European Commission, 2012, p. 1). It

must be returned to society the possibility of deciding over its future. Therefore, autonomy of all stakeholder must be preserved. A sound framework for excellence in the research and innovation process entails that societal challenges are framed on the basis of widely representative social, economic and ethical concerns and common principles (ibid.). This means a public engagement of all parties on equal basis also as regards the gender representativeness (ibid.).

The equal participation is strategic for giving voice to all the represented interests and producing values that should be at the core of the process itself in a bottom-up manner. In this sense, the process (i.e. participation), which leads to the creation of values whereon the science and innovation can be anchored, is the sole value.[110] For this reason, the process must be non-partisan with regard to the values followed by all parties.

The emphasis of the socio-empirical approach on the structure of the process, led, for example, to use the stage gate architecture typical of management of innovation processes (Cooper, 1990).

Stage gate systems are frameworks where the process of decision-making is guided through the explicit provision of phases 'being subject to formal or informal approval at a decision "gate"' (Owen, 2014, p. 13). The stage gate architecture was used, for example, in the SPICE project (Stratospheric Particle Injection for Climate Engineering project), a project on geoengineering funded by UK Research Councils in 2010 which tried to develop a more democratic and legitimate framework for science and innovation by opening up 'to a broad anticipation, reflection and inclusive deliberation, with the aim of making policy more responsive' (Stilgoe et al., 2013, p. 10).[111]

This approach is not normative, 'in the sense that it has defined a process but not the values upon which this should rest' (Owen, 2014, p. 7). On the contrary, the normative dimension of values is the

[110] Thus, as far as the socio-empirical version underpins the value of the democratic participation, it can be deemed as prescriptive (like the normative one), but it does not move from some prefixed legal norms. It distinguishes from normative version since it eludes from the outset the normative dimension of rules and legal principles. In other words, it believes in the exclusive productivity of societal dimension, which tends to substitute that of (legal) norms.

[111] On the SPICE project see also Chapter 8 Part II on the right to healthy environment.

outcome of the process of deliberation. For this reason, values 'will differ according to the context in which the framework is applied and will be culturally-sensitive' (ibid., p. 7). In other words, values can differ according to the sociocultural and even technological context. Values differ not only according to the cultural context (for example, BRICS countries will focus on a certain set of values),[112] but they also differ according to which technology is concerned. Values in nanomedicine are different from those in SynBio applications in bioremediation and so forth.

In this framework, reflexivity and responsiveness are key features of this model since it leads all the concerned parties to reflect on purposes of science and innovation (on what innovation has to do and not to do); it maintains opened all options, increasingly includes new perspectives and permits to correct errors while they occur (resilience). 'This introduces the principle of deliberative democracy into the dimension of responsiveness' (Owen et al., 2013, p. 35).

The possibility that all parties contribute to the definition of values at the core of the process is thus crucial.

In context of uncertainty the negotiation, inclusive and democratic, is the main value at stake and it testifies to the commitment in setting the agenda of innovation (Owen et al., 2012, p. 4). This is the reason why this version expresses a form of a rationality that focuses only on how the process (of negotiation) is conducted since the process as such is the means through which principles driving regulatory tools are chosen (Heydelbrand, 2003, p. 238). Here the process grounds (societal) values that are at the basis of a given field of science and technology.

Another aspect of this version is the lack of normativity.[113] Here the normative dimension of prefixed rules and principles is eluded. There is no way to understand in abstract what to responsibly act

[112] This objection is made by Groves (2015, p. 327).

[113] Namely, it does not address any normative dimension of both legal and moral nature on which reality ought to conform. In other words, the difference between the two versions cannot be interpreted in terms of the prescriptive/descriptive polarity since both versions are clearly prescriptive and identify a model able to transform the status through, on the one hand, the process (of negotiation), through norms, on the other.

means, in as much as the prefixed values in a given context (e.g. EU goals) can be nothing more of a provisional starting point which can much differ from the final outcome (Owen, 2014, p. 7). Only the reality can teach us what responsible innovation means, meaning that rules and principles are the final outcome of the process of negotiation of actors at play. In these terms it can be deemed as socio-empirical. Then, there is the need to collect a multitude of cases, i.e. a number of *de facto* governance arrangements in place,[114] wherein this model has been realized in view of extrapolating its main features (e.g. (Sutcliffe, 2011, pp. 19–26)).[115] There is no normative dimension upstream, no principle or value is prefixed in this framework, except that of the mere negotiation, since the reality is the only normative dimension able to build the theoretical model of RRI. In this sense, the dimension of normativity can only implode and collapse into that of reality.

3.5.5 Instead, the normative approach focuses mainly on the role of these normative filters established, for example, in the EU law, meant as factors of steering European policies towards anticipatory, participatory and responsible outcomes (von Schomberg, 2010, 2011a, 2011b, 2013; van den Hoven et al., 2013). In this framework the EU objectives emerge as the inescapable starting point of any initiative of governance in the field of emerging technologies. These goals should work as 'normative anchor points' in the context of governance by allowing EU institutions to anticipate choices of policy and to make decisions through their right balancing.

The role of these filters appears almost central in the normative version of RRI since they tend to bind European governance on the achievement of some goals laid down by EU treaties. Thanks to the interaction of these constitutional goals the success of the chance of both anticipating policy choices and fostering the stakeholder engagement would be ensured. Therefore, not only 'normative

[114] See Stilgoe et al. (2013, p. 7).

[115] A concrete example of this version is the SPICE project on geoengineering (i.e. the deliberate manipulation of the earth's climate) funded by UK Research Councils which tried to develop a more democratic and legitimate framework for science and innovation by opening up 'to a broad anticipation, reflection and inclusive deliberation, with the aim of making policy more responsive' (Stilgoe et al., 2013, p. 10).

anchor points' shape EU research funding programmes, documents of policy, guidelines, codes of conduct, but they also work as a centre of gravity of processes of public engagement such as social dialogue and consultations. In other words, they are a source of structuring of the entire governance. In this sense, here (constitutional) values also found processes of participation.

These basic values are laid down in constitutions and, in Europe, they are set out at the heart of the EU law.

According to von Schomberg (2013, p. 57), for example, they are 'normative targets which we can find in EU Treaty on the EU'. As noted by some, this points out the mainly European origin of the RRI model.[116] And this could represent a limit in abstract outside from this context. 'Normative anchor points' are goals institutionalized at the EU level within EU treaties. In other words, they are legal norms, which are at the summit of the EU law and steer (should steer) the action of all EU authorities.

But what are these constitutional guides of governance in Europe?

By referring to Article 3 of the Treaty on the European Union[117] 'anchor points' are EU goals, namely: the promotion of technoscientific advance'; market competitiveness; sustainability (which includes also precautionary principle); the promotion of social justice, equality, solidarity and fundamental rights; the protection of human health and environment. In particular, the RRI framework provides that 'research and innovation must consider the principles on which the European Union is founded, i.e. the respect of human dignity, freedom, democracy, equality, the rule of law and the respect of human rights, including the rights of persons belonging to minorities' (Directorate-General for Research and Innovation of the European Commission, 2012, p. 1).

In this regard, the reference to fundamental rights among other common values at the core of the EU makes this model an interesting

[116] http://www.scidev.net/global/innovation/opinion/responsible-innovation-european.html. Accessed 15 December 2016.

[117] European Union (2010) *Treaty on the European Union* (consolidated versions 2010/C 83/01) *Official Journal of the European Union* 2010/C/83/01, 30 March 2010 (TEU post-Lisbon).

case of a *rights-based model of governance* (Ruggiu, 2013, p. 211; 2015a, p. 224; Arnaldi and Gorgoni, 2016).

Notwithstanding the normative version means to emphasize the integration of some EU targets within the EU action, it is not problem-free with regard to their role, function and scope, especially with regard to just fundamental rights.

In abstract the interaction of these normative goals should overtake a case-by-case approach, which is notably the current approach of EU (Stoke and Bowman, 2012), and lead to reach simultaneously anticipatory and participative outcomes. In fact, they anticipate the directions of the EU policy by pre-determining the space of possible and legitimate choices for policymakers and identify 'positive impacts' at the early stage, contributing in steering the allocation of research funding (von Schomberg 2011b, p. 53; 2013, p. 59). Their action in the distribution of funding through the discernment of ethically sound research projects from those that are outside the space of legitimate choices of policy, makes 'anchor points' a powerful anticipation factor in EU governance. In this way, the compliance with fundamental rights of the EU Charter should determine the ethical acceptability of research and, once those projects are commercialized, of innovation (von Schomberg, 2011b, p. 50).

Their contribution to the social dialogue and participation is due to the rationale, which legitimates their presence in democratic societies, in particular in the EU law. The justification of the recourse to 'normative anchor points' is rooted on the peculiar context of the public discourse in modern societies (von Schomberg, 2010). Since 'the consequences of technological innovation are usually the result of collective action or effects of social systems', rather than resulting from the actions of individuals, there is the need of an ethics of co-responsibility (Ibid., p. 61). Therefore, given both the current state of scientific uncertainty and the current lack of consensus even in the scientific community, as well as within the society, the collective responsibility can be based only on fundamental constitutional principles such as fundamental rights. In pluralistic societies divided in a multitude of views and opinions, fundamental rights are the only common ground rooted on consensus, democratic, able to overcome disagreement in matter of science.

If in the case of conflict, the disagreement can be overcome thanks to the recourse to constitutional rights, this should happen even when the disagreement affects innovation. In this sense these principles, understood as procedural norms of the public deliberation according to the Habermasian theoretical framework (Habermas, 1992), found the public discourse also in technoscientific field.

In this sense, if any conflict can be solved with the reference to these principles, even public engagement has to be based necessarily on them. In this theoretical framework 'dimensions of responsibility [. . .] are value- and not rules-based', meaning that they are anchored on some EU fundamental goals (Owen et al., 2012, p. 756). Even though these normative filters 'are in themselves results of public and policy deliberation and enable consensual decision making at the policy level [. . .] they need to be consciously applied and be subject of public monitoring' (von Schomberg, 2011b, p. 48). In this sense, 'normative anchor points' need to be accordingly concretized in EU instruments of policy, as well as governance.

In this framework, the right balance among 'normative anchor points' acquires though a strategic role since the final outcome of EU governance depends exclusively on it.

3.5.6 A particular interpretation of the 'new governance' turn sees in the usage of flexible forms of government the rise of a new model of rationality counterpoised to the old one understood as founded on a goal rationality. This new logic is now based on a *process rationality* (Heydelbrand, 2003). In this sense, while the socio-empirical approach mainly reflects a process rationality, the normative one should follow a *goal rationality*, namely a type of rationality that focuses mainly the objectives (the values) which should steer any process so that the process is fair in as much as the principles at its basis are fair (ibid., p. 236). The transformation of the global framework led to 'the eclipse of regulation and the decentralization of state and economy' and the rise of a 'new mode of governance based on a logic of informal negotiated processes within social and socio-legal networks' (ibid., p. 326).

The current age is governed by this rising paradigm. This shift led to substitute the solutions of conflicts through rules that are an

application of principles set out at the summit of our constitution with solutions based on processes of negotiation of all parties at stake. In this latter case what counts is how the process is devised and enacted. 'Colloquially, this is often interpreted as getting the right people at the table, and one will get substance' (ibid., p. 328). In other words, while the final outcome depends in the first case on goals (namely values) laid down at the beginning of the process, in this latter case it depends on the forming process of the deliberation on what values should govern at the end (Ruggiu, 2015a, p. 220). Only the democratic nature of the process of negotiation can ensure that a fair solution is reached in a societal conflict, whatever it is. On the contrary, the goal rationality believes that only constitutional principles can ensure the right working of democracy especially when the conflict affects crucial questions even in the field of science and technology.

This confirms the actuality of the debate, which counterpoised advocates of democracy (Waldron, 1999) and advocates of constitutional rights (Dworkin, 1996). Are good outputs founded on decisions based on democratic processes or on right principles?

Although the role of 'normative anchor points' within the normative version appears quite clear and would permit to solve problems concerning policy choices at the institutional level, it is not problem-free.

These normative targets for innovation 'embed tensions, complex dilemmas, as well as areas of contestation and outright conflict' (Owen et al., 2013, p. 37). As recognized by Weber (1922, p. 332ff.), values are intrinsically conflictual. Therefore, in regime of moral pluralism the risk is to pave the way to a state of permanent conflict about values, leading to the paradox that the more they are institutional, the more they are contested in society. For this reason, only the openness of the democratic debate in the field of science and innovation can embed new perspectives in front of an ever evolving context, granting thus the capacity of the system to revise its decisions and trajectories (Sutcliffe, 2011, p. 10; Holbrook and Briggle, 2014, p. 54).

According to this argument only the parties at stake are legitimized to choose values under which to develop their activity

(Holbrook and Briggle, 2014, p. 62). The top-down method of values setting can only stiffen the debate and lead to weak decisions.

Against the opinion that these values are already legitimized by democratic processes, this argument points out the increasing lack of legitimation which exists in modern societies (ibid., p. 60). This legitimation crisis now affects also founding values, for example fundamental rights.

However, one could note that the values addressed by the normative version are very general and refer to the current interests at stake within the civil society, though expressed in a bureaucratic manner (Ruggiu, 2015a, p. 224). For example, enterprises and governments have the interest in the more competitiveness of the market. Research institutions and funding organizations, as well as policymakers, have the interest in the advance of science and technology. Civil society organizations and the citizens in general can have the interest in the increment of occupation, the growth of sustainable activities of firms, as well as in the protection of health, safety of products, and, in general terms, in individual rights. It is hard to imagine different goals at stake, although we can imagine that the technoscientific progress affects them in different ways. For example, the rights affected by Electronic Health Record Systems (the right to the protection of personal data, privacy, the patient's right to consent for electronic health exchange) are presumably different from those affected by enhancing technologies (right to bodily integrity, self-determination, human dignity). Moreover, the same right can be affected differently depending to the technological context. This should also imply a different impact assessment, even in the same field (e.g. ICTs) depending the application at stake (Internet, healthcare).

As said, another problem is the moral disagreement existing within modern societies (Owen et al., 2013). Even if we may agree on these goals, in concrete situations we may disagree on their meanings and applications. As expressed by only Article 3 (TEU post-Lisbon), they can be quite indeterminate and semantically ambiguous so as they need to refer to other more specific norms of the EU treaties. For example, the goal of the market competitiveness can be linked to free circulation of goods and services such as Article

26,2 (Internal market),[118] Article 28ff. (Free movement of goods)[119] and Article 56 (Free movement of services)[120] of the Treaty on the functioning of the European Union.[121]

We need also to bear in mind that some ambiguities can exist among 'normative anchor points' themselves.

For example, the 'anchor point' of the 'quality of life, high level of protection of human health and environment' can cover both the State's interest of the Public health (e.g. Article 168 TFEU),[122] namely a public interest, and the right to health, namely a fundamental right of the individual (Art. 31 of the EU Charter – Fair and just working conditions[123]; Article 35 of the EU Charter – Health care[124]).

Moreover, the same article can lead to conflicting uses and applications. For example, Article 35 of the EU Charter deals with the same interest both as an individual right and as a legitimate EU aim of public nature.[125] The problem is that public interests on health and safety entail a given trade-off by public authorities and can conflict with individual rights, as well as with the level of

[118] 'The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties'.

[119] 'The Union shall comprise a customs union which shall cover all trade in goods and which shall involve the prohibition between Member States of customs duties on imports and exports and of all charges having equivalent effect, and the adoption of a common customs tariff in their relations with third countries'.

[120] 'Within the framework of the provisions set out below, restrictions on freedom to provide services within the Union shall be prohibited in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended'.

[121] European Union (2008) *Treaty on the functioning of the European Union* (consolidated versions 2010/C 83/01) *Official Journal of the European Union* 2008/C/115/08, 9 May 2008 (TFEU).

[122] 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.

[123] 'Every worker has the right to working conditions which respect his or her health, safety and dignity'.

[124] 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices'.

[125] 'A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities'.

protection required by supreme courts in the application of national constitutions and human rights treaties (Ruggiu, 2015a, p. 229).

In this sense, the public interest in the 'high level of protection of health' should not be confused with the individual right to health as such. These ambiguities, content indeterminacy and semantic unclearness can affect the understanding of stakeholders, even when the values at stake can be deemed as sharable in abstract. For example, semantic concerns on EU goals clearly emerged in the instance of the code of conduct for responsible nanoscience and nanotechnology research[126] (EC CoC), which represents an interesting case of 'normative anchor points' in action (von Schomberg, 2010; Sutcliffe, 2011, p. 22; Ruggiu, 2014b).[127]

3.5.7 RRI leads to the overcoming of the liability paradigm. According to the normative version, since the benefits of technology are (eventually) demonstrated by the market success, the market finally decides what counts as an 'improvement' in current societies (von Schomberg, 2013, p. 54). In this context unpredictable and positive impacts run the risk of being solely justified in economic terms. While, thanks to the retrospective paradigm of legal liability there is anyway a responsibility for negative impacts after the launching of products into market, '[t]here is no equivalent for a formal evaluation of the benefits' (von Schomberg, 2013, p. 55). In this framework a retrospective approach based on paradigms of accountability, liability and legal responsibility tends to prevail but the value of opportunities is neglected. Risk regulation is an important framework for the growth and development of innovation. However, the ambition of RRI is to anticipate the

[126] European Commission (2008) Recommendation *on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research* C(2008) 424 final, available at http://ec.europa.eu/research/science-society/document_library/pdf_06/nanocode-apr09_en.pdf. Accessed 29 September 2017.

[127] For example, translation problems of the word 'accountability' were apparent during the NanoCode survey. Indeed, 'the French and the German translations of the "accountability" principle as "responsibility" earned mistrust as they were interpreted with a connotation of *implying legal liabilities* as well as suggesting that scientists are held responsible for what is done with their work by decision outside their control or by other actors in the future' (Meili et al., 2011a, p. 6 – italics mine).

assessment of positive impacts of research and innovation by creating a responsibility framework for all actors.

To evaluate positive impacts there is the need of public engagement.

Forms of co-responsibility of stakeholders can be built only if all parties are involved from the outset in search of 'right impacts' by turning the retrospective standpoint into a prospective and proactive one. In this sense, the public investment in research and innovation cannot be justified only in macro-economic terms any longer. But since we cannot appeal to the Aristotelian ideal of good life, we need to resort to another basis. This normative dimension, which allows us to distinguish right impacts from unintended negative consequences, is expressed, as we know, by the values embedded in the Treaty on European Union referring to, in its turn, fundamental rights of the Nice Charter[128] (von Schomberg, 2013, p. 58).

Elements of this new perspective can be found in FP7 and other research funding programs, such as Horizon 2020 (van den Hoven et al., 2013, p. 21). As Horizon 2020 shows, European policy is increasingly legitimized in terms of public values and these values are currently expressed in the Charter of fundamental rights of the European Union. In fact, they draw the normative framework needed to define the impacts as legitimate.

According to the Shared Value Creation Theory there is an alternative way to create value into the market between for-profit and non-profit (Kramer, 2011).

'Society's needs are huge – health, better housing, improved nutrition, help for aging, greater financial security, less environmental damage' (ibid., p. 7). Surprisingly they represent the greatest unmet needs in the global economy. In advanced economies there is an increasing demand for products and services that meet societal needs which can support an alternative way of market. The development of enterprise forms that address these needs represent thus an alternative way of increasing productivity and expanding

[128] European Union (2000) *Charter of Fundamental Rights of the European Union*, adopted in Nice on 7 December 2000 (came into force on 1 December 2009). After the entry into force of the Lisbon Treaty (1 December 2009) the Nice Charter is now legally binding according to Art. I-6 §2 Lisbon Treaty.

their markets through responsible innovation. It joins together the self-interested behaviour to create economic value with the creation of societal value (ibid., p. 17). By fostering innovation, improving production techniques and building supportive industry clusters at company locations in order to increase firms' efficiency, yields, product quality and sustainability, the market can simultaneously solve social problems and creates profit (ibid., p. 5).

The premise is that both economic and social progress must be addressed by using value principles, better connecting the companies' success with the societal improvement (ibid., p. 7). A feature of the shared value is that it focuses 'on the right kind of profits – profits that create societal benefits rather than diminish them' (ibid., p. 17).

This conceptual framework can be deemed the ground which leads the innovation to meet 'Grand Challenges' addressed by the Lund Declaration (2009): namely 'global warming, tightening supplies of energy, water and food, aging societies, public health, pandemics, and security' (ibid., p. 1). Market and innovation can respond to societal needs by pursuing success and profit and addressing these fundamental goals that are at the summit of the EU law. In this way the 'Grand Challenges' can be seen as 'normative ends of responsible innovation' (Stilgoe et al., 2013, p. 10), i.e. a manifestation of those 'normative anchor points' expressed in the Treaty on the European Union.

In this sense, 'Grand Challenges' represent 'an alternative justification for investing in research and innovation' from the standpoint of societal needs (von Schomberg, 2013, p. 59). Although they tend to maximize the impacts of science and innovation on society, by concentrating funding in some specific areas, 'Grand Challenges' express that normative dimension where European governance needs to be anchored. But, differently from 'anchor points' they speak the language of the society by referring to needs and ambitions, instead of that of (ethical) values and goals.

In sustainable science there is the need to 'define criteria for R&D processes that are more problem-oriented and transdisciplinary, [to] take into account social needs and therefore [to] contribute to the solution of Grand Challenges' (van den Hoven et al., 2013, p. 20). This implies the increasingly integration of studies on ethical, legal,

and societal aspects of emerging technologies in the public debate at the earlier stage in order to widen the scope of issues at play (Kearnes and Rip, 2009, pp. 9, 12ff.). The integration of social and ethical aspects in the research and innovation process can foster the quality of research, the development of more successful products and improve the market competitiveness (van den Hoven, et al., 2013, p. 22).

This integrative effort would tend thus to shift the focus of the discussion from the consideration of mere risks to the evaluation of opportunities of science and innovation embedding views of futures into the debate on responsible innovation. 'Grand Challenges' focus on some specific opportunities (supply of energy, water and food, etc.). Therefore, according to the normative approach also opportunities of development need to be prefixed.

As noted, while the normative version tends to propose a fixed anchorage of the European governance (values and 'Grand Challenges'), the anchorage should be movable and variable for the socio-empirical one (Owen, 2014).

According to the socio-empirical version, dynamic processes of society need to be free in order to express needs that are emerging within the societal body. In this sense there is no 'Grand Challenge' upstream since only the democratic participation of all parties can addresses the most urgent social needs, by allowing to maintain the dialogue open on current trajectories of science and innovation and to correct possible errors of direction (Owen et al., 2013, p. 37).

Innovation must be a collective effort of *co-design* by users whose needs have to be taken into account from the outset by shaping direction of research, as well as of development of products that will be commercialized in the future (Groves 2015, p. 328). Only users are in the best position for evaluation which needs the consumers have. This is the deep meaning of quest for the democratization of innovation of socio-empirical approaches.

As rightly pointed out, to fix some upstream goals would only mean to stiffen research and innovation and loose opportunities of improving the societal conditions (ibid., p. 329; Ruggiu, 2016, p. 115). To focus on just some opportunities of innovation would mean to lose all other opportunities of innovation at stake.

In this context the socio-empirical version casts the doubt that the best economic growth in science and innovation needs the convergence of funding in some given areas. It would be a deprivation of the process of science and technology.

Instead of focusing on 'Grand Challenges', the course of innovation needs to be articulated in terms of visions and expectations that would take place in public and democratic fora (Owen et al., 2013, p. 30). Visions are the result of the listening of needs of users. Only thanks to visions needs of recipients of innovation can be highlighted and can shape its trajectories.

This could be a way to make the society as creator of innovation caring about its products by bearing the responsibility of its destiny (Grinbaum and Groves, 2013, p. 132). It is a process of re-appropriation of innovation by the society. In this sense, visions and expectations are the privileged location for considerations of responsibility as long as they express a proactive attitude in the development of science and technology (Simakova and Coenen, 2013, p. 252). However, by anchoring research on public engagement exactly like 'Grand Challenges' do, here the risk is to tell science *what* to must do. In other words, the collection of inputs from the society runs the risk of taking the place of science and technology in their tasks, while it could only be a good opportunity for new studies and new products (Ruggiu, 2016, p. 115).

3.5.8 In this framework we cannot but notice that the socio-empirical and the normative approaches tend to address also two different modes of anticipation of the innovation impacts.

Here a clarification is needed by distinguishing three modes of our relation with the future.

First of all, we need to distinguish anticipation from forecasts and foresight (Poli, 2015).

Forecast is data-based. It has a predictive scope and calculable nature. It tends 'to adopt either a very short – as with econometric models – or a very long – as with climate change models – temporal window' (Poli, 2015, p. 90). It is often quantitative and develops under assumptions of continuity. This model of calculating the future works since 'its structure remains essentially the same or the laws governing it remain the same' (ibid.).

Instead, foresight is not predictive and it aims at addressing a number of possible futures. These futures take form of scenarios. Foresight has mainly qualitative nature by focusing on discontinuity. In other words, it is the field of possible scenarios, which can have an explorative aim (they develop from the present to the future) or a normative aim (they shift from the future to the present).

Finally, anticipation is different from the data elaboration from main trends (forecast), as well as from the exploration of possible scenarios (foresight). Anticipation aims at identifying systemic models able to change human behaviours in order to better cope with futures. Anticipation refers to processes and structures able to regulate future negative consequences still uncertain. This is the field of governance and policy-making and it is linked to the resilience of the system to increasing societal insecurities (Poli, 2014, p. 17). 'A system behaving in an anticipatory way – an anticipatory system – takes its decisions in the present according to "anticipations" about something that may eventually happen in the future' (Poli, 2015, p. 97).

New governance models therefore address specific anticipation models. In this sense, the two RRI versions also address two different anticipation models of governance.

According to the socio-empirical version the main problem of innovation is due to the fact that only a part of risks is known.

These risks are correctly treated by risk assessment tools since they are most of all foreseeable. In this sense they are a typical case of forecast. However not all risks of innovation are foreseeable. Some risks cannot be foreseen at the stage of research and tend to be detected several years after the commercialization of products. This create not only a state of mass experimentation since '[s]ociety becomes the laboratory' of innovation (Felt and Wynnne, 2007, p. 26), but also reveals a recursive move of the innovation process, called 'reflexive uncertainty' (Groves, 2015, p. 322).

Risks, especially those unknown, can always come back. To treat only known risks is not sufficient. Therefore, to make innovation really fair, there is the need a criterium for sharing those unknown risks before they occur. In this sense, society must be involved in a reflection on the purposes of science and innovation in order to clarify what risks can be reasonably uphold by the whole society

(Stilgoe et al., 2013, p. 2). This process of common thinking is 'aimed at increasing resilience while revealing new opportunities for innovation and shaping of agendas for socially-robust risk research' (ibid., p. 3).

This does not mean that risk assessment is completely outdated.

Traditional tools are still confirmed within this anticipation model, but since innovation produces also unknown risks that will be discovered much later, there is the need to novel tools to face this unforeseen baggage of the uncertainty (Groves, 2013, p. 133).

In this framework risk assessment shifts from a mode wherein it is dealt with in a technocratic manner according to a traditional linear cause-effect model, to a mode which requires a socio-empirical approach when new futures are being formed such as in the case of foresight. This new model of risk assessment is called by some the Analytical-Deliberative model (Renn, 2016; Rosa et al., 2013).

Here risk assessment is melt with theories of visions and tends to be absorbed in a broader framework in which expectations and societal practices converge. The craftwork of creating scenarios is the main tool now. This skill is a craft-like knowledge ($\tau\,\chi\,\nu\eta$, téchne) which must transcend individual boundaries. Society therefore must be involved in this collective work.

Shared imaginaries are built by imaginative and non-representational practices that underline the influence of images and texts on societal vision of the future (Groves, 2013, p. 186). This could also be deemed a venue for democratizing the thinking about future (Miller and Bennet, 2008). This process of selection and strengthening of visions would allow the identification of right impacts, meant as those impacts that affected parties feel as more desirable according to their individual views. This process of sharing of visions is therefore the final result of the anticipatory attitude of the system in front of the challenges of emerging technologies. This should also absorb risk assessment processes, since in a context where risks of innovation are mainly unknown, it is primary the question of choosing which risks the society wants to uphold (Groves, 2015, p. 324). In this framework risk assessment does not disappears technically speaking, but maintains a residual role mainly confined on known risks. Therefore, this model of

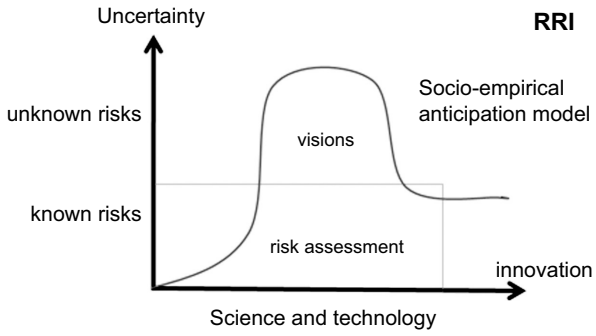

Figure 3.2 As innovation moves forward, known risks are subject to traditional risk assessment while unknown risks are treated via public engagement. As knowledge increases and the unknown diminishes, also the space of risk assessment increases.

anticipation ultimately rests on the capacity of the system to build a shared framework of imaginaries of the future, namely foresight.

If, according to this perspective, the production of values rests on the democratic engagement of stakeholders against any prefixed value, the position of stakeholders appears fragile. What stakeholder is legitimate to take part to the process? Which modes of public engagement can lead to responsible outcomes? Participation does not mean necessarily more democracy nor good outcomes (Smismans, 2008). This logic correlation does not exist. For example, the participation of some parts of civil society can lead to a given outcome, which could have been different if some other parts of civil society would have taken part.[129] In this regard the composition of the sample of stakeholders appears decisive in view of the final outcome. Besides, also the modes, wherein the involvement of the parts at stake occurs, appear crucial. For example, in the Italian case of Stamina,[130] the great involvement of citizens through media

[129] For example, animal rights organizations took part to the first consultation aimed at drafting the EC CoC in 2007, while neither trade union, nor any consumers' or patients' organization were involved (European Commission, 2007).

[130] Stamina is a protocol for the extraction, manipulation and re-infusion of stem cells in patients with diverse diseases ranging from Parkinson's disease, Alzheimer's and muscle-wasting disorders. Davide Vannoni, the inventor of the Stamina protocol, has been sentenced in 2015. On this see Abbott (2013).

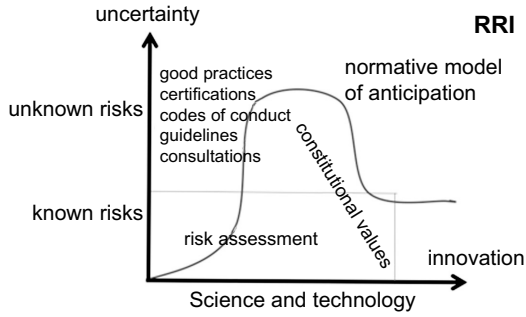

Figure 3.3 As innovation moves forward, known and unknown risks are subject to the same constitutional values, which are also embedded in the risk assessment tools and forms of soft law, aimed at fostering public engagement.

distorted the final outcome, giving legitimacy to an unproven and unscientific process (Abbott, 2013, p. 418). Notwithstanding the great involvement of some parts of civil society (e.g. media, patients' families, journalists), the outcome was completely distorted and considerably diverges from the paradigm of RRI. Therefore, this could be deemed as an emblematic case of 'irresponsible innovation' despite the participation.

According to the normative version traditional, instead, tools of risk assessment need to be reshaped on the basis of the prefixed values of the system. Research funding programmes, for example, clearly have this aim. In this model of anticipation known and unknown risks produced by innovation are handled according to the homogeneous criteria that shape not only means of risk assessment, but also any other governance tool, even public engagement. Certification systems, guidelines, codes of conduct, consultation, social dialogue and good practices need to be articulated around of a clear set of goods that are protected at the summit. This produces coherence and a more coordinated action of governance. In this context 'Grand Challenges' represent a clear example of optimizing processes and structures of governance towards a common goal.

However, in the RRI framework, even in its normative version, the process of balancing of institutional goals (fundamental rights

and other EU objectives) does not provide any particular guarantee for the protection of individual rights. Especially, in a situation of scientific uncertainty there is no reason of penalizing an interest of any nature (e.g. the internal market, competitiveness, or even public health or sustainibility) for avoiding a potential or unknown risk. There is no reason to consider one responsible for consequences that cannot be foreseen at the time of action (Owen et al., 2013, p. 32). And without data, which are not available per definition in the field of emerging technologies (Ruggiu, 2013c), and are fundamental for establishing any causal relation of harm, no precaution could be justified, even in the name of rights. As seen, the framework of anticipation drawn by the RRI normative version is strongly conditioned by the process of balancing among anchor points. If the process of balancing among anchor points means finding a compromise between opposite interests, this compromise risks being unsatisfactory every time individual rights are at play (Ruggiu, 2015a).

3.6 Rights-Based Models of Governance of Emerging Technologies

3.6.1 RRI is the final stage of a process of evolution which has involved the European governance of emerging technologies. This process started with the rise of biotechnology as promising field in the world and continued with nanotechnologies first, and synthetic biology then.

With biotechnology we find the seeds of the current case-by-case approach and ethics gained a crucial role in the development of governance of emerging technologies in the European context.

This premise was consolidated with nanotechnologies when the new governance paradigm arose. In this framework ELSI studies were joined by a mature governance strategy aimed at using flexible tools of governing such as EP resolutions, EC communications, agencies, networking, comitology, social dialogue and consultations for preparing the subsequent consolidation in hard law instruments (revision of existing regulations, new regulations and directives