

Regulating Nanotechnologies: The EU Approach to the Food Sector¹

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Abstract

In recent decades technoscientific innovation has pushed the food boundaries to a new frontier of nanofood. Such a term refers to an array of food products, whose processes of growing, production, and packaging involve nanoscale (Nanosciences and Nanotechnologies) knowledges and applications. This contribution focuses on the analysis of the European regulatory framework in the field of agri-food nanotechnology, by considering the legal instruments (hard and soft law) designed by European institutions to deal with the novel challenges posed by nanomaterials. A balance between hard and soft 'nanoregulation' requires a dynamic, transparent, and inclusive approach, in order to assure the highest standards of food safety for the protection of citizens' health.

Introduction

Undoubtedly, the need for regulation of Nanosciences and Nanotechnologies (N&N) represents one of the most relevant dilemmas to have emerged since the dissemination of the first documents on the subject: from the first Commission Communication (2004) to the European Parliament Resolution (2009); from the first scientific opinions (well-known is the U.K. Royal Society report in 2004) to the consultative bodies' publications (for instance, the Italian National Committee for Bioethics).

In such a prescriptive framework, the unsolved issue is whether the current ruling context, created for other new technologies, is appropriate to respond to the problems concerning the abilities of nanotechnologies to create products, whose structures and systems present new features (Miller 2007, 172). Nanotechnologies lack a uniform nomenclature, an internationally acknowledged standardization of materials, products, substances and applications, as well as a shared language and a universal toxicological evaluation and exposition (Miller 2007, 160).

According to part of the doctrine (Mandel 2009), in order to deal with the risks generated from nanotechnologies, a *tout court* review of the current regulation does not appear either realistic or purposeful, as it would mean a guaranteed expense and a waste of resources without any assurance of better and more efficient prescriptive frameworks. But others (Lin 2007) find that the current regulation is inadequate to respond to the uncertainties of nanotechnologies. Therefore, both an immediate prescriptive response, and a harmonization of the discipline at an international level, have turned out to be necessary. However, at the same time, it is emphasized (Phelps 2007, 193) that an *overregulation* should be avoided in order not to depress the impulse of 'nano innovation'.

Except that, according to another part of the doctrine (Marchant et al. 2009), providing for a *sui generis* regulation might generate an irrational discrimination towards common products not subjected to nanotechnological applications. Therefore, within the policy decision-making processes, the acquisition of a more 'sophisticated' understanding of the prescriptive needs and different technical jargon, which are usually used in nano innovation contexts, becomes one of the most important goals to achieve in the short-term.

As observed (Brownsword 2009), the question brought to notice is not whether there are legislative provisions valid for nanotechnological applications too, but which aspects of nanotechnologies require prescriptive attention and why. Moreover, when should the lawmaker intervene? Which instruments could be used? In every prescriptive action, there is a tension between need for clarity, calculability, and certainty on the one hand, and for flexibility and quick-response skills on the other.

Of course, there is no coercive solution to such a problem, considering the characteristics that mark out all the emerging technologies: technoscientific uncertainty (which may turn to factual normative and value uncertainty²); ambiguity in the meanings and values intrinsic to the processes and products of such technologies; and the implications not only of economic and technical nature, but also ethical and social (Nuffield Council on Bioethics 2012).

Besides this, there are two further dilemmas that determine the regulation of nanotechnologies. First, coordination between the different national

and international levels where prescriptive processes are brought forth. Second, a choice between regulations focused on disciplining a specific sector and general regulations applying consolidated procedures. Whereas the first one allows a better definition of every aspect of the sector to discipline, as well as a framework contemplating the interests of both the legislator and the recipient, the second one appears to be less suited to adjust to the new technology, although it would enable delineation of a clearer and better outlook (Nuffield Council on Bioethics 2012).

Then, what might the regulation models be (Guerra & Piccinni 2010)? My goal is to outline the evolution of the European regulation model on nanotechnology used in a specific sector—the food industry—through the analysis of the prescriptive tools used within the European Institutional bodies, in order to respond to the sector's needs.

The employment of nanotechnologies within the agri-food sector implies considerations of legal, ethical, economic, and social issues, which require specialists from different fields of study to confront and cooperate. Whereas it is undeniable that food law is based on the general principle of protection of the consumer and human health, it is also true that many of its rules are affected by market needs (Costato 2007, 2).

Starting from a close scrutiny of both the main nanotechnological applications in the food industry and their following risks, 'nanofood discipline' will be analyzed in the terms elaborated within the chambers of the European Commission, European Council, and European Parliament. Such an approach will allow assessing the suitability of the nanofood legislative regulation to respond to the numerous requests coming from the food business and the consumer. On the one hand, the food company demands legislative means to solve both the issue of source fragmentation and prescription instability. On the other hand, the consumer demands prescriptions imposing safety and information obligations, and providing for food producer accountability in the case of detrimental behaviors to consumer-trust itself (Germanò 2007, 1).

Clearly, in case of risk regulation, the law acquires a 'temporary character' considering the evolution of the scientific knowledge. The decision becomes a risk itself, but it is necessary, as society may welcome well its technological applications (Paterson 2003).

Nanotechnologies within the agri-food sector

Current definitions of nanotechnologies are not based on a specific field of application of production process, they are rather based on the study and analysis of the nanometer dimension.³ In fact, the multiplicity and variety of the applications make nanotechnologies actual ‘converging’ or ‘enabling’ technologies. That is, they are so flexible and pervasive to permeate every technological sector. If it is true that—according to the European Strategic Agenda on Nanoelectronics—electronics and materials sectors record the highest development within R&D activities, the innovative and economic perspectives in the agri-food sector ‘from farm to table’ are not less relevant. Therefore, the term ‘nanofood’ is used purposefully to indicate ‘food that has been cultivated, produced, processed or packaged using nanotechnology techniques or tools, or to which has been added manufactured nanomaterials’ (Joseph & Morrison 2006).

In relation to the information currently available, engineered nanomaterials (ENM), which could be used in food products, may be divided into three categories: inorganic ENM, organic, and functionalized materials (Chaudhry et al. 2010). The first category includes transition metals (e.g. silver and iron), alkaline earth metals (e.g. calcium and magnesium), and non-metals (e.g. selenium and silicates). The second category includes food additives (e.g. citric acid and ascorbic acid) and integrators (e.g. vitamin A, vitamin E, beta-carotene, fat acids, omega-3, and coenzyme Q-10).

The surface functionalized nanomaterials are instead peculiar for their antimicrobial activity and for being preserving particles. That is, they enable the creation of elaborated paths for gas molecules inside a material (in particular the one used for food packaging). The consequences of such a chemical behavior are oxygen impenetrability and carbon dioxide withholding.

Food companies are growing interested in the potentialities associated with the characteristics of the aforementioned nanomaterials, as it was found that their employment in food-processing improves food quality through innovative refinement processes, as well as provides for a more accurate supervision of contaminating pathogens. Possible solutions out-

line a direct intervention on either food design through the manipulation of molecules and originating atoms, or on a highly sensitive assessment of the purity level of the products. Scientific convergence opens interesting scenarios in the agri-food industry: from the remote tracking and localization of planting, to the delivery of pesticides and fertilizers through innovative systems (FAO/WHO 2010).

Thanks to the evolution of the aforementioned framework, a recent report released by *Cientifica* estimates that in 2012 the global market value concerning nanotechnological applications within the food industry reached USD 5.8 billion, with more than 400 companies involved worldwide in research and development (e.g. ConAgraFood, Nestlé, Kraft Foods, PepsiCola, Unilever, Sara Lee, and Hershey).⁴

However, besides this great enthusiasm, the scientific community is growing interested in the nanomaterial properties themselves, and the debate on the opportunity to assess the possible interactions between nanoparticles and living systems is growing heated. As it emerges from the SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) scientific opinion (2006), the assessment on health and environmental risks associated with the exposure to nanoparticles should not exclude any of their chemical and physical properties: shape, composition, surface area, and water solubility.

In fact, the interaction between nanomaterials and the human body raises questions and preoccupation related to the consequences on human health and environmental impact, which are still unsolved. In the nanotechnology sector, as in the biotechnology sector, there are many issues associated with safety and security risks. Whereas the first category includes accidental risks in the correct employment of nanomaterials (e.g. during their manipulation in the lab), the second category—despite security requirements—originates in the unlawful and malevolent use of nanoparticles (e.g. alteration of the metabolic process of chemical substances).

In either case, considerations on such a subject imply the problem of working in very close contact with not fully-known materials, which clearly makes them unsafe for researchers. It is well-known now within the scientific community that, firstly, the pathogenicity of nanoparticles

increases almost exponentially with the decrease of their diameter, and secondly, the smaller the diameter, the faster the absorbing process. Although the effect of the nanoparticle shape on the level of toxicity is still widely unknown, the square area per mass unit is an important parameter to define the nanoparticle toxicity, as well as the interaction between nanoparticles and biological macroparticles (e.g. collagen, DNA, receptors, proteins, etc.) (Oberdorster et al. 2005).

Further, recent studies have shown that in some cases an augmented superficial reactivity (and the consequential augmented biological activity) may have toxic effects including oxidative stress induction and cytotoxicity (Oberdorster et al. 2005). And, it was shown that nanoparticle ability to relocate from their access point in the human body to other places inside of it—brain and blood included—is still limited, despite the dedicated scientific literature.

Nanoparticle levels of biopersistence and biodegradability are two further factors that might determine their potential impact on human health and the environment. In fact, non-degradable nanoparticles may accumulate in organs and cells, causing long-term biological alterations. The scenario gets further complicated if one considers that, all along the food chain, nanomaterials and nanostructures are subject to changes due to production processes, as well as through the interaction with the substances (e.g. lipids and proteins) in the food matrix. Such variations, combined with the effect induced by the digestive process on the ENM chemical and physical features in foodstuffs, represent a clear obstacle to a correct scientific evaluation of risk exposition (D'Aurelio et al. 2009). Therefore, scientific uncertainty that revolves around potential negative effects deriving from the employment of nanomaterials requires an optimal regulation, able to combine flexibility and affectivity.

The European legal framework for nanofood

After building a solid knowledge base in the field of N&N, the European Union decided to create a strategy in favor of such a sector through the release of the first document on the matter on 12 May, 2004. Specifically, it consists in a communication which helped identify a series of

actions for the creation and appreciation of knowledge through research and development, for the benefit of the whole community. Both this communication and the following documents on the matter, as well as a recommendation carrying the Code of Conduct,⁵ fall within the category of 'soft law' instruments. Such an expression refers to legal tools whose acceptance is voluntary without any enforcement. In fact, they are non-sanctionable, but able to produce legally relevant effects (Snyder 1994, 198). The main feature is the ability of soft law to influence the recipient behavior, such as the private actor and the institution, although it does not provide for any legal sanction in case of non-complying actions.

Therefore, the integrated proactive approach on 'nanoproducts' has initially been put into effect through a series of 'soft and diminished legal instruments' in order 'to accompany and foster a useful, beneficial, profitable and consensual exploitation and application of N&N in the EU' (EC 2005, 12). In fact, according to the opinion expressed in the first communication, the European Commission considered that 'maximum use should be made of existing regulation' (EC 2004, 18), exhorting Member States to 'review and, where appropriate, modify national legislation to take into account the specificities of N&N applications and use' (EC 2005, 11). Such position was confirmed in 2007, following a review of the existing legislative framework in order to determine whether a new regulatory action was required on the risks associated with nanomaterials.⁶

The European Parliament decided to take a more critical approach to the matter. Although it celebrated the Commission action plan, it was perplexed by the lack of explicit prescriptions on nanotechnologies within the community law. If its 2006 Resolution already emphasized the need for a codification of nanomaterials, which was supposed to work out a further series of prescriptions to locate potential risks,⁷ the following 2009 Resolution on the prescriptive aspects of nanomaterials marked the same necessity. That is,

a multi-faceted, differentiated and adaptive body of law based on the precautionary principle, the principle of producer responsibility and the polluter-pays principle to ensure the safe production, use and disposal of nanomaterials before the technology is put on the market, while avoiding systematic recourse to gen-

eral moratoria or undifferentiated treatment of different applications of nano materials.⁸

The European Parliament also deplored the lack of appropriate assessments on the application of general dispositions of Community law, in light of nanomaterial nature.⁹

Such behavior dissented from the Commission conclusion on the suitability of the then-regulations to prevent risks deriving from the employment of nanomaterials themselves.¹⁰ The Parliament expressly required

to review all relevant legislations within two years to ensure safety for all applications of nanomaterials in products with potential health, environmental or safety impacts over their life cycle. Besides, it encourages ensuring that legislative provisions and instruments of implementation reflect nanomaterials peculiar features to which the worker, consumer and/or the environment may be exposed.¹¹

The aforementioned review is necessary not only for the sake of human health and environmental safety, but also for the sake of the certainty owed to the retailer and the trust owed to the citizen¹² as a guarantee of safety against the current and predictable nanotechnology applications.

The Parliament resolution appears to be particularly interesting in consideration of both the precautionary principle and the opinion on the regulation issues raised by nanotechnology applications and products. In order to discipline such new technological products, it is undeniable how resorting to effective prescriptive tools is fundamentally the result of a need to strengthen the safety levels for citizens. Thus, the Parliament position not only reignited the debate between the longstanding 'old and new', bind or not to bind, but it also drew attention to the positions that the legislation should take in dealing with the technoscientific knowledge.

Therefore, following this intervention, the European approach to nanotechnologies shifted towards testing new forms of normativity (Tallacchini 2009), combining classic 'command and control' legal tools with soft law tools. As a result, some regulations encompassing dispo-

tions addressing specifically nanomaterials have made their entrance in the food sector. In particular, specific mentions were made in both the 2009¹³ and 2011¹⁴ regulations with reference to smart and active materials (i.e. they extend food duration or they react in case of food degradation), and plastic objects, respectively. Such regulations give dispositions for substances of particle sizes (e.g. nanoparticles), and explicitly for a risk evaluation on a case-by-case basis, as long as further information are not available.¹⁵

An additional disposition on this matter is included in the rules on plastic materials and objects. Between nanoparticles and bigger particles there are significant differences of both chemical and physical properties, that may carry new toxicological properties. Therefore, it was judged purposeful and necessary to elucidate 'that authorizations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles' (Recital No 23 of Regulation No 10/2011). Thus, nanomaterials need to be assessed before to be used in plastic foodstuff packages.

On the other hand, with reference to food enzymes, the pertinent regulation¹⁶ states that,

a food enzyme already included in the Community list under this Regulation which is prepared by production methods or using starting materials significantly different from those included in the risk assessment of the Authority, or different from those covered by the authorization and the specifications under this Regulation, should be submitted for evaluation by the Authority (Recital No 12 of Regulation No 1332/2008).

Among the 'significantly different' production methods and raw materials, the regulation provides for those that *inter alia* might cause 'a change in particle size' (Recital No 12 of Regulation No 1332/2008).

Yet, it is in the regulation on food additives that there is no clear reference to the use of nanotechnologies. Article 12 of Regulation No 1333/2008, listed as 'Changes in the production process or starting materials of a food additive already included in a Community list,' states:

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.

A further disposition specific for nanomaterial has been recently introduced into a new body of regulations on food labelling.¹⁷ In March 2009 the European Parliament intervened on the topic of labelling nanomaterials contained in foodstuffs. By expressing its opinion on the Commission proposal of changing the discipline of novel foods, the Parliament stated the need for labelling nanomaterials in the list of ingredients,¹⁸ due to the uncertain nature of the related risks. In the same year, 'in a sign of its growing resolve on questions of nanotechnology regulation' (Falkner et al. 2009, 8), the Parliament in Strasbourg adopted another resolution, requiring, *inter alia*, that 'all ingredients present in the form of nanomaterials in substances, mixtures or articles should be clearly indicated in the labelling of the product.'¹⁹ It was not only meant to protect human health, but also to boost citizen trust.

Through the acknowledgment of such a dictate from the European Parliament, article 18.3 of Regulation No 1169/2011 states the following: 'all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.' In the need of 'taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements' (Recital No 25 of Regulation No 1169/2011), the discipline meets the request of many consumer associations (i.e. the European Environmental Bureau and the European Consumers' Organization) to adopt 'better labelling provisions as part of a broader attempt to ensure the consumer right to know and to make an informed choice' (Falkner et al. 2009, 10). From such a point of view, labelling is perceived as a tool that enables us 'to follow a comprehensive and evolutionary approach to the information provided to consumers relating to food they consume' (Recital No 14 of Regulation No 1169/2011).

Hard law and soft law for the regulation of nanofood

Since 2008, the European regulation on nanotechnologies in the agri-food sector has been characterized by a series of dispositions concerning nanomaterials enclosed in other regulations. Their peculiarity is that they have extended the secure, integrated and accountable strategy of the European Commission. Such dispositions are namely those on food additives, smart packaging, and food labeling. Originally articulated in a set of non-binding acts in the soft law category, within the current nanofood regulation the N&N strategy identifies a dynamic synergy between hard law and soft law. Therefore, 'legislation is often only part of a broader solution combining formal rules with other non-binding tools such as recommendations, guidelines, or even self-regulation within a commonly agreed framework' (EC 2001, 20).

Although there is not a general consensus on the nature and form that the legal framework on nanomaterials is supposed to have, the European response to risk management combining hard and soft law tools has received widely positive acknowledgement in the dedicated literature (Bowman & Hodge 2009; Lee 2012; Marchant et al. 2009; Pariotti 2009; Siune & Markus 2009). In fact, resorting exclusively to command and control tools is regarded as potentially restrictive for both the regulation and knowledge development within the nanotechnology sector, once its nature and dynamics are acknowledged.

The European 'co-regulatory strategy' (Bowman & Hodge 2009, 160), which combines prescriptive—centralized and institutionalized—actions with non-binding tools, has no comparison and is regarded as 'unavoidable' (Bowman & Hodge 2009), as it enables the institutionalization of soft law within the R&D sector. As a consequence, it qualifies for determining what it is safe and acceptable for the citizen, as well as for encouraging public confrontation and facing challenges that the emerging technologies represent. Such an approach seems to favor the increase and spread of information, as well as the involvement and participation of the actors working in the development and employment of nanotechnologies.

Undoubtedly, there is a large variety of engines for such non-binding actions: from the need to avoid government interventions that might appear inappropriate and ineffective, to the purpose of increasing citizen trust in both the government and the ability of companies to responsibly develop new technologies. Other reasons lie as much in the soft law potential, as in the will to provide for a nanotechnology pragmatic structure (Bowman & Hodge 2009, 159). The first would bring forth a legal framework easy to adjust to the advancing technoscientific process, while the latter would be able to be reviewed and implemented by virtue of the acquisition of new knowledge.

In relation to environmental and human health safety, as well as product quality, soft regulation might not only favor the creation of arenas for the examination of the consequences of such technologies and their acceptability, but also allow achieving higher standards of effectiveness and homogeneity (Pariotti 2009). However, the urgency to coordinate heterogeneous legal tools sets quite a number of problems in the sector of the emerging technologies, as it is ruled by scientific uncertainty, whose technoscientific convergence ‘raises serious questions relating to ethics, safety, security and respect for fundamental rights.’²⁰ In particular, two specific issues remain unsolved. They both concern the voluntary character of such tools and their legitimization (Pariotti 2009).

With regards to the voluntary character of soft law tools, it was said (Shelton 2008) that, although their lack of limits may reduce the level of enforcement on the short-term, a rigid compliance with their prescriptions cannot be prevented, because of the reasons of their creation and spread. From this perspective, soft law is considered ‘mostly law rather than soft’ (Poggi 2007, 375), becoming itself as binding for the relevant actor in the application of nanotechnologies as are hard law tools.

As for the issue of soft law legitimization—that is its legal soundness—one of the most compelling objections against its spread concerns the issue of ‘democratic deficit’. Thus, within the rule of law, the individual is not acknowledged as a normative jurisdiction which might go beyond the limits of the private jurisdiction. It was then counter-argued (Pariotti 2009) that resorting to soft law cannot exclude coordination with both the European law and international law. Such coordination

aims to rule the individual's behavior that is central, according to bottom up logic, to face successfully challenges set by fast developing technologies.

In light of the aforementioned arguments, soft law tools may be categorized as 'normative discourses' (Wynne & Felt 2007, 43) in order to capture normative developments having a legal or quasi-legal function, of which the European institutions decided to take advantage in the process of transforming Europe from an economic community to a political entity. Once it is set up in these terms, soft law is not in sharp opposition to hard law anymore, but rather they are bound in a complementary function (Malloy 2012). This leads the way to new discussions and democratic solicitations (e.g. let us think about a review of the contents of behavior codes).

Nonetheless, although the combination of hard with soft law represents undoubtedly an innovative and flexible path to provide legal responses to scientific changes, at the same time it requires a constant monitoring of the state of scientific integrity and business activities. Special attention must be paid to the institutionalization of the soft law in the R&D field, 'but that these mechanisms, as a result, do not become subject to capture' (Lee 2012, 117).

But, an effective regulation should also aim to 'justify risk-exposures in terms of the countervailing benefits' (Wynne & Felt 2007, 84). In fact, the usual tendency is to avoid a critical analysis due to the dominating assumption, upon which new nanotechnological processes and/or products always entail benefits for the whole society. Alternatively, why not subject 'nanofood' to a public procedure for a formal assessment of the putative benefits that might derive from its introduction on the market?

Food is more than just nourishment—it is also culture. Centuries-old written sources and countless ethnographic studies prove that food-stuffs not only represent necessary means for survival, but they are also given social, religious, ethnic, and symbolic meanings (Di Renzo 2010). Such values are proof of man-made cultural interventions on the regulation of the food sector; for instance through the denomination mechanisms (e.g. Protected Geographical Indication), or prescriptive practices enforced to protect food quality (Di Renzo 2010). From such a perspective,

the acknowledgment of food as a 'discourse' to handle on a knowability level turns out to have unavoidable repercussions on the creation of the individual as much as the collective ethnic identity. Then, what impact might nanofood have on the European food traditions, in terms of social benefits?

As it would likely respond to one's needs and desires—in comparison to traditional foodstuffs—would it be the most favored food and would it be endowed with a deeper existential value? In fact, it was observed how nanotechnological process are able to affect some of good characteristics, such as flavor, aroma, and other organoleptic qualities.

These considerations lead to examining nanofood regulation as a law based on the same logic guiding any other prescriptive reality. Namely, achieving a legal-scientific architecture able to balance the individual freedom to make the most appropriate choices with interventions preventing from potential external aggressions. This form of controlled freedom responds to the individual principles of self-responsibility and self-protection, as well as to the institutional duty of citizen health protection. It is also affected by the socio-cultural contexts of origin.

Notes

- ¹ This paper was supported by the Ernst-Mach-Stipendien granted by the OeAD (Austrian Agency for International Cooperation in Education & Research), financed by the Austrian Federal Ministry of Science and Research (BMWF).
- ² 'Whereas science was previously understood as steadily advancing in the certainty of our knowledge and control of the natural world, now science is seen as coping with many uncertainties in policy issues of risk and the environment. In response, new styles of scientific activity are being developed. The reductionist, analytical worldview which divides systems into ever smaller elements, studied by ever more esoteric specialism, is being replaced by a systemic, synthetic and humanistic approach. The old dichotomies of facts and values, and of knowledge and ignorance, are being transcended. Natural systems are recognized as dynamic and complex; those involving interactions with humanity are "emergent", including properties of reflection and contradiction. The science appropriate to this new condition will be based on the assumptions of unpredictability, incomplete control, and a plurality of legitimate perspectives' (Funtowicz & Ravetz 1993, 739).

- ³ For instance, according to the National Nanotechnology Initiative (the U.S. Government research and development initiative involving the nanotechnology-related activities of 20 department and agency units) 'nanotechnology is the understanding and control of matter at dimension of roughly 1 to 100 nanometres, where unique phenomena enable novel applications ... At this level the physical, chemical and biological properties of materials differ in fundamental and valuable ways from the properties of individual atoms and molecules or bulk matter' (see <http://www.nano.gov>).
- ⁴ See: Observatory Nano (2010), http://www.observatorynano.eu/project/filesystem/files/Agrifood_Report_2010.pdf [14 January 2014].
- ⁵ All documents published up to now are available at http://ec.europa.eu/nanotechnology/policies_en.html [26 February 2014].
- ⁶ 'Current regulation addresses in principle concerns about health and environmental impacts. On the basis of scientific developments or regulatory needs in specific areas, regulatory changes may be proposed. In the course of this exercise, the EC will take account of reports on regulatory gaps produced in various Member States' (EC 2007, 9).
- ⁷ See Paragraph No 20 of the European Parliament resolution on nanosciences and nanotechnologies. An action plan for Europe 2005-2009, 2006/2004(INI), Strasbourg, September 28.
- ⁸ Paragraph Q of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ⁹ Paragraph No 2 of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ¹⁰ See Paragraph No 3 of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ¹¹ Paragraph No 5 of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ¹² See Paragraph No 6 of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ¹³ Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.
- ¹⁴ Commission Regulation (EC) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
- ¹⁵ Recital No 14 of Regulation No 450/2009 and Recital No 23 of Regulation No 10/2011.

134 Luca Leone

- ¹⁶ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97.
- ¹⁷ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
- ¹⁸ 'Parliament calls for the provision of information to consumers on the use of nano-materials in consumer products: all ingredients present in the form of nano-materials in substances, mixtures or articles should be clearly indicated in the labelling of the product (e.g. in the list of ingredients, the name of such ingredients should be followed by the word 'nano' in brackets)' (See European Parliament (2009), Press Release. *Novel Food., MEPs set new rules*, <http://www.europarl.europa.eu/sides/getDoc.do?language=en&type=IMPRESS&reference=20090422IPR54260>) [01 February 2014].)
- ¹⁹ Paragraph No 17 of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.
- ²⁰ Consideration Y of the European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, 2008/2208(INI), Strasbourg, April 24.

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