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Nanotechnology and Risk Governance in the European Union: The Constitution of Safety in Highly Promoted and Contested Innovation Areas

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Abstract: The European Union (EU) is strategically committed to the development of nanotechnology and its industrial exploitation. However, nanotechnology also has the potential to disrupt human health and the environment. The EU claims to be committed to the safe and responsible development of nanotechnology. In this sense, the EU has become the first governing body in the world to develop nano-specific regulations, largely due to legislative action taken by the European Parliament, which has compensated for the European Commission's reluctance to develop special regulations for nanomaterials. Nevertheless, divergences aside, political bodies in the EU assume that nanotechnology development is controllable and take for granted that both the massive industrial use of nanomaterials and a high level of environmental and health protection are compatible. However, experiences such as the European controversy over agri-food biotechnology, which somewhat delegitimized the regulatory authority of the EU over technological safety and acceptability, arguably show that controllability assumptions are contestable on the grounds of alternative socio-economic and cultural preferences and values. Recently developed inclusive governance models on safety and innovation, such as "Responsible Research and Innovation" (RRI), widely claim that a diversity of considerations and issues are integrated into R&D processes. Even so, the possibility of more radically alternative constitutions of socio-technical safety seems to be seriously limited by the current ideology of innovation and economic imperatives of the global, knowledge-based, capitalist economy.

Keywords: EU risk governance, nanotechnology, uncertainty, agri-food biotechnology, inclusive governance, RRI

Introduction

Nanotechnology has become a promising field of research and commercialization. It has been said that it will revolutionize all sectors of industrial activity. Governments and firms around the world are investing heavily in nanotechnology [121, 123] in areas such as energy, health, environment, ICTs, food, or defense [125, 133, 148], in order to reap the economic and societal benefits that development in this area seems to promise.

However, nanotechnology also has the potential to disturb the environment and human health [91]. The European Union (EU), which is no exception when it comes to making major efforts in nanotechnology research and development in the context of our global, knowledge-based economy (e.g. [60], [62]), claims to develop nanotechnology in a "safe and responsible" ([42] 3) way. Nevertheless, the extent to which safety will be valued in the development of nanotechnology, which is a highly significant technological innovation in economic terms, is an issue that needs to be tackled. In this article, I analyze the way in which nanotechnology safety is being handled in the EU.

First, I present the dominant institutional discourse at EU level regarding both the economic significance of nanotechnology and the need to promote nanotechnology responsibly in terms of environmental and health safety. I argue that the need to fulfill these two goals is characterized by a certain tension that breeds divergent opinions on the most appropriate way to analyze and regulate nanomaterials.

I then appraise the early concerns of the EU regarding the regulatory adequacy and implementation of the pre-nanotechnology regulatory framework in light of fundamental knowledge deficiencies in nano-safety. In that respect, in 2008, the European Commission (EC) conducted a review of legislation applicable to nanomaterials, where it concluded that their health, safety and environmental risks were covered "in principle" ([46] 11) by pre-nanotechnology regulation. In contrast to the EC's reluctance to develop special regulations for nanomaterials, the EP advocated the development and application of specific regulatory provisions for them from the outset [66]. The regulatory dynamics concerning nanomaterials in the EU have been characterized by this tension between different political institutions and their opinions [94].

Finally, I claim that the high level of environmental and health safety protection that the EU is trying to achieve through the special regulation of nanomaterials goes hand in hand with a very strong institutional commitment to the massive industrial exploitation of nanotechnology, destined to play a key role, together with other technological innovations in stimulating a "world-class competitive industry" ([55] 2).[1] This arguably implies that the safe or controlled development of nanotechnology is practically taken for granted. I argue that this assumption is potentially problematic and contestable. I present a controversial antecedent of one technological development, the European backlash against agri-food biotechnology, which may not only

[1] For instance, estimates show that 160,000 nano-related jobs already existed globally in 2008, representing a 25% increase from 2000, and that every euro invested in research areas such as nanotechnology results in a tenfold return, largely affecting small and medium-sized enterprises (SMEs). SMEs are expected to account for most nano-related jobs. In Germany, for example, 80% of nanotechnology firms are small or medium-sized ([55] 3-4).

represent a regulatory discrepancy on some specific, controllable risks, but a more profound societal uneasiness with the more basic institutional assumptions of progress, control and safety. I describe how political bodies in the EU, differences of opinion on regulation aside, tend to assume that the massive industrial development of nanotechnology in the context of a highly competitive, knowledge-based economy can be conducted in a safe and responsible way.

European publics are increasingly concerned about safe and socially responsible techno-industrial progress. The relative but considerable societal reluctance to accept agri-food biotechnology, which has questioned the EU's regulatory authority over technological safety and acceptability to a considerable extent, may represent a good example. In fact, it should probably be taken into account in order to understand the eagerness of the EU to create and apply special regulations on nanomaterials [29]. However, as already stated, a serious reconsideration of innovation plans for nanotechnology does not seem to be contemplated, irrespective of developments towards more inclusive risk governance and research models such as "Responsible Research and Innovation" (RRI). It can be argued that the potential for more alternative safety scenarios, not only concerning nanotechnology, but technological innovations in general, is seriously constrained by the imperatives of a global, knowledge-based, capitalist economy.

The value of health and environmental safety in nanotechnology innovation

Science and technology are prime forces behind economic growth and competitiveness. Industrialized countries are continually increasing funding for research and development to cope with pressing economic challenges in both domestic and international arenas, such as high unemployment, outsourcing of production, and emerging economies [10, 108, 124]. The capacity to innovate, i.e. to create marketable knowledge and technologies, is rendered fundamental for socio-economic progress (e.g. [43, 57]). This is manifest in the EU's current ideology on innovation:

> Europe has set out its ambition to move to a new economic model based on smart, sustainable and inclusive growth. This type of transformation (…) will require much higher capacity for basic research and science-based innovation fuelled by radical new knowledge, allowing Europe to take a leading role in creating the scientific and technological paradigm shifts which will be the key drivers of productivity growth, competitiveness, wealth, sustainable development and social progress in the future industries and sectors ([76] 125).

This European discourse on innovation characterizes scientific knowledge as "technoscience", meaning that science is conceived as a means whose aim is not to improve knowledge of the world, but to satisfy a set of economic, social or environmental goals [35].

However, as an activity that transforms the world according to specific interests and worldviews, technoscience is also a source of social concern and controversy in terms of the ecological, health and moral risks that it poses. Thus, while science and technology are institutionally promoted as critical factors for achieving social and economic well-being, they also need to be approached as a potential threat that must be managed.

Nanotechnology is no exception here. On the one hand, it is a very attractive area of research for both policy-makers and the private sector, due to its high economic potential. The EC defines nanotechnology as the "science and technology at the nanoscale of atoms and molecules, and (…) the scientific principles and new properties that can be understood and mastered when operating in this domain" ([42] 4). Owing to this capacity to operate at atomic and molecular levels, it is an "enabling" or "horizontal" research area with a "'revolutionary' potential" ([15] 1) to pervade virtually all technological industrial sectors, including medicine, information technologies, energy, materials science, manufacturing, instrumentation, security, food, water and the environment ([42] 4-5). This implies that "if you have one breakthrough in nanotechnology you can use it across sectors. And that's why everybody, including Europe, is working hard in the nanotechnology area", as stated by Janez Potočnik, former European Commissioner for Science and Research (2004-2010) (quoted in [81] 418).

On the other hand, there are serious concerns about the safety of nanotechnology innovations. The property that makes nanotechnology so promising—the fact that it operates at the scale of atoms and molecules, transforming the way in which the same materials behave on larger scales—creates the potential for new environmental and health risks "possibly involving quite different mechanisms of interference with the physiology of human and environmental species" ([46] 3).

My interest here is not just to point out this duality, but to analyze how the issue of safety is approached in relation to a hugely economically significant research area such as nanotechnology. The EU, through its executive branch, the EC, claims to be committed to developing nanotechnology "in a safe and responsible manner" ([42] 3), meaning that the assessment of health and environmental risks of nanomaterials should "accompany the R&D and technological progress" ([42] 20).[2] However, in the context of a highly competitive, global economy, how highly is safety valued with regard to nanotechnology R&D, which represents for the EU—and other industrialized countries—an enterprise that "should not be delayed,

[2] "Responsible innovation" for the EC not only refers to environmental, health and safety (EHS) risks, but also to ethical and societal consequences.

unbalanced or left to chance" ([45] 2) and, as such, a "Key Enabling Technology" (KET)?[3] As claimed by the EC:

> Those nations and regions mastering these technologies [such as nanotechnology] will be at the forefront of managing the shift to a low carbon, knowledge-based economy, which is a precondition for ensuring [the] welfare, prosperity and security of its citizens. Hence the deployment of KETs in the EU is not only of strategic importance but is indispensible [*sic*] ([50] 2).

In answer to this question, the first thing to be considered—as obvious as it may seem—is that risk analysis is not the primary goal of any research and development program for innovation. Rather, it is an accompanying task which operates in strategic areas of research. Ultimately, institutional risk analysis, despite its constraining role, is structurally committed to the main overall goal of an innovation-based economy.[4]

In fact, if we look back in history, we see that Western industrialized countries, led by the United States (US), also instituted technological risk analysis and regulation as a way to legitimize techno-industrial progress ([31] 261-306). This happened during the late 1960s and early 1970s, at a time of widespread social questioning of science and industrialism informed by a counter-cultural ideology [136]. Hence, governmental reaction to social criticism of scientific progress did not consist of a profound transformation of the industrial society and its basic political, economic, legal and cultural premises. The policy commitment to the capitalist system of production and unbounded material growth remained solid under the risk analysis regime, which does not approach environmental problems generated by industrialism as fundamental anomalies of the economic and political system but as collateral problems which can be mastered and controlled by scientific and policy expertise ([86] 32-33). After all, contemporary liberal democratic states, irrespective of their ideology, are particularly interested in obtaining proper conditions for economic growth ([34] 83-84, 94, 142-143, 165), meaning that "the dimensions of environmentalism that pose a more radical challenge to the imperatives of industrial society and its governments belong in civil society" ([34] 112)—i.e. are hardly institutionalized.

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[3] For instance, global public and private investment in nanotechnology R&D had risen to more than US$18 billion annually during the last decade ([112] 174); the world market for nanomaterials has been evaluated at 11 million tonnes (having a market value of €20 billion); direct employment in the nanotechnology sector stands at 300,000-400,000 jobs across the EU, and products underpinned by nanotechnology are estimated to be worth €2 trillion ([89] 93).

[4] The funds allocated in the EU to the assessment of the environmental, health and occupational risks of nanomaterials are low compared to overall investment in nanotechnology R&D. For example, the EU Sixth Framework Programme for R&D (2002-2006), or FP6, devoted 2% (€28 million) of its total expenditure (€1.4 billion) on nanotechnology R&D to risk assessment research ([3] 7, [45] 3), and FP7 (2007-2013) 2.9% (€102 million) until 2011 ([96] 5, 19).

However, the legitimizing effect of risk analysis has been somewhat threatened in the European context over last two decades due to a series of safety failures. The food crises that affected Europe in the 1990s, namely "mad cow disease" or BSE (Bovine Spongiform Encephalopathy), food and mouth disease in cattle and dioxin in chickens, highlighted the weaknesses of risk analysis and regulatory procedures, and created a general perception that policy-makers tended to be more aligned with the interests of industry than with public interest, which "undermined public confidence in expert-based policy-making" ([40] 19). In addition, the European controversy over agri-food biotechnology, having not been motivated by any particular safety catastrophe, arguably expressed a critical stance maintained by a broad sector of the European publics (ecological groups, politicians, consumer representatives, civil society organizations, farmers' organizations, experts, the lay public) with the way in which technology was being developed. Health, environmental and ethical risks were often claimed to be under-analyzed and under-regulated in the interest of big corporations [82]. The conflict was fueled by demands for more inclusive regulatory reforms, as well as by participatory and deliberative opportunities—and limitations—afforded by successive regulatory developments [30, 80, 109]. The controversy resulted in the stifling of institutional and industrial innovation plans, while at the same time the original regulatory framework became tougher (see sub-section "The EU controversy surrounding agri-food biotechnology").

It is under these circumstances that institutional risk analysis in Europe, whose authority to impose decisions risk to society is based on its privileged (i.e. expert) access to the reality of the risks, "has become a crucial but often highly controversial component of public policy", as the EC acknowledges ([41] 23). After all, in the context of a knowledge-based economy and fast-growing technological innovations, where knowledge of possible negative impacts is often uncertain, the socio-economic stakes are high and there is an important social demand for health and environmental protection, controversies surrounding safety measures can be considered normal [130]. Complaints about the biased nature of risk assessments, the underestimation of uncertain risks or the expert-based, undemocratic nature of risk-related decisions are commonly proffered by social groups who disagree with institutional risk framing and its alleged indulgence in industrial interests and demands [126, 142].

Thus, the EU innovation system must deal with the tension between the primary goal of economic growth and competitiveness through science and technology, and the need to satisfy high societal demands for safer innovation. For example, adopting the precautionary principle—whereby decisions on risks based on incomplete (i.e. uncertain) scientific evidence are claimed to be systematically taken on the side of caution—as a basis of regulatory decision-making in European policy [39] could be interpreted, in this sense, as an attempt to institutionalize (i.e.

accommodate) more demanding social attitudes on the safety of scientific-technological progress without renouncing the basic ideology of innovation.

In the next section I will argue that the policy debate on the regulation of nanotechnology between different political bodies in the EU has been characterized by the difference between the advocated levels of safety protection. While the executive branch of the EU, the EC, considered pre-nanotechnology risk assessment methods and regulatory restrictions to be sufficiently adequate to guarantee the safe development and use of nanomaterials, the European Parliament (EP) has emphasized consumer and environmental safety and advocated the development and application of more restrictive regulatory measures. The EP directly represents the interests of the EU voters by whom it was elected and is one of the legislative bodies of the EU, along with the European Council, which represents the interests of the member states.

Political divergences regarding the regulation of nanotechnology within the EU

As already noted, a possible toxic potential (effect) is, inter alia, related to specific physical or structural properties that only occur at molecular or atomic levels, meaning that the behavior of nanomaterials cannot be extrapolated from the behavior of their larger chemical counterparts ([137] 55). Due to their size, nanomaterials have: (i) greater mobility, implying that they are more easily taken up by the human body and other living organisms, and can pass through biological membranes, cells, tissues and organs more readily than larger materials ([98] 216); and: (ii) a higher surface-area-to-mass ratio, increasing their surface energy and biological reactivity and, consequently, their toxicity ([95] 144, 147, [118] 8-9). Among properties determining the toxicity of nanomaterials are surface chemistry, solubility and shape ([111] 267). For instance, special concerns have been raised with regard to poorly soluble or insoluble nanofibres (i.e. particles with two sizes on the nanoscale[5] and the third being significantly larger), such as carbon nanotubes, due to their particular ability to penetrate into the lung and induce pulmonary toxicity (inflammation, fibrosis, cancer).[6] Poorly soluble or insoluble metal or metal-oxide nanoparticles (i.e. particles with all their sizes on the nanoscale) such as silver, gold or titanium also cause concern, while highly soluble nanoparticles such as sodium chloride nanoparticles, lipid nanoparticles, flour nanoparticles, sucrose-nanoparticles and amorphous silica are of low concern

[5] Namely in the size range from approximately 1nm (nanometer) to 100 nm, according to the definition of the International Organization for Standardization (ISO): https://www.iso.org/obp/ui/#iso:std:iso:19430:ed-1:v1:en:term:3.1. Accessed 21 March 2017.

[6] Due to their shape similarities (long and needle-like); carbon nanotubes have been seen to have asbestos-like impacts on mice [128].

([59] 14, 19, 21-23; see also: [16, 37, 145]).[7] In any case, when assessing the toxicity of nanomaterials, not only must their specific, or inherent, potential toxicity be taken into account, but also the exposure conditions (routes of entry, duration and frequency) and uptake dynamics (individual susceptibility and life habits, sites of deposition in the body, evolution and translocation of nanomaterials inside the body) ([132] 14).

Nonetheless, despite the different toxic effects of nanomaterials being reported in several scientific studies (e.g. [99] 716), a group of EC advisers, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), concluded that the causal mechanisms governing nanomaterial toxicity basically remain uncertain, meaning that "there is not yet a generally applicable paradigm for nanomaterial hazard identification" ([139] 10). The behavior and fate of nanomaterials (including their variability and tendency to (de)aggregate/agglomerate during their life cycles under particular biological and environmental conditions), estimation and measurement of nanomaterial exposure, dynamics underlying the biological uptake of nanomaterials and their translocation across body organs, or the exact (or specific) factors triggering toxicity have all been diagnosed as largely uncertain [6, 90, 92, 93, 95, 110, 117]. That is, the basic ways through which nanotechnology could endanger the environment and human health are not very well known. It should be noted that these are not mere uncertainties about the values of some well-known parameters, but rather "about the potentially unique or significantly modified causal mechanisms themselves" ([138] 27). This, to a large extent, prevents the very possibility of conducting risk assessment on the risks of nanomaterials. What is at stake, in the words of the OECD, is: "the systematic development of science and principles which will support future risk assessment of nanomaterials" ([119] 49).[8] Nano-safety assessment will therefore have to rely principally—at least in the short to medium term—on judgment; namely, on subjective inference from available knowledge on toxicity characteristics [8, 95].

In spite of the important uncertainties surrounding the potential health and environmental effects of nanomaterials, more than 2,600 nanotechnology-based consumer products have already been marketed worldwide (the EU included).[9] These products have mostly been placed on the market in the absence of a regulatory framework specifically devoted to nanomaterials, under the assumption that pre-nanotechnology regulatory resources—which were developed in the EU and

[7] The abovementioned categories of nanomaterials represent classes and, therefore, toxic capacity will be different among single nanomaterials, with relevant variations in their physicochemical properties ([9] 335).

[8] The OECD's Working Party on Manufactured Nanomaterials (WPMN) launched in 2007 a Sponsorship Programme for the Testing of Manufactured Nanomaterials. The goal of this programme is to verify the testing methods used on manufactured nanomaterials: http://www.oecd.org/chemicalsafety/nanosafety. Accessed 17 March, 2017.

[9] Figure taken from "The Nanodatabase", developed by the DTU Environment, Danish Ecological Council and Danish Consumer Council. See: http://nanodb.dk/en. Accessed 2 March 2017.

elsewhere without nanotechnology in mind—were sufficiently adequate to deal with their risks, according to different studies conducted by the OECD and its member countries [120, 122]. In this sense, the EC, in its 2008 Communication on *Regulatory Aspects of Nanomaterials*, concluded that "Current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials" ([46] 11).

This assumption of the validity of the pre-nanotechnology regulatory framework to deal with the qualitatively new risks of nanomaterials downplays their complexity and specificities.[10] For example, the REACH (Registration, Evaluation and Authorization of Chemicals) legislation on chemicals, dated 2006, failed to include any specific safety provisions for nanomaterials, meaning that they would be treated exclusively according to their chemical composition, irrespective of their peculiar physical characteristics. The REACH authorization system only demands the registration and evaluation of existing and new chemical substances that are produced at certain levels. Manufacturers and importers have to provide a registration dossier, but only for substances that are manufactured or imported at or above 1 ton per year, and a chemical safety report only for substances at or above 10 tons a year ([46] 4). Mass does not seem, however, to be the most relevant factor when determining the safety of nanomaterials. This is not only because very few nanomaterials would reach any of the production thresholds triggering regulation ([106] 188),[11] but also because the effects of nanomaterials are not solely the consequence of their chemical composition, but of their physical properties as well, as we have already seen. In this sense, focusing on "production expressed as mass (…) rather than particle size" would "severely underestimate the potential contribution of nanoparticles to the overall risk posed by the substance" ([137] 47).

The EP took a different stance to the EC on the appropriateness of EU regulation to deal with nanomaterials. Based on a report conducted by its Committee on the Environment, Public Health and Food Safety concerning the EC Communication on *Regulatory Aspects of Nanomaterials* [22], the EP adopted a resolution by ample majority in April 2009 in which it:

> Does not agree (…) with the Commission's conclusions that a) current legislation covers in principle the relevant risks relating to nanomaterials, and b) that the protection of health, safety and the environment

[10] In fact, what seems to be at stake is rather more than just developing a new set of rules. Societal regulations are often outpaced by extremely fast, market-oriented mass development and the application of emerging technologies such as nanotechnology, which would arguably demand a new regulatory paradigm—or "predisposition" [144]—based on principles such as flexibility, adaptation and participation [107].

[11] And even where production levels reach the threshold, "the usually low concentration of nanoparticles in the final article is likely to exclude many nanoengineered articles from the REACH legislation, since no registration is required when the concentration of a substance is lower than 0.1% w/w [weight by weight]" ([104] 212).

needs mostly be enhanced by improving implementation of current legislation, when due to the lack of appropriate data and methods to assess the risks relating to nanomaterials it is effectively unable to address their risks ([66] 87).

The EP therefore did not accept the EC's conclusion that the current regulatory framework is adequate to handle the uncertain risks of nanomaterials. Based on this conclusion, the EP, in this same resolution, called on the EC "to review all relevant legislation" ([66] 87) in order to re-determine the validity of the regulatory framework for coping with the special characteristics of nanomaterials. In this second report, the EC concluded, among other things, "that REACH sets the best possible framework for the risk management of nanomaterials (…) but more specific requirements for nanomaterials within the framework have proven necessary" ([56] 11).[12] In fact, in the meantime, the EP's position was already having consequences in EU legislation for specific sectors. New regulations on food and cosmetics approved at the end of the last decade included special safety measures for nanomaterials. By means of these regulations, the EU became the first governing body (at both national and supranational level) to incorporate pieces of legislation specifically designed for nanomaterials [14]. Among the regulations approved toward the end of the first decade of the 2000s including nano-specific safety provisions, which I list chronologically, the Regulation on cosmetic products was of special significance, in terms of specialization and variety of norms related to the safe development and use of nanomaterials:

- "Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives" [72] requires that a new safety evaluation of a food additive already approved is necessary where a food additive is produced using "significantly different" production methods, such as nanotechnology ([72] 17), and that these food additives should be considered "different additive[s]" and included as a new entry on the Community list ([72] 23). Here it should be noted that the initial regulation proposal prepared by the EC [44]—which is the institution responsible for developing new draft bills in the EU—made no reference to nanotechnology, and that the introduction of specific nano-safety requirements was based on EP amendments and the European Council's position regarding the original EC document ([19] 17, [20] 7, 10-11, [25] 5).
- "Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food" demands a differentiated, more precautionary, treatment of nanoparticles, which "should be assessed on a case-by-case basis as

[12] The EC has envisioned amendments to several of the technical provisions in the REACH Annexes ([63], [87] 302-303), expected to be published in May 2017 [38].

regards their risk until more information is known about such new technology" ([51] 4).[13] In this regulation, where the EC implements parts of the general rules laid down by "Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food" by providing specific rules for active and intelligent materials and articles ([51] 3), the EC seems to be influenced by the EP's stance in relation to the special risk characteristics of nanomaterials.[14]

- "Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products" [73] includes a section (Article 16) exclusively devoted to nanomaterials and integrates a wide variety of safety provisions specifically related to them. This regulation—which states that "For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured" ([73] 70)—includes a definition of "nanomaterial" ([73] 65), demands for nano-specific risk assessment ([73] 61) and a mandatory requirement to label all cosmetic products containing nanomaterials ([73] 73).[15] In addition, anyone placing a cosmetic product containing nanomaterials on the EU market must supply the EC with the product safety information six months prior to it being placed on the market ([73] 70).[16] As was the case with the regulation of food additives, the initial legislative proposal launched by the EC made no reference to nanotechnology [47]. The nano-specific safety provisions included in the regulation are the result of EP amendments to the initial EC text [21], amendments that the European Council accepted as presented by the EP ([67] 224).

Nevertheless, more demanding measures have not been accepted by the European Council or the EC. Such was the case, for instance, with the amendments made by the EP to the EC's 2008 legislative proposal on novel foods [48]. This proposal mentioned nanotechnology and nanoscience once—as part of the characterization of novel food—but with no special safety demands for them. Among the different amendments made by the EP—some of which reproduced previous amendments already included in the regulation on cosmetic products—there

[13] This demand needs to be understood in the context of the "functional barrier", meaning, in the field of intelligent packaging systems, "a barrier within food contact materials or articles preventing the migration of substances from behind the barrier into the food" ([51] 4). Behind the functional barrier, substances that are not included in the "Community list" of authorized substances can be used (under certain conditions) ([51] 6). Nanoparticles, however, are considered a special technology requiring specific treatment, and they "should not be covered by the functional barrier concept" ([51] 4).

[14] The EC is the executive branch of the EU. However, the European Council confers, to the Commission, under certain conditions, or procedures, "powers for the implementation of the rules which the Council lays down" ([24] 23).

[15] Ingredients with nanomaterials "shall be followed by the word 'nano' in brackets" ([73] 73).

[16] Moreover, under this regulation, the EC was required to compile a catalog, by January 2014, of all nanomaterials used in cosmetic products placed on the market, indicating the cosmetic product categories and reasonably foreseeable exposure conditions ([73] 71). An annual status report was also to be sent to the EP and European Council on developments in the use of nanomaterials in cosmetic products within the Community, and on issues such as the progress made in developing nano-specific assessment methods and safety assessment guidelines ([73] 71).

was one which stated that foods produced using nanotechnologies should not be allowed on the EU market "until specific [risk assessment] methods have been approved for use, and an adequate safety assessment on the basis of those methods has shown that the use of the respective food is safe" ([68] 246). In other words, this was a call for a moratorium. However, the EP amendment was supported by neither the EC nor the European Council, who probably did not wish to place too great a regulatory burden on the interests of industry. The EC defended the validity of the available risk assessment methodologies, claiming that "The Commission does not agree with the EP assumption that the general methodology used for the risk assessment of foodstuffs would not be applicable for that of nanomaterials in food" ([52] 5). The European Council, which co-legislates with the EP, accepted that engineered nanomaterials require appropriate risk assessment methods but proposed the application of the "precautionary principle" when there is "doubt concerning the safety of foods containing nanomaterials" ([26] 12). This means that the European Council believed that available risk assessment methods could be improved, but were still valid for assessing the safety of nano-foods. In addition, the European Council assumed that there was enough time to develop new methods of risk assessment for engineered nanomaterials before the Regulation took effect ([26] 12). The finally approved legislation (in 2015), Regulation (EU) 2015/2283, demands applicants to demonstrate that the most updated methods have been used for testing the safety of nanomaterials: "test methods, including non-animal tests, which take into account specific characteristics of engineered nanomaterials may be needed" ([77] 6), and when these nano-specific test methods are used, "an explanation should be provided by the applicant of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations and adjustments that have been made in order to respond to the specific characteristics of those materials" ([77] 6).

The other regulations with specific nano-provisions that have been approved up until now are as follows: Regulation (EU) No 10/2011 on plastic food materials [53], Regulation (EU) No 1169/2011 on the provision of food information to consumers [74] and Regulation (EU) No 528/2012 on biocidal products [75].

The development of specific nano-regulations demands an accordingly precise definition of "nanomaterial" in order to determine what materials fall within the scope of their legislation and risk assessment. In 2011 the EC recommended a definition of "nanomaterial" ([54] 40)—which has yet to be approved—, and some of the sector-specific regulations, namely regulations on cosmetic products (1223/2009)—as already mentioned—, food information (1169/2011), biocidal products (528/2012) and novel food (2015/2283), provide their own definitions ([92] 495, [129] 225). All definitions are based on size, using a 1 to 100 nm (nanometer) size range, but they also differ in some respects ([92] 495-496). For instance, the EC Recommendation covers "natural, incidental or manufactured" materials ([54] 40) whereas the regulation on biocidal

products refers to “natural or manufactured” but not incidental ones ([75] 11). Regulation on food information only covers “intentionally” produced materials ([74] 26), and regulation on cosmetics is even more restrictive, limiting the definition to intentionally manufactured “insoluble or biopersistant” materials ([73] 65). Such differences, besides leading to confusion, may also create regulatory inconsistency as the same substance could be treated as a nanomaterial or not, depending on the specific legislation ([4] 466). Divergent perspectives and preferences also exist at political and broader societal levels. For instance, in light of the legislative debate on novel foods, the EP amended the EC definition claiming that the proposed 50% nano-particle threshold for a food ingredient to qualify as “nano” needed to be lowered to 10% ([69] 1). In contrast, the industry—which would primarily prefer to switch the measurement unit from particle number to mass—has been reported to demand a much higher percentage (up to 90%) of particles for a material to be considered a nanomaterial. However, other stakeholders such as ecological organizations and concerned scientists demand a threshold as low as 0.15% (based on the opinion of SCENIHR, [140] 26), as well as a wider size range (e.g. between 0.3 nm and 300 nm) for a particle to be considered a nano-particle ([17] 5).[17]

The way in which “nanomaterial” is defined affects many interests, which explains, to a large extent, why it is such a controversial issue. In any event, once again we see that, at EU institutional level, it is the EP, a democratically elected body that represents the interests of EU citizens, which seems to advocate more than any other political institution inside the EU for “Non-corporate interests such as consumer or environmental concerns” ([13] 41). The development of nano-specific regulatory measures in EU legislation has been commanded by this institution. The EP amendments have thereby clearly complemented the EC’s initial legislative proposals, where nanotechnology has been largely ignored. Through these amendments, the EP has influenced the European Council’s stance on the regulation of nanomaterials and new legislation has consequently been approved in which they are treated in a differentiated (i.e. more precautionary) manner. In the aftermath of the public backlash against agri-food biotechnology, and influenced by high societal expectations for safety protection, the EP shows a more demanding attitude on safety. Its stance could be understood as “a wake-up call for the European Commission and industry alike” ([149] 171), meaning a call not to assume the validity of pre-

[17] It should be noted that difficulties relating to the definition of “nanomaterial” transcend the issue of inconsistent formulation. On the one hand, at the moment there is a lack of one single measurement method to detect and characterize nanomaterials according to defined characteristics, and the task becomes even more complicated when we take into account that the properties of nanomaterials are susceptible to change in their life cycle ([6] 411). On the other hand, the limits set by the definition(s) are constitutively (or necessarily) conventional, meaning that materials that do not fall within such limits (i.e. that are not classified as nanomaterials because of their size of percentual presence) may display nano-related risks in certain contexts of use or in relation to certain properties ([11] 122).

nanotechnology regulatory resources and to attend more vigorously to societal demands for safety protection.

It was not by chance that, in the context of the European controversy surrounding agri-food biotechnology, the EU was the first governing body (either national or supranational) to incorporate more specific, stricter or precautionary regulation for nanomaterials. In this respect, the EU seems to have learned the "lesson" of the agri-food biotechnology fiasco, where demands for tighter control have complicated the industrial development of this particular technology in Europe [29]. However, basic institutional discourses and attitudes toward the promotion and safety of nanotechnology are built on the fundamental assumption that nanotechnology needs to be vigorously developed and is controllable in terms of environmental and health safety. Working from this standpoint, the way in which nanotechnology innovation is being handled in the EU would not address the arguably more profound and widespread societal skepticism toward the ideology of innovation and techno-industrial progress [154]. I shall illustrate this idea below by analyzing some basics behind the constitution of EU regulation on agri-food biotechnology.

Limits and possibilities in the constitution of safety

In this section, divided into two sub-sections, I first highlight key moments in the European controversy over agri-food biotechnology. This serves as an example of profound societal uneasiness with basic institutional assumptions regarding the controllability of technological risks. It also shows how technological safety in our societies, based on a different set of socio-economic assumptions, can be approached in more radical or alternative ways than those usually accepted by policy-makers and industrial stakeholders. This controversy would not only express a divergence of opinions on particular and controllable risks of such technology, but also a more basic reaction against the assumption that safe, responsible technological development is compatible with an industrially-oriented innovation system in the context of a global, hyper-competitive, knowledge society. I then argue that beyond their differences in terms of procedural or regulatory matters, EU political bodies assume deep down that expert-based risk analyses and regulatory measures are capable of controlling the risks of massive industrial development and application of nanomaterials. In this respect, the EU is adopting a more precautionary approach toward nanotechnology, yet operating under the fundamental assumption that a massive nano-transformation of the world can be regulated and safely controlled. Recent updates toward inclusive risk governance and research models such as "Responsible Research and Innovation" (RRI) seem to have remarkable, yet limited, potential to help constitute more critical socio-technical safety scenarios in light of the dominant pro-techno-industrial innovation ideology.

The EU controversy surrounding agri-food biotechnology

Based in part on the argument that genetically modified organisms (GMOs) posed a risk to both human health and the environment, ecological non-governmental organizations (NGOs) such as Greenpeace, which played a central interlocutory role between public opinion and public and private organizations, initiated an aggressive campaign against the commercialization of the first GMOs in the EU in the second half of the 1990s [5]. This campaign triggered huge controversy and concern among European publics. As a result, some EU member states re-evaluated and criticized their risk assessment procedures for market approval and suspended the authorization of GMO products—previously authorized by the EC at community level—based on safety considerations ([2] 344-345). Genetically modified (GM) products were originally authorized under a simplified procedure based on the idea of "substantial equivalence", whereby a specific risk assessment was not required for a GM product considered to be equivalent to a safe, non-GM counterpart, as established in Regulation 258/97 on novel foods and novel food ingredients ([103] 36).

Besides, early approvals of GM crop cultivation in the 1990s were issued on the assumption that the potential ecological impacts of GMOs, such as the spread of herbicide tolerance traits from GM crops to weeds either as a consequence of gene flow or as a result of herbicide-provoked selection pressures, did not constitute a danger, but were "mere 'agricultural problems'" ([101] 353). This was made possible by establishing "the familiar problems of intensive agriculture" ([101] 354) as the main grounds for comparison, which was contested by some member states, including Denmark and Austria, who were seeking to defend their national policies in favor of more organic forms of agriculture ([101] 353-354).

Societal and political resistance to GM products was exacerbated by the fact that the original regulatory framework did not require their labeling and traceability, thereby preventing consumers from identifying them on the shelves. Together with safety concerns, this opacity triggered an aggressive NGO-led public boycott of GMOs. Despite the introduction of labeling regulation during the second half of the 1990s ([1] 69), the industry tried to accommodate the ever-growing public suspicion and resistance toward GM food independently. Several European retailers (e.g. Sainsbury's, Marks & Spencer, Carrefour-Promodes, Effelunga, Superquinn) decided to remove transgenic ingredients from their brand products—simultaneously exerting commercial pressure on farmers and food processing companies to refrain from using GMOs—even though these ingredients (GM soybean and maize) had obtained safety approval by the EU. Their goal was to gain public trust and market advantage in this context of relative, yet important, societal hostility toward GM foods and their alleged unnaturalness and unsustainability. The decision to distance their products and themselves from GMOs therefore needs to be understood in strategic terms ([100] 31-36). In any case, these circumstances forced the EU authorities to impose a *de facto* moratorium on GMOs in June 1999 ([113] 758), and only when the EU had

developed a new battery of regulations with more stringent safety rules and labeling requirements (among other changes) was the ban lifted in July 2003 ([2] 345-346).[18]

These regulatory reforms toughened risk assessment criteria by acknowledging a higher level of complexity and uncertainty in the ecological and health-related behavior and effects of GMOs. For instance, besides repealing 1990 Directive 90/220/EEC [23], subsequent Directive 2001/18/EC, on the deliberate release of GMOs into the environment, also introduced the requirement for the post-market monitoring of GM products (absent from the earlier 1990 Directive), "in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs (…) after they have been placed on the market" ([70] 3). This demand represents explicit acknowledgement of the systematic and inherent uncertainties of agri-food biotechnology applications, and of the idea that the anticipatory assessment of risks is limited. In consequence, GMO safety assessment needs to be extended to the market stage—since the only way to learn more about the risks of GMOs is by implementing these organisms in the real world.[19]

In addition to tougher assessment criteria, subsequent Regulation 1829/2003 on GM food and feed broadened the scope of regulatory issues. Prompted by growing concern and belligerence from some EU countries over the hitherto ignored—i.e. non-regulated—risk in the involuntary mixing of GMOs and conventional and organic crops (Upper Austria, for instance, declared itself a "GM-free zone" ([102], 271)), Regulation 1829/2003 amended Directive 2001/18 by allowing member states to "take appropriate measures to avoid the unintended presence of GMOs in other products" ([71], 21).

EU policy-makers thus opted to develop new regulatory requirements in order to accommodate social demands for safety and other issues[20] .They allow the commercialization and development of agri-food biotechnology in the EU even though these regulatory developments have proved to be only partially successful in normalizing the use of agri-food biotechnology

[18] Regulatory measures constraining the commercialization and use of GMOs taken in this period, such as the EU moratorium and other safety bans enforced individually by some member states, also seriously affected international trade relations. The importation of GM products to the EU from major producer and exporting countries such as the US, Canada and Argentina was blocked. In response, the above countries filed a World Trade Organization (WTO) case against the EU, claiming that regulatory measures in Europe were scientifically unjustified and violated compulsory trade agreements. The WTO ruled against the EU, based on legal criteria established by its Appellate Body in other, past disputes, where more precautionary regulations and considerations were approached as illegitimate [156, 157].

[19] In relation to this cautious perspective on the uncertain risks of agri-food biotechnology, Directive 2001/18/EC—unlike previous Directive 90/220/EEC—limited the validity of GMO authorizations to a ten-year period ([70] 10). Authorization renewal was granted after a new application detailing the behavior of the GMO during the previous ten-year period had been approved ([70] 11).

[20] The public backlash against agri-food biotechnology was not only motivated by safety concerns. Regulatory reforms included rules for the mandatory labeling of products containing GMOs, mandatory information to the public prior to the commercialization of GMOs, the introduction of ethical advice as an additional criterion for decision-making, and the socio-economic assessment of approved GMOs [70].

among EU member states and publics. For instance, several countries—including Germany, France, Austria and Italy—prohibited the growing of transgenic crops in the name of safety, going against the scientific opinion of the European Food Safety Authority (EFSA) and EC authorizations [97]. In addition, and bans aside, many supermarkets continue to refrain from adding legally approved genetically modified ingredients to their brand products, and a large number of producers have renounced the use of transgenic organisms in their products (see, for example, Spain, [84]).

In any event, the regulatory answer to the question of the dangerousness of biotechnology cannot be simply interpreted as responding to an unequivocal scientific representation of risk (i.e. "objective risk"). Regulatory developments are probably better understood along the lines of the emergence of a series of socio-political circumstances with economic significance. Ultimately, policy-makers also had to develop stricter regulatory measures in order to make the commercial liberalization of agri-food biotechnology possible in the EU. As former EC Commissioner for Research, Innovation and Science (2010-2014) Máire Geoghegan-Quinn stated, the EU has developed GMO risk analysis "not only to ensure consumer safety, but also to (…) facilitate the international trade of agricultural commodities and industrial products" ([83] 8). In that sense, safety-related regulatory developments are legitimately approachable in light of the techno-economic imperative. For example, the EU has faced the abovementioned prohibition by several member states to grow transgenic crops via Directive (EU) 2015/412, which amends Directive 2001/18/EC, where member states are allowed to restrict or prohibit the cultivation of GMOs on the grounds of "national concerns which do not only relate to issues associated with the safety of GMOs for health or the environment" ([78] 2); namely "environmental or agricultural policy objectives, (…) town and country planning, land use, socioeconomic impacts, coexistence and public policy" ([78] 3). In that sense, this further regulatory broadening of the scope and meaning of "risk" is based on a drastic separation between scientific and societal issues, as the market placement and importation of GMOs "remain regulated at Union level to preserve the internal market" ([78] 2) on the basis of a "uniform scientific assessment" ([78] 3).

In fact, institutions in the EU have tended to represent risk as a "fact", or "objective" issue, namely as a *limit* to the extent techno-industrial innovations such as agri-food biotechnology can be legitimately criticized and resisted on the grounds of safety concerns. However, controversy-triggered regulatory developments concerning GMO safety should not be simply interpreted as a shift from an objective or scientific approach toward risk to a subjective or social approach, as suggested by some chief policy-makers in the EU.[21] Ultimately, the way in

[21] For example, Günter Verheugen, former EC Vice President for Enterprise and Industry (2004-2009), stated that: "The debate must (…) remain science-based, and we must take a balanced view on matters of concern, such as GMOs, and avoid taking extreme positions" [150].

which risk is approached cannot be split from broader conceptions regarding society [33]. Different assumptions about the extent to which socio-economic principles and habits are transformable in order to implement a given safety framework may have an important influence on the kind of opinions and knowledge that can be produced and maintained with regard to technological risks [88].[22] As we have seen, higher levels of complexity and uncertainty regarding the effects of GMOs on health and the environment were acknowledged in certain contexts of societal contestation and demand. This meant that the very criterion for scientifically considering something "safe" was influenced by a socially embedded perspective.

Different assumptions and demands affecting regulatory oversight, economic growth, uncertainty, or nature, and the ways in which these dimensions should relate, have stiffened the initial safety framework, and still pose an obstacle to the socialization of agri-food biotechnology in the EU. In this sense, the perspective of environmental NGOs, who, in Europe, generally oppose agri-food biotechnology altogether ([103] 38), seems, to some extent, to be influencing the dynamics of acceptability and uptake of GMOs in the EU, in parallel with the decisions and measures taken at EU level. This could be interpreted as representing a more profound rejection of the idea of technological safety and industrial development, going beyond the debate on the regulation of particular and controllable risks. In other words, it is not simply the regulation of technological risks which seems to be at stake, but the technology itself and the socio-economic assumptions behind it.

The political assumption of safe nanotechnology development in the EU

As seen in the previous sub-section, the issue of technological safety can be approached in a more flexible and open manner than is often acknowledged by controlling institutions. However, the issue of technological safety has tended to be formulated in simpler terms by policy-makers: as an objective dimension to be grasped by experts, who will provide a sound scientific representation of the real risks of technological innovations. For example, the Head of the EC's "Nano- and Converging Sciences and Technologies" Unit, Renzo Tomellini, approached the issue of nanotechnology safety and its relevance with regard to its public acceptance as a simple "Is it dangerous?" question with a one-dimensional "appropriate knowledge and science-based" answer [147]. What "appropriate science" or "dangerous" mean is, nevertheless, a contested issue, one that cannot be determined by disregarding broad considerations concerning society in terms of the

[22] This is even true of scientific safety assessments. The vulnerability of knowledge to the influence of "subjective", or ideological, considerations should be approached as characteristic rather than accidental. As the consequences of mistakes in the evaluation of safety hypotheses and models, to a large extent proposed on a relative lack of evidence, are non-epistemological—i.e. they are environmental and sanitary, as well as economic—, science-related decisions based on ambiguous and insufficient evidence are said to be necessarily taken under the influence of social criteria ([32] 87-114, [105] 397-403).

way in which technological innovations, the economy and public values should be prioritized and related to each other [158].

For example, the ETC Group (Action Group on Erosion, Technology and Concentration), a Canadian NGO, based on the "concerns raised over nanoparticle contamination in living organisms and unanswered questions about potential dangers of new forms of carbon", called for "an immediate moratorium on commercial production of new nanomaterials" in 2002 ([36] 6). The EC responded that since the implementation of a hard precautionary measure such as a total moratorium on nanotechnology research and development would deny society the benefits of nanotechnology, it could only be supported "in the event that realistic and serious risks" were identified ([42] 19). The ecologists' opinion was institutionally dismissed as disproportionate, as not grounded on facts (i.e. on "realistic and serious risks"). However, even if this dismissal was justified on the grounds of an objective absence of risks, some already identified negative effects and severe uncertainties regarding the riskiness of nanomaterials were, it seems, minimized by the EC. Economic interests would seem to have prevailed over the NGO's primary goal of preserving health and the environment.

Ultimately, the EC's attitude must be understood in the context of a hyper-competitive, knowledge-based, global economy and the conviction that the industrial development of nanotechnology should be vigorously pursued and is compatible with a high level of safety. This basic assumption regarding the controllability of the environmental and health risks posed by the massive, competitive industrial development of nanotechnology is, furthermore, arguably shared by the different political bodies in the EU, in spite of their important and non-trivial differences on procedural or regulatory matters. For example, knowledge gaps regarding the risks of nanomaterials are not conceived by the EP as pointing to a fundamental incapability to control the transformation of the world absolutely at molecular and atomic levels (as stated, for example, in [116]), but as a temporary gap in knowledge that will be filled in time. The EP thereby adopts a critical and relevant point of view when it demands that the EU invests more in nanomaterial risk assessment, but always under the assumption that appropriate effort will "close the knowledge gaps" ([66] 84).

However, the comprehensive risk assessment of nanomaterials appears to be a challenging task. The SCENIHR argued that because knowledge of "systematic rules that govern the toxicological characteristics of all products of nanotechnology" is absent, the risk assessment of nanomaterials "will need to be made on a case by case basis" ([137] 58).[23] Nevertheless, given the "likely flood of new nanomaterials" that is expected ([151] 10), it has been argued that it is

[23] The European Food Safety Agency (EFSA) reached the same conclusion [65].

unrealistic to expect a casuistic safety assessment of every single nanomaterial ([153] 252).[24] Even where there is a relatively limited number of potential nanomaterials of concern, such as carbon fullerenes, nanotubes, metal oxides, quantum dots, dendrimers and nanoscale metals, differences in size, shape, surface area and chemistry, coatings, etc. can lead to thousands of possible variants that affect the way in which these nanomaterials impact human health and the environment ([153] 252). Furthermore, toxic characteristics can change with methods of production, preparation and storage processes, and when they are introduced into biological and environmental systems ([117] 93).

The complex set of ecological and biological parameters influencing the toxic potential of nanomaterials makes it difficult to provide a comprehensive and accurate picture of their risks. Wickson ([155] 11-12), for instance, identified the following parameters that need to be considered in relation to the toxic potential of nanomaterials:

(i) The entire life cycle of a nanomaterial has to be analyzed in order to understand how toxic the nanomaterial is because: (ia) the interaction of a nanomaterial with environmental factors (e.g. water, salinity, pH, organic matter) can alter its toxicity,[25] and: (ib) during the different stages of its life cycle, a nanomaterial could follow different routes of exposure, affecting parts of the human body other than those initially considered;

(ii) the environmental fate and behavior (e.g. in water, air, soil) of a nanomaterial has to be taken into account in order to calculate the risk of human exposure to the nanomaterial;

(iii) one and the same nanomaterial can affect different species of animals in different ways due to their different susceptibilities, meaning that a risk analysis conducted on a single species would not be sufficient to understand more global environmental risks;

(iv) effects on living organisms other than acute toxicity need to be considered, such as chronic effects, effects of bioaccumulation, and sublethal impacts (e.g. behavioral change and reduced immunity).

In the face of this complexity—which, incidentally, is not exclusive to nanomaterials but characterizes the inherent uncertainties and ignorance related to the behavior of manufactured substances in their socio-ecological environments in general (e.g. [28])—, the extent to which an accurate estimation is attainable of the risks of each of the thousands of different nanomaterials to be marketed in the future is, to say the least, doubtful [114]. However, any serious reconsideration of the institutional and industrial promotion of nanotechnology on the grounds of safety seems to

[24] It was estimated that the hazard testing of the nanomaterials available at the time (i.e. 2009), in itself, could take between 3 and 5 decades, and would require an investment greater than $1 billion [18].

[25] Synergies between nanomaterials also occur. The agglomeration of nanomaterials may change their properties, which would affect "their behavior in the indoor and outdoor environments as well as their potential exposure and entry into the human body" ([131] 7).

be considered unthinkable. The EC, for example, in its foundational, strategic document on nanotechnology R&D, approached the issue of the public perception of the risks of nanomaterials claiming that:

> Without a serious communication effort, nanotechnology innovations could face an unjust negative public reception. (…) The public trust and acceptance of nanotechnology will be crucial for its long-term development and allow us to profit from its potential benefits ([42] 19).

The EC assumed here that any hypothetical public contestation of nanotechnology innovations based on safety concerns would be "unjust"—i.e. groundless, and the product of ignorance—and that "a serious communication effort"—namely, a serious effort of dissemination—of the "objective" risks to an uneducated public should be conducted in order to avoid an anti-nanotechnology backlash in the EU. Rather than the issue of public perception per se, or the real possibility or reasonable expectation of such a backlash, it would be particularly interesting to look at the way in which, when considering this particular dimension, hypothetical future recalcitrant risks seem to be simply dismissed as an inconceivable scenario whilst the integral development and industrial exploitation of nanotechnology are assumed. After all, as the EP stated, "the safe development of nanomaterials can make an important contribution to the competitiveness of the European Union's economy and to the achievement of the Lisbon strategy[26]" ([66] 84). The EP is also implicitly assuming here that the "safe development of nanomaterials" is an attainable goal even in the context of fierce, international economic competition. The plausibility of a highly responsible form of development of nanotechnology innovations, where a systematic and massive nano-transformation of the world does not surpass human control abilities, is practically taken for granted.

The more demanding institutional normative discourses on the safe development of nanotechnology could be said to be based on this idea of the fundamental controllability of nanomaterials: over-demanding normative discourses assume that their demands can be (largely or, at least significantly) fulfilled. For example, the EC's voluntary *Code of conduct for responsible nanosciences and nanotechnologies research*, includes a norm stating that nanotechnology research and development activities "should not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future" ([49] 6). Here, the heavy (even unreal) burden of safety demanded (albeit on a voluntary basis) points to a scenario which is probably unattainable. In this sense, the norm could be interpreted as acting more as a justifying or legitimizing narrative than an effective regulator of relations

[26] The Lisbon Strategy, established in 2000, aimed to make the EU "the most competitive and dynamic knowledge-based economy in the world" by 2010 ([64] 12).

between nanotechnology, society and the environment. Safety may therefore be understood as being substantially subordinated to the imperatives of technological progress and economic growth. Both the EP and EC, who differ in their procedural perspectives, basically share the assumption that massive industrial development of nanotechnology in the context of a hyper-competitive, knowledge-based, global economy and high levels of environmental and health safety protection are compatible, irrespective of the regulatory framework that these institutions consider most appropriate.

Nevertheless, it seems doubtful that risk can be framed here simply as a univocal, technical problem (i.e. as "objective risk"), which is considered *in principle* to be scientifically appraisable. Nano-safety—and the other relevant regulatory aspects related to techno-industrial innovation— may well be better addressed if the ideological and normative principles guiding innovation policies and interests are considered and debated at the same time; namely, if a broader point of view regarding "innovation governance" [79] is adopted. In other words, complex issues such as the risks of nanomaterials would demand to be appraised by incorporating the societal ideologies, interests and commitments surrounding innovation dynamics into safety governance explicitly and constitutively [134].

In that respect, European institutions have increasingly claimed that innovation processes at the EU must become more *inclusive*. For instance, in the opinion of Christos Tokamanis, Head of the EC's "Advanced Materials and Nanotechnologies" Unit (D.3), nanotechnology innovation "is not simply about creating or improving products", but rather a whole "socio-political project" which should "engage citizens as early as possible in all developments and processes" ([146] 10). In a similar vein, the EC has claimed that research and engineering activities under "Horizon 2020" (2014-2020) shall be conducted according to a "Responsible Research and Innovation" (RRI) framework. This means that "all societal actors [including citizens] (…) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of European society" ([58] 4). In other words, according to RRI, the goals and processes of innovations should be open to a wide variety of understandings and interests, rather than relying exclusively on expert- and policy-based anticipated benefits and risks [152].

However, it seems appropriate to temper the disruptive (i.e. transformative) potential of inclusive proposals such as RRI in light of the stringent strategic constraints that our highly competitive knowledge-based global economy imposes on the meaning, scope and direction of innovation ([12], [127] 174-176). For instance, inclusive risk governance at EU level has come to be formulated—and, consequently, limited—in terms of a distinct separation between the technical and societal factors of safety: inclusiveness has been concerned with how to appraise an

allegedly objective risk inclusively in the risk management process, "understood as a process of weighing the outcome of the risk assessment with political and socio-economic factors" ([85] 6).

At the same time, however, scientists in Europe and elsewhere are demanding more interactive risk governance processes. The risk governance proposal put forward by a committee of experts from the US National Research Council (NRC) in 2009 is a remarkable example. Faced with the complexity and high socio-economic relevance of the issues at stake, the report assumes the need to develop "improvements that might increase the utility of risk assessments for decision-making" ([115] 22). In this sense, it highlights the need to undertake risk analysis by conducting a pre-assessment investigation where managers, scientists and other stakeholders work together in order to agree on the main problems and scoping, management options and required assessment tools. Socio-political input also claims a role in risk assessment planning and conduct evaluation ([115] 10-13, 240-257). The need to develop "more policy- and management-relevant" ([141] 7) risk assessments has also more recently been acknowledged by EC scientific committees on Health and Environmental Risks (SCHER), Consumer Safety (SCCS) and SCENIHR, who call for "extending the dialogue to all stakeholders" ([141] 8). Nevertheless, it must be said that assessment and management practices are conceived on the grounds of a clear functional differentiation, where "science should not be influenced by values and political issues" ([141] 11).[27]

In that vein, for example, when European Directive 2014/87/Euratom on nuclear safety stipulates that "Member States shall ensure that the general public is given the appropriate opportunities to participate effectively in the decision-making process" ([27] 49), it does so on the principle that risk regulation "should be established without any undue external influence" of the sort that might arise from social, political or economic pressures ([27] 43). The insulation of risk objectivity from subjective, or socio-economic, factors, arguably limits the impact of inclusive policies in terms of constituting more alternative socio-technical safety scenarios. Institutionalized inclusiveness has been proved to have limited disruptive potential, compared at least with the explicit integration of industrial and economic issues into R&D processes [135]. In that sense, we may well ask what the possibilities are of safety constitution for nanotechnology, which is considered to be a socio-economically "indispensible [*sic*]" ([50] 2) innovation field.

Considered from this perspective, EU leadership in regulating nanomaterials in the name of precaution and social responsibility seems to be relevant not only in terms of avoiding and controlling potential environmental and health damages per se, but also in terms of managing

[27] NRC experts also make it very clear when stating that "The involvement of decision-makers, technical specialists, and other stakeholders in all phases of the processes leading to decisions should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines" ([115] 11).

societal response and facilitating the societal uptake of nanotechnology innovations by European society. Since societal resistance to new technologies—which represents a potential threat to innovations being introduced on the market—is often fueled by safety considerations [7], a stricter set of rules for nanomaterials could help to prevent any potential experiences of societal resistance that may endanger the industrial development of nanotechnology. The possibility of more radically skeptical safety scenarios for nanotechnology could therefore be downplayed by the institutional discourse on "responsible innovation" and inclusiveness, and the assumption of controllability with regard to the massive and competitive industrial development of nanotechnology.

The high societal demand in the EU for technological safety, as expressed, for example, in the societal uneasiness with the manner in which agri-food biotechnology has been developed, may explain the fact that the EU is spearheading nano-specific regulation worldwide, adopting a set of stricter and more precautionary rules concerning the development and use of nanomaterials. However, at the same time, these regulatory efforts need to be understood in the context of a core ideology of economic growth and competitiveness through technological innovation; an ideology that characterizes current industrial capitalist societies and fundamentally constrains the constitution of safety by means of setting certain limits [143]. From this perspective, European movements toward the regulation of nanomaterials represent both an unavoidable endeavor to promote nanotechnology responsibly, and a hugely strong and defining commitment to the modern principles of progress, rationalization and control.

Conclusion

This article attempts to elucidate the dynamics and assumptions underlying the constitution of safety in the European Union (EU) with regard to nanotechnology research and development. We have first seen how the EU claims to develop nanotechnology innovations safely and responsibly. This means that the environmental and health risks of nanomaterials should be properly analyzed and managed throughout the course of their development.

We have also seen that political opinions concerning the regulation of nanomaterials in the EU diverge. It is through the European Parliament's (EP) initiative and legislative capacity that the EU has become the first governing body in the world to create nano-specific regulations. The EP has, through its initiative, to some extent corrected the European Commission's (EC) more conservative opinions on the validity of the pre-nanotechnology regulatory framework for dealing with the risks of nanomaterials. The EP's actions are likely motivated by previous technological fiascos in Europe, such as the public backlash against agri-food biotechnology, which was partially fueled by a fundamental societal discordance with institutional safety assumptions and regulatory measures.

In spite of political divergence on the best way to regulate nanotechnology innovations, the different political bodies in the EU share the assumption that the industrial development of nanotechnology within the context of a competitive, knowledge-based, global economy is compatible with environmental and health safety. This assumption of control is informed by the economic imperative of growth and technological progress, and determines to what extent safety can be constituted in our societies with regard to nanotechnology and other technological innovations in general.

This institutional perspective downplays more critical standpoints on the actual controllability of technologies, such as those expressed in the European controversy over agri-food biotechnology. It reduces the debate on the technological risks of progress to a debate on the regulation of specific risks without opening the door to more fundamental questioning of technologies themselves and the socio-economic assumptions behind them. It is true that the constitution of technological safety in the EU responds to a strict, precautionary set of norms and regulations, but always under the principle that technological progress at the service of industrial capitalism can be safely conducted, or rationalized, through scientific and political measures. It is also true that recently developed inclusive governance models on safety and innovation such as RRI generally claim to integrate diverse considerations and issues in R&D processes. However, it remains to be seen to what extent these inclusive efforts are able to approach complex issues such as the risks of nanomaterials by explicitly and constitutively incorporating the ideologies, interests and commitments surrounding innovation policies into safety governance; bearing in mind that the EC represents techno-industrial risk as a collateral and controllable “potential impact” [61].

To this extent, the possibility of radically alternative socio-technical scenarios are curtailed by the fundamental subordination of the safety dimension to the dynamics of techno-capitalism, which would arguably imply that the issue of safety in the context of the EU innovation system appears to play a disruptive and normalizing role at the same time.

References

1. Aarts HJM, van Rie J-PPF, Kok EJ (2002) Traceability of genetically modified organisms. Expert Rev Mol Diagn 2(1):69-76. doi: 10.1586/14737159.2.1.69
2. Abels G (2005) The long and winding road from Asilomar to Brussels: science, politics and the public in biotechnology regulation. Sci Cult 14(4):339-353. doi: 10.1080/09505430500369087
3. Aguar P, Murcia Nicolás JJ (comps) (2008) EU nanotechnology R&D in the field of health and environmental impact of nanoparticles (version: 28 January 08). European Commission, Research DG, Brussels

4. Amenta V, Aschberger K, Arena M, Bouwmeester H, Moniz FP, Brandhoff P, Gottardo S, Marvin HJP, Mech A, Pesudo LQ, Rauscher H, Schoonjans R, Vettori MV, Weigel S, Peters RJ (2015) Regulatory aspects of nanotechnology in the agri/feed/food sector in EU and non-EU countries. Regul Toxicol Pharm 73(1):463-476. doi: 10.1016/j.yrtph.2015.06.016
5. Ansell C, Maxwell R, Sicurelli D (2006) Protesting food: NGOs and political mobilization in Europe. In: Ansell C, Vogel D (eds) What's the beef? The contested governance of European food safety. The MIT Press, Cambridge, MA and London, pp 97-122
6. Aschberger K, Christensen FM, Rasmussen K, Jensen KA (2016) Feasibility and challenges of human health risk assessment for engineered nanomaterials. In: Xing B, Vecitis CD, Senesi N (eds) Engineered nanoparticles and the environment: biophysicochemical processes and toxicity. Wiley, Hoboken, NJ, pp 409-441
7. Bauer M (ed) (1995) Resistance to new technology: nuclear power, information technology and biotechnology. Cambridge University Press, Cambridge
8. Beaudrie CEH, Kandlikar M, Gregory R, Long G, Wilson T (2015) Nanomaterial risk screening: a structured approach to aid decision making under uncertainty. Environ Syst Decis 35(1):88-109. doi: 10.1007/s10669-014-9529-y
9. Bhattacharya K, Mukherjee SP, Gallud A, Burkert SC, Bistarelli S, Bellucci S, Bottini M, Star A, Fadeel B (2016) Biological interactions of carbon-based nanomaterials: from coronation to degradation. Nanomedicine: NBM 12(2):333-351. doi: 10.1016/j.nano.2015.11.011
10. Biegelbauer P, Borrás S (eds) (2003) Innovation policies in Europe and the US: the new agenda. Aldershot and Burlington, VT, Ashgate
11. Bleeker EAJ, de Jong WH, Geertsma RE, Groenewold M, Heugens EHW, Koers-Jacquemijns M, van de Meent D, Popma JR, Rietveld AG, Wijnhoven SWP (2013) Considerations on the EU definition of a nanomaterial: science to support policy making. Regul Toxicol Pharm 65(1):119-125. doi: 10.1016/j.yrtph.2012.11.007
12. Blok V, Lemmens P (2015) The emerging concept of Responsible Innovation. Three reasons why it is questionable and calls for a radical transformation of the concept of innovation. In: Koops B-J, Oosterlaken I, Romijn H, Swierstra T, van den Hoven J (eds) Responsible Innovation 2: concepts, approaches, and applications. Springer, Cham, pp 19-35
13. Bomberg E (1998) Green parties and politics in the European Union. Routledge, London
14. Bowman DM, van Calster G, Friedrichs S (2010) Nanomaterials and regulation of cosmetics (Correspondence). Nature Nanotechnology 5(2):92. doi: 10.1038/nnano.2010.12
15. Busquin P (2004) Foreword. In: European Commission. Towards a European strategy for nanotechnology. Office for Official Publications of the European Communities, Luxembourg, p 1

16. Card JW, Zeldin DC, Bonner JC, Nestmann ER (2008) Pulmonary applications and toxicity of engineered nanoparticles. Am J Physiol Lung Cell Mol Physiol 295(3):L400-L411. doi: 10.1152/ajplung.00041.2008
17. Center for International Environmental Law (2014) Nanomaterials definition fact sheet (November 2014). http://www.ciel.org/wp-content/uploads/2015/07/Nano_definition_Nov2014.pdf. Accessed 11 March 2017
18. Choi J-Y, Ramachandran G, Kandlikar M (2009) The impact of toxicity testing costs on nanomaterial regulation. Environ Sci Technol 43(9):3030-3034. doi: 10.1021/es802388s
19. Committee on the Environment, Public Health and Food Safety - European Parliament (2007) Report on the proposal for a regulation of the European Parliament and of the Council on food additives (COM(2006)0428 – C6-0260/2006 – 2006/0145(COD)). FINAL A6-0154/2007, 20.4.2007. Rapporteur: Åsa Westlund
20. Committee on the Environment, Public Health and Food Safety - European Parliament (2008a) Recommendation for Second Reading on the Council common position for adopting a regulation on the European Parliament and of the Council on food additives (16675/2/2007 – C6-0141/2008 – 2006/01/0145(COD)). A6-0180/2008, 13.5.2008. Rapporteur: Åsa Westlund
21. Committee on the Environment, Public Health and Food Safety - European Parliament (2008b) Report on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM (2008)0049 – C6-0053/2008 – 2008/0035 (COD)). A6-0484/2008, 8.12.2008. Rapporteur: Dagmar Roth-Behrendt
22. Committee on the Environment, Public Health and Food Safety - European Parliament (2009) Report on regulatory aspects of nanomaterials (2008/2208 (INI)). A6-0255/2009, 7.4.2009. Rapporteur: Carl Schlyter
23. Council of the European Communities (1990) Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (90/220/EEC). Official Journal of the European Communities, L 117 (8.5.90), pp 15-27
24. Council of the European Union (1999) Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/468/EC). Official Journal of the European Communities, L 184/23 (17.7.1999), pp 23-26
25. Council of the European Union (2008) Common Position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on food additives. Brussels, 29 February 2008. Interinstitutional File: 2006/0145 (COD). 16675/07 ADD 1
26. Council of the European Union (2010) Council Position at first reading with a view to adopting a Regulation of the European Parliament and of the Council on novel foods,

amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001. Brussels, 2 March 2010. Interinstitutional File: 2008/0002 (COD), 11261/09 ADD1 REV 1

27. Council of the European Union (2014) Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations. Official Journal of the European Union, L 219 (25.7.2014), pp 42-52
28. Cranor CF (2017) Tragic failures: how and why we are harmed by toxic chemicals. Oxford University Press, New York
29. David K, Thompson PB (eds) (2008) What can nanotechnology learn from biotechnology? Social and ethical lessons for nanoscience from the debate over agrifood biotechnology and GMOs. Academic Press, Amsterdam
30. Dąbrowska P (2007) Civil society involvement in the EU regulations on GMOs: from the design of a participatory garden to growing trees of European public debate. J Civil Soc 3(3):287-304. doi: 10.1080/17448680701775788
31. Dickson D (1984) The new politics of science. Pantheon Books, New York
32. Douglas HE (2009) Science, policy, and the value-free ideal. University of Pittsburgh Press, Pittsburgh, PA
33. Douglas M, Wildavsky A (1982) Risk and culture. An essay on the selection of technological and environmental dangers. University of California Press, Berkeley
34. Dryzek JS (2000) Deliberative democracy and beyond: liberals, critics, contestations. Oxford University Press, Oxford
35. Echeverría J (2003) La revolución tecnocientífica. Fondo de Cultura Económica, Madrid
36. ETC Group (2002) No small matter! Nanotech particles penetrate living cells and accumulate in animal organs. ETC Communiqué 76 (May/June 2002)
37. ECHA, European Chemicals Agency (2015) Update of the Workplan on Nanomaterials. 39th Meeting of the Management Board 24-25 September 2015 (MB/41/2015). ECHA, Luxembourg
38. ECHA, (2016) Summary of status of ECHA guidance updates on the REACH regulation relevant to the 31 May 2018 registration deadline not finalized before 31 May 2016 – this update as at 22/09/2016. European Union, Helsinki
39. EC (2000) Communication from the Commission on the precautionary principle. COM(2000) 1 (02.02.2000), Brussels
40. EC (2001) European governance: a white paper. COM(2001) 428 final (25.7.2001), Brussels
41. EC (2002) Science and society action plan. Office for Official Publications of the European Communities, Luxembourg

42. EC (2004) Towards a European strategy for nanotechnology. Office for Official Publications of the European Communities, Luxembourg
43. EC (2006a) Putting knowledge into practice: a broad-based innovation strategy for the EU. COM(2006) 502 final (13.9.2006), Brussels
44. EC (2006b) Proposal for a Regulation of the European Parliament and of the Council on food additives. COM(2006) 428 final, 2006/0145 (COD) [28.7.2006], Brussels
45. EC (2007) Nanosciences and nanotechnologies: an action plan for Europe 2005-2009. First Implementation Report 2005-2007. COM(2007) 505 final (6.9.2007), Brussels
46. EC (2008a) Regulatory aspects of nanomaterials. COM(2008) 366 final (17.6.2008), Brussels
47. EC (2008b) Proposal for a Regulation of the European Parliament and of the Council on cosmetic products. COM(2008)49 final/2, 2008/0035 (COD) [14.4.2008], Brussels
48. EC (2008c) Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure]. COM (2007) 872 final, 2008/0002 (COD) [14.1.2008], Brussels
49. EC (2008d) Commission Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research. C(2008) 424 final (07/02/2008), Brussels
50. EC (2009a) Preparing for our future: developing a common strategy for key enabling technologies in the EU. COM(2009) 512 final (30.09.2009), Brussels
51. EC (2009b) Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food. Official Journal of the European Union, L 135/3 (30.5.2009), pp 3-11
52. EC (2010) Opinion of the Commission pursuant to Article 294, paragraph 7, point (c) of the Treaty on the Functioning of the European Union, on the European Parliament's amendments to the Council's position regarding the proposal for a *Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) N° 1331/2008 and repealing Regulation (EC) N° 258/97 and Commission Regulation (EC) N° 1852/2001*. COM(2010) 570 final, 2008/0002 (COD) [11.10.2010], Brussels
53. EC (2011a) Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Official Journal of the European Union, L 12/1, pp 1-89
54. EC (2011b) Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU). Official Journal of the European Union, L 275 (20.10.2011), pp 38-40
55. EC (2012a) A European strategy for Key Enabling Technologies – A bridge to growth and jobs. COM(2012) 341 final (26.6.2012), Brussels

56. EC (2012b) Second regulatory review on nanomaterials. COM(2012) 572 final. Brussels.
57. EC (2013a) Innovation Union: a pocket guide on a Europe 2020 initiative. Publications Office of the European Union, Luxembourg
58. EC (2013b) Horizon 2020. Work Programme 2014–2015: 16. Science with and for Society. C(2013)8631 of 10 December 2013. Brussels
59. EC (2014) Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work. Guidance for employers and health and safety practitioners. Brussels
60. EC (2015a) Work Programme 2014–2015: 5ii. Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing (Revised). C(2015)2453 of 17 April 2015. Brussels
61. EC (2015b) Nanotechnologies (Horizon 2020). http://ec.europa.eu/programmes/horizon2020/en/h2020-section/nanotechnologies. Accessed 23 October 2015
62. EC (2016a) Work Programme 2016–2017: 5ii. Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing. C(2016) 4614 of 25 July 2016. Brussels
63. EC (2016b) Possible amendments of Annexes to REACH for registration of nanomaterials (Inception Impact Assessment). Brussels
64. European Council (2000) European Council, 23 and 24 March 2000, Lisbon: Conclusions of the Presidency. Bulletin of the European Parliament (27.03.2000), 01/S-2000, PE 289.667, pp 9-29
65. EFSA (2009) The potential risks arising from nanoscience and nanotechnologies on food and feed safety. Scientific Opinion of the Scientific Committee (Question No EFSA-Q-2007-124a). Adopted on 10 February 2009. The EFSA Journal 958:1-39
66. European Parliament (2009a) European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)). Nanomaterials, P6_TA(2009)0328. Official Journal of the European Union, C 184 E/82 (8.7.2010), pp 82-89
67. European Parliament (2009b) European Parliament legislative resolution of 24 March on the proposal for a regulation of the European Parliament and of the Council on cosmetic products (recast) (COM(2008)0049 – C6-0053/2008 – 2008/0035(COD)). Cosmetic products (recast) ***I, P6_TA(2009)0158. Official Journal of the European Union, C 117 E/223 (6.5.2010), pp 223-224
68. European Parliament (2009c) European Parliament legislative resolution of 25 March 2009 on the proposal for a regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX [common procedure] (COM(2007)0872 –

C6-0027/2008 – 008/0002(COD)).” Novel foods ***I, P6_TA(2009)0171. Official Journal of the European Union, C 117 E/236 (6.5.2010), pp 236-254

69. European Parliament (2014) Novel Foods: MEPs call for moratorium on nano-foods and labeling of cloned meat. Press Release, 25-11-2014. http://www.europarl.europa.eu/news/en/news-room/20141125IPR80424/novel-foods-meps-call-for-moratorium-on-nano-foods-and-labelling-of-cloned-meat. Accessed 26 October 2016
70. European Parliament and Council of the European Union (2001) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities, L 106/1 (17.4.2001), pp 1-38
71. European Parliament and Council of the European Union (2003) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union, L 268 (18.10.2003), pp. 1-23
72. European Parliament and Council of the European Union (2008) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Official Journal of the European Union, L 354/16 (31.12.2008), pp 16-33
73. European Parliament and Council of the European Union (2009) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast). Official Journal of the European Union, L 342/59 (22.12.2009), pp 59-209
74. European Parliament and Council of the European Union (2011) Regulation (EU) No 1169/2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. Official Journal of the European Union, L 304/18 (22.11.2011), pp 18-63
75. European Parliament and Council of the European Union (2012) Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products. Official Journal of the European Union, L 167/1, pp 1-123
76. European Parliament and Council of the European Union (2013) Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC. Official Journal of the European Union, L 347 (20.12.2013), pp 104-173

77. European Parliament and Council of the European Union (2015a) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. Official Journal of the European Union, L 327 (11.12.2015), pp 1-21
78. European Parliament and Council of the European Union (2015b) Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. Official Journal of the European Union, L 68 (13.3.2015), pp 1-8
79. Felt U, Wynne B et al (2007) Science and governance: taking European knowledge society seriously (EUR 22700). European Commission, Brussels
80. Ferretti MP (2007) Why public participation in risk regulation? The case of authorizing GMO products in the European Union. Sci Cult 16(4):377-395. doi: 10.1080/09505430701706723
81. Garkov V, Bontoux L, Martin P (2010) Into the unknown. Public Service Review: European Union 19:417-420
82. Gaskell G (2008) Lessons from the bio-decade: a social scientific perspective. In: David K, Thompson PB (eds) What can nanotechnology learn from biotechnology? Social and ethical lessons for nanoscience from the debate over agrifood biotechnology and GMOs. Academic Press, Amsterdam [et al], pp 237-259
83. Geoghegan-Quinn M (2010) Introduction. In: European Commission. A decade of EU-funded GMO research (2001-2010) [EUR 24473]. Publications Office of the European Union, Luxembourg, pp 7-8
84. Greenpeace (2015) Guía roja y verde de alimentos transgénicos (5th edition, 24 June 2015). Greenpeace España, Madrid
85. Greiving S (rapporteur) (2009) Goverscience seminar on inclusive risk governance (European Commission, EUR 23910). Office for Official Publications of the European Communities, Luxembourg
86. Hajer MA (1995) The politics of environmental discourse. Ecological modernization and the policy process. Clarendon Press, Oxford
87. Hansen SF, Baun A (2015) DPSIR and stakeholder analysis of the use of nanosilver. Nanoethics 9(3):297-319. doi: 10.1007/s11569-015-0245-y
88. Healy S (2003) Public participation as the performance of nature. In: Szerszynski B, Heim W, Waterton C (eds) Nature performed: environment, culture and performance. Blackwell Pub. / The Sociological Review, Oxford and Malden, MA, pp 94-108

89. High-Level Expert Group on Key Enabling Technologies (2015) KETs: time to act (Final Report, June 2015). European Commission, Brussels
90. Hristozov D, MacCalman L, Jensen KA, Stone V, Scott-Fordsmand J, Nowack B, Fernandes T, Marcomini A (2014) Risk assessment of engineered nanomaterials: state of the art and roadmap for future research. In: Monteiro-Riviere NA, Tran CL (eds) Nanotoxicology: progress toward nanomedicine, 2nd edn. CRC Press, Boca Raton, FL, pp 459-478
91. Hull M, Bowman D (eds) (2014) Nanotechnology environmental health and safety: risks, regulation, and management, 2nd edn. Oxford, William Andrew/Elsevier
92. Jahnel J (2015) Addressing the challenges to the risk assessment of nanomaterials. In: Dolez PI (ed) Nanoengineering: global approaches to health and safety issues. Elsevier, Amsterdam [et al], pp 485-521
93. Jamier V, Gispert I, Puntes V (2013) The social context of nanotechnology and regulating its uncertainty: a nanotechnologist approach. J Phys Conf Ser 429(1) 012059. doi: 10.1088/1742-6596/429/1/012059
94. Justo-Hanani R, Dayan T (2015) European risk governance of nanotechnology: explaining the emerging regulatory policy. Res Policy 44(8):1527-1536. doi: 10.1016/j.respol.2015.05.001
95. Kandlikar M, Ramachandran G, Maynard A, Murdock B, Toscano WA (2007) Health risk assessment for nanoparticles: a case for using expert judgment. J Nanopart Res 9(1):137-156. doi: 10.1007/978-1-4020-5859-2_14
96. Katalagarianakis G (2011) Overview of the EC EHS research plans and perspective. FP7 and future research needs – Most recent calls for proposals and those anticipated. European Commission, Research & Innovation (7th Framework Programme), 31/03/2011. http://www.nano.gov/sites/default/files/pub_resource/katalagarianakis_march_10.pdf. Accessed 25 October 2016
97. Kershen DL (2014) European decisions about the “Whack-a-mole” game. GM Crops 5(1):4-7. doi: 10.4161/gmcr.27777
98. Kimbrell GA (2007) The potential environmental hazards of nanotechnology and the applicability of existing law. In: Cameron NM de S, Mitchell ME (eds) Nanoscale: issues and perspectives for the nano century. Wiley, Hoboken, NJ, pp 211-238
99. Kimbrell GA (2009) Governance of nanotechnology and nanomaterials: principles, regulation, and renegotiating the social contract. J Law Med Ethics 37(4):706-723. doi: 10.1111/j.1748-720X.2009.00442.x
100. Levidow L, Bijman J (2002) Farm inputs under pressure from the European food industry. Food Policy 27(1):31-45. doi: 10.1016/S0306-9192(01)00025-2
101. Levidow L, Marris C (2001) Science and governance in Europe: lessons from the case of agricultural biotechnology. Sci Public Pol 28(5):345-360. doi: 10.3152/147154301781781345

102. Levidow L, Carr S, Wield D (2005) European Union regulation of agri-biotechnology: precautionary links between science, expertise and policy. Sci Public Pol 32(4):261-276. doi: 10.3152/147154305781779452
103. Levidow L, Murphy J, Carr S (2007) Recasting "substantial equivalence". Transatlantic governance of GM food. Sci Technol Hum Val 32(1):26-64. doi: 10.1177/0162243906293885
104. Linkov I, Satterstrom FK, Monica JC Jr, Hansen SF, Davis TA (2009) Nano risk governance: current developments and future perspectives. Nanotechnol Law Bus 6(2):203-220
105. Longino HE (1989) Biological effects of low level radiation: values, dose-response models, risk estimates. Synthese 81(3):391-404. doi: 10.1007/BF00869323
106. Ludlow K (2008) Nanoregulation—Filtering out the small stuff. Nanoethics 2(2):183-191. doi: 10.1007/s11569-008-0037-8
107. Marchant GE (2011) The growing gap between emerging technologies and the law. In: Marchant GE, Allenby BR, Herkert JR (eds) The growing gap between emerging technologies and legal-ethical oversight. Springer, Dordrecht [et al], pp 19-33
108. Marklund G, Vonortas NS, Wessner CW (eds) (2009) The innovation imperative: national innovation strategies in the global economy. Edward Elgar, Cheltenham
109. Marris C, Wynne B, Simmons P, Weldon S (2001) Public perceptions of agricultural biotechnologies in Europe. Final report of the PABE research project (FAIR CT98-3844 [DG12 - SSMI]). European Commission, Brussels
110. Mattsson M-O, Simkó M (2017) The changing face of nanomaterials: risk assessment challenges along the value chain. Regul Toxicol Pharm 84:105-115
111. Maynard AD, Aitken RJ, Butz T, Colvin V, Donaldson K, Oberdörster G, Philbert MA, Ryan J, Seaton A, Stone V, Tinkle SS, Tran L, Walker NJ, Warheit DB (2006) Safe handling of nanotechnology. Nature 446:267-269. doi: 10.1038/444267a
112. Maynard A, Rejeski D (2009) Too small to overlook. Nature 460:174. doi: 10.1038/460174a
113. Meldolesi A (2002) Political will to lift the GMO moratorium emerging in Europe. Nat Biotechnol 20:758-759. doi: 10.1038/nbt0802-758
114. Miller G, Wickson F (2015) Risk analysis of nanomaterials: exposing nanotechnology's naked emperor. Rev Policy Res 32(4):485-512. doi: 10.1111/ropr.12129
115. NRC - Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies (2009) Science and decisions: advancing risk assessment. The National Academies Press, Washington, DC
116. Nordmann A (2005) *Noumenal* technology: reflections on the incredible tininess of nano. Techné 8(3):3-23

117. Oberdörster G (2010) Safety assessment for nanotechnology and nanomedicine: concepts of nanotoxicology. J Intern Med 267(1):89-105. doi: 10.1111/j.1365-2796.2009.02187.x

118. Oberdörster G, Maynard A, Donaldson K, Castranova V, Fitzpatrick J, Ausman K, Carter J, Karn B, Kreyling W, Lai D, Olin S, Monteiro-Riviere N, Warheit D, Yang H (2005) Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy. Part Fibre Toxicol 2(8):1-35. doi: 10.1186/1743-8977-2-8

119. OECD (2012a) Important issues on risk assessment of manufactured nanomaterials. Series on the safety of manufactured nanomaterials, No. 33 (ENV/JM/MONO(2012)8). Paris

120. OECD (2012b) Six years of OECD work on the safety of manufactured nanomaterials: achievements and future opportunities. Paris

121. OECD (2013) Data brief – Key biotechnology & nanotechnology indicators: a comparison (November 2013). Paris

122. OECD (2014) Report of the questionnaire on regulatory regimes for manufactured nanomaterials 2010-2011. Series on the safety of manufactures nanomaterials, No. 42 (ENV/JM/MONO(2014)28). Paris

123. OECD (2015a) Science, technology and industry scoreboard 2015: innovation for growth and society. Paris

124. OECD (2015b) The innovation imperative: contribution to productivity, growth and well-being. Paris

125. Palmberg C, Dernis H, Miguet C (2009) Nanotechnology: an overview based on indicators and statistics. STI Working Paper 2009/7. OECD, Paris

126. Pellizzoni L (2001) Democracy and the governance of uncertainty: the case of agricultural gene technologies. J Hazard Mater 86(1-3):205-222

127. Pellizzoni L (2015) Ontological politics in a disposable world: the new mastery of knowledge. Ashgate, Farnham and Burlington, VT

128. Poland CA, Duffin R, Kinloch I, Maynard A, Wallace WAH, Seaton A, Stone V, Brown S, MacNee W, Donaldson K (2008) Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study. Nat Nanotechnol 3:423-428. doi: 10.1038/nnano.2008.111

129. Rauscher H, Rasmussen K, Sokull-Klüttgen B (2017) Regulatory aspects of nanomaterials in the EU. Chem Ing Tech 89(3):224-231. doi: 10.1002/cite.201600076

130. Ravetz J (2003) A paradoxical future for safety in the global knowledge economy. Futures 35(8):811-826. doi: 10.1016/S0016-3287(03)00037-5

131. Ray PC, Yu H, Fu PP (2009) Toxicity and environmental risks of nanomaterials: challenges and future needs. J Environ Sci Heal C 27(1):1-35. doi: 10.1080/10590500802708267

132. Ricaud M, Witschger O (2012) Nanomaterials: definitions, toxicological risk, characterisation of occupational exposure and prevention measures (ED 6050). Institut National de Recherche et de Sécurité (INRS), Paris
133. Roco, MC (2016) National nanotechnology investment in the FY 2017 budget. In: American Association for the Advancement of Science (AAAS) and Intersociety Working Group. Science & Technology in Congress FY 2017. AAAS, Washington, DC, pp 78-84
134. (Removed.)
135. (Removed.)
136. Roszak T (1969) The making of a counter culture: reflections on the technocratic society and its youthful opposition. Doubleday, Garden City, NY
137. SCENIHR (2006) Modified Opinion (after public consultation) on: The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies (SCENIHR/002/05). European Commission, Health & Consumer Protection Directorate General, Brussels
138. SCENIHR (2007) Opinion on the appropriateness of the risk assessment methodology in accordance with the technical gidance documents for new and existing substances for assessing the risks of nanomaterials. European Commission, DG for Health & Consumer Protection, Brussels
139. SCENIHR (2009) Risk assessment of products of nanotechnologies. European Commission, DG for Health & Consumers, Brussels
140. SCENIHR (2010) Scientific basis for the definition of the term “nanomaterial”. European Union, DG for Health & Consumers, Brussels
141. SCHER, SCENIHR, SCCS (2013) Making risk assessment more relevant for risk management. European Union, DG for Health & Consumers, Brussels
142. Shrader-Frechette K (2007) Taking action, saving lives: our duties to protect environmental and public health. Oxford University Press, Oxford
143. Sodano V, Gorgitano MT, Quaglietta M, Verneau F (2016) Regulating food nanotechnologies in the European Union: open issues and political challenges. Trends Food Sci Tech 54:216-226. doi: 10.1016/j.tifs.2016.05.022
144. Stokes E (2012) Nanotechnology and the products of inherited regulation. J Law Soc 39(1):93-112. doi: 10.1111/j.1467-6478.2012.00572.x
145. Thompson EA, Sayers BC, Glista-Baker EE, Shipkowski KA, Taylor AJ, Bonner JC (2014) Innate immune responses to nanoparticle exposure in the lung. J Environ Immunol Toxicol 1(3):150-156. doi: 10.7178/jeit.23
146. Tokamanis C (2011) Nanotechnology becomes a socio-political project (Interview). In: Bonazzi M (ed) Successful European nanotechnology research. Outstanding science and

technology to match the needs of future society. Publications Office of the EU, Luxembourg, pp 9-12

147. Tomellini R (2003) Is nanotechnology dangerous? “We need to know”, says Renzo Tomellini (Interview) EurActiv: EU news and policy debates across languages (17 November 2003). http://www.euractiv.com/section/nanotechnology/news/is-nanotechnology-dangerous-we-need-to-know-says-renzo-tomellini/. Accessed 22 March 2017
148. UNESCO (2016) Nanotechnology is a growing research priority. http://www.unesco.org/new/en/natural-sciences/science-technology/single-view-sc-policy/news/nanotechnology_is_a_growing_research_priority/. Accessed 24 February 2017
149. van Calster G (2009) Simply swallow? – The application of nanotechnologies in European food law. Eur Food and Feed Law Rev 4(3):167-171
150. Verheugen G (2005) The Commission’s new biotech policy (SPEECH/05/536). Presented at the Biotechnology Policy Day High Level Roundtable. Brussels, 22 September 2005. http://europa.eu/rapid/press-release_SPEECH-05-536_1.htm. Accessed 29 November 2014
151. von Schomberg R (2010) Introduction: understanding public debate on nanotechnologies. Options for framing public policy. In: von Schomberg R, Davies S (eds) Understanding public debate on nanotechnologies. Options for framing public policy (A Report from the European Commission Services). European Commission, Brussels, pp 5-12
152. von Schomberg R (2013) A vision of Responsible Research and Innovation. In: Owen R, Bessant J, Heintz M (eds) Responsible Innovation: managing the responsible emergence of science and innovation in society. Wiley, Chichester, pp 51-74
153. Walker NJ, Bucher JR (2009) A 21st century paradigm for evaluating the health hazards of nanoscale materials? Toxicol Sci 110(2):251-254. doi: 10.1093/toxsci/kfp106
154. Welsh I, Wynne B (2013) Science, scientism and imaginaries of publics in the UK: passive objects, incipient threats. Sci Cult 22(4):540-566. doi: 10.1080/14636778.2013.764072
155. Wickson F (2009) What you should know about nano (Policy Brief No. 8, November 2009). The Australian Institute (TAI), Canberra
156. Winham GR (2009) The GMO Panel: applications of WTO law to trade in agricultural biotech products. J Eur Integr 31(3):409-429. doi: 10.1080/07036330902782261
157. Wirth DA (2013) The World Trade Organization dispute over genetically modified organisms: the precautionary principle meets international trade law. Vermont Law Rev 37(4):1153-1188
158. Wynne B (2010) Strange weather, again: climate science as political art. Theory Cult Soc 27(2-3):289-305. doi: 10.1177/0263276410361499