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ARTICLE

Prospects for the regulation of nanotechnology applied to food and biofuels

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ABSTRACT

The article discusses the possibilities for nanotechnology regulation applied to food and biofuels. In this sense, we seek to study the risks and hazards of this junction, as well as some alternative regulatory taking as reference formulas, not derived from the State and the Legislature, but coming from international agencies, the companies involved and programs voluntary compliance with the rules and principles already in place, but not directly related to nanotechnology. Thus, the study address law possibilities to join the perspectives opened by the Nanotechnology Revolution, encouraging the fulfillment of standards which have mainly focused on the health and safety of human and environmental preservation.

KEYWORDS: Nanotechnology; Food; Biofuels; Regulation

Introduction

Nanotechnologies represent one of the most intriguing technoscientific revolutions ever undertaken. They are found in a variety of production and commercialization sectors, and they exhibit innovative characteristics and properties that are unprecedented in science. Furthermore, nanotechnologies, which are associated with technoscientific perspectives, are no longer theoretical; research has paved the way for practical applications. The power and value of the prefix "nano" are acknowledged in the market, and high economic gains are projected within the industrial and commercial contexts.

Given the absence of a regulatory framework, this article assesses regulation options in structuring plural forms of the governance of risks posed by nanotechnology applied to foods and biofuels. This is challenging for the law, which must alter its ways of regulation and open up to other areas of knowledge in order to develop the management of nanotechnology-associated risks in a transdisciplinary manner.

In this scenario, the present article addresses the issue of contradictions, similarities, and possible convergences between different forms of nanotechnology regulation in food and biofuel development: conventional regulation (command and control regulation) and alternative soft law regulation aimed at private sector activities.

The hypothesis points to the promotion of manifestations of social regulations, which are not included in the traditional sources of the law and result from decision-making processes that involve non-state stakeholders such as non-governmental organizations (NGOs), research institutions, research financing bodies, businesses, and international organizations.

Method

Comparative, historical, and structural methods as well as case studies were used for analysis. The research techniques included bibliographic research and review of documental research, which involved analysis of legal documents and publications by international bodies linked to regulation of nanotechnology issues.

The theoretical-dialectic perspective of law developed by François Ost and Michel van de Kerchove was adopted[1]. In "*De la pyramide au réseau? Pour une théorie dialectique du droit*," the authors propose a reflection on structural changes within the legal system, which is currently in a paradigmatic transition in which the linear verticality of the pyramidal hierarchy of the legal structure and state regulation lead to a complex regulation and governance network that involves various state and non-state stakeholders.

Various sectors of the law are undergoing a transformation in which the influence of transnational regulation, technical regulation, and private self-regulation is increasing in comparison to that of the prevailing state law. The positivist, unitary view of the law, which is centered on the territoriality of the state and enclosed in a formal and hierarchical system represented by a metaphorical pyramid[2], gives way to new legal structures. Issues involving emerging themes such as human rights, new technologies, the environment, and international trade require a plurality of regulation forms, which can be described as a complex network involving mandatory and sanctionary conventional state regulations as well as new legal manifestations composed of non-mandatory regulations known as soft law, which are unrelated to the formal processes of legislative production. Moreover, important structural changes are observed in the exercise and legitimation of power, particularly in emerging areas such as the regulation of new technologies. During this movement, the state monopoly on the implementation of the law and management of public goods (government) loses ground related to decision-making processes (governance) to legal pluralism and the diversity of social stakeholders (businesses, organizations of professional representatives, regulation and certification institutions, and NGOs).

Theoretical Grounds

Technoscientific convergence and new challenges: Creating a new (?) nanoscale world

Traditionally, science developed on the basis of characteristics such as the quest to understand the world in order to "[...] describe it; interpret it; understand it; explain it; and, in the best scenario, predict and retrodict events, thus explaining them more effectively"[3]. However, this scientific paradigm has gradually changed, particularly with regard to how it operates and to the process of producing scientific knowledge. Currently, science is encouraged as a path toward technological development, reduced to a logic of productivism, and transformed into technoscience, increasingly guided by the laws of the market. Different values serve to motivate the research; for example, "for a scientist, knowledge is an end in itself, whereas for a technoscientist, it is a means to achieve other objectives"[3]. Moreover, most institutions that fund research tend to reproduce the productivist logic, favoring research aimed at technological applications. There is a constant and growing quest for technological innovation, which involves the development of new processes and products, in order to address the demands of the consumer market.

As a result of these changes, contemporary science can no longer be described "[...] as a discourse or a cosmovision; it is a conscious and deliberate activity that is developed by teams, usually large teams, that possess distinct interests and forces, such as theory, practice, and administration"[4]. The technoscientific attitude is significantly more aggressive because it is not contemplative and exploratory but interventionist and transforming. It aims at reconstructing the surrounding world and "invading" all corners of nature, which seems to be an obstacle that needs to be overcome. It is in this context that nanotechnoscience is developed, suggesting that science and technology do not exist separately but are intertwined on a

nanoscale. The aim is not to "[...] describe the processes of nature on a nanoscale but to actively transform the aspects of nature on which it works." It should be noted that nanoscience is not a science in the traditional sense; it is a "frontier science"[4]. Therefore, it is important to identify the (ethical) frontier of this science. This is necessary because nanoscience is an alternative to promoting the convergence between various sciences: life sciences, information sciences, and knowledge sciences such as cognitive sciences. In addition, another question arises: how will the science of law address this technoscientific revolution? Thus, this article's primary focus is finding creative and flexible alternatives for developing legal solutions without depending on state activity[5].

In the era of nanotechnological innovation, human rights are preliminary fundamental ethics that circumscribe the field of nanoscale research and the development of regulatory frameworks. "Today, nanotechnology, in the broadest sense, refers to technologies involving products of a minute size, i.e., less than one-tenth of a micron, 100 nm, or a hundred-billionth of a meter"[6]. Thus, the law must be able to consolidate this technoscientific revolution[7] by renewing its assumptions and developing creative responses to the rights and challenges that this innovation will bring about in society. Moreover, in addition to strongly interacting with nature, nanotechnology will promote physical changes, which will be "[...] at the same time formed by technology and the creators of technology, continuously generating new references to capture immediate experience. Technology is a part of man." The interface brain machine provides unusual experiences: "[...] technology has become an end in itself, and society faces new issues triggered by this reality—genetic engineering, nanotechnology, stem-cell research, etc." This creates a worrying degree of "[...] mismatch between morale (collectively and slowly developed) and the pace of technical progress. There exists a risk of the emergence of a totalitarian technocracy, with science being driven by cutting-edge performance, to the detriment of the discovery of truths that give meaning to life"[8]. To address these aspects of complexity that have emerged in the era of technoscience and are exemplified by nanotechnologies, the development of science specialization must be reviewed. "The specialization of science, which took place in the 19th-20th century, resulted in the training of scientists specialized in increasingly narrow areas of knowledge"[9]. The technological convergence of nano-bio-info-cogno does not appear to correspond to this specialization of scientific knowledge. On the contrary, it requires transdisciplinary formulas for the construction of knowledge in the technoscientific context. In particular, the law should allow for this transdisciplinary perspective in order to socially, politically, ethically, and legally establish adequate regulatory frameworks.

Thus, there is strong evidence that nanotechnologies will pose significant challenges to the creation of a new world, because, in the characterization of nanomaterials, i.e., of materials created on a nanoscale and through human intervention, two characteristics are observed: a) the smaller the surface area, the higher the concentration of atoms, and b) the quantum effect, which states that on a nanoscale, the bond between atoms differs because of the presence of shared orbital energy levels, producing changes in electrical, magnetic, thermal, mechanical, chemical, and optical properties[10].

These characteristics indicate a set of innovations brought about by nanotechnologies. Why use the plural? Because it is a set of various technologies that allows the research and production of nanoscale objects, and it may be used in the cosmetics, pharmaceutical, food, and clothing industries.

Enabling the development of regulatory frameworks for nanotechnologies applied to foods and biofuels

Regulatory issues cover various areas of knowledge involving nanotechnologies. They represent the most recent challenge to balancing technological progress and the protection of human health and the environment. This is a familiar situation: technology progresses rapidly and offers regulation potential for social well-being; however, it presents substantial uncertainty in terms of risks to human health and the environment[11], including foods and biofuels.

However, it is essential to distinguish between risky situations because this difference will influence regulatory formulations. Risk can be perceived as an uncertain consequence of an event or human activity. Thus, risk includes a social dimension that involves its public perception and the level of risk one is willing to take. This is probably the key issue for anticipating potential risks involving nanotechnologies on the basis of three components: risk assessment, management, and communication[12]. To these closely connected elements, one needs to add risk dimensions, namely, the likelihood of an event and the magnitude of its consequences. Therefore, the final decision is based on the result of this equation of risk calculation. There is a difference between risk and danger as the former also considers potential exposure. Danger in itself does not constitute "risk": the characterization of health risk should consider both the danger and potential exposure[13].

Other aspects of risk should also be considered. Nanotechnologies promote the development of systemic problems because a) new technologies (including nanotechnologies) influence economic and political structures and often raise concerns related to the values and cultures of a society, such as its concept of nature, perception of privacy, attitudes regarding the power to make decisions on the continuation of research and commercialization of products and individual control, as well as views on distributive justice, and b) the structural paths of society via policies and institutions to support, regulate, and determine the safety of technologies are highly responsible for guiding this development[14]. These aspects show that in addition to the potential toxicological effects, nanotechnologies can have social and political impacts on society that are being discussed and whose perception is more incipient than that of the first category of risks. These impacts are as or more important than the toxicological effects and also need to be understood and regulated by law.

Nanofoods include not only foods and beverages that contain nanoparticles in their composition but also substances that come into contact with such foods and beverages, such as animal feeds, vaccines, pesticides, and packaging. The following are examples of nanofoods: a) nanoparticles and nanocapsules that are aggregated with foods and beverages to change their taste and texture (already present in leading brands in the market); b) nanoparticles added to chicken feed, having an antibiotic effect; c) pesticides, which are easily absorbed by plants; d) vaccines to treat fish; e) food packaging to increase shelf life, control temperature variation, protect foods against fungi and bacteria, etc[i,15]. There is a wide variety of materials used in nanofoods, and such products are already available in foods, kitchen utensils, refrigerators, or food packaging. For example, silver nano[ii,16] is used for its antibacterial effect.

Other similar materials include the following: a) nano-selenium, which is used as an additive to intensify the effects of green tea; b) nanocalcium, which has been patented for its use in chewing gum, and nanocalcium salts and nanomagnesium are used as food supplements[17]; and c) carbon nanotubes[iii,18], which are developed to produce potent insecticides and fungicides. Researchers claim that there may be a revolution in the production of foods and vegetables for the production of biofuels[19]. In this context, an OECD report indicates innovations involving DNA analysis in the agricultural sector, which may allow agricultural businesses to predict, control, and improve production. The technology for manipulating molecules and atoms in foods would provide high-quality, precise, and low-cost production methods to the food industry, thus improving sustainability. The combination of DNA technology and nanotechnology may generate new nutrition systems that carry substances to specific parts of the human body. These systems are called "atomically modified organisms" (AMOs), which have the potential to stimulate more intense debates than do genetically modified organisms (GMOs)[20].

Biofuel production results from this combination of nanotechnologies and vegetables. Great effort has been invested in utilizing biotechnology for the production of biofuel, including the development of technologies, particularly genetically modified microorganisms, as well as other possibilities that may be included in the group associated with ethanol[21]. The uncertainties regarding nanoparticles in relation to foods, packaging, and agricultural production also apply to biofuels with nanoparticles. Although they offer potentially reduced consumption, replacement of fossil fuels as energy sources, less pollution, and less wear on vehicle parts[22], empirical evidence is required to determine the effects of nanoparticles on human beings and the environment. Due to the limited available data, knowledge from previous experiences related to the remaining uncertainties needs to be taken into consideration[iv,23]. A proactive attitude with regard to risk management should be adopted within the framework analyzed in this study.

The scenario presented, based on examples of nanotechnologies applied to foods and biofuels, indicates a wide range of risks that have not been scientifically confirmed; however, these products are already being produced and are available in the market. This provides the perfect backdrop for the debate on regulatory frameworks. In addition, methodologies, criteria, and guidelines for risk assessment, management, and communication must be developed to enable decision making regarding the present and future of these new technologies.

For this purpose, the development of scientific tools and information is essential to perform informed risk assessments with regard to this emerging technology. The Comprehensive Environmental Assessment (CEA) of the US Environmental Protection Agency (EPA) is an example of this effort.

Figure 2 shows[24] the holistic approach of the CEA in assessing the environmental consequences of selecting different chemical products and technologies. The CEA may be used to identify and prioritize research to support future assessment efforts and/or contribute to risk management in more specific decision-making processes. It offers a structure to systematically organize information by incorporating and building analytical methods including the conventional life-cycle analysis, exposure evaluation, risk analysis, and characterization[24].

It is worth noting that any decision related to nanoparticles should be assessed by evaluating its potential repercussions on the set of energies and forces reciprocally established by nature, thus questioning the means by which and environmental conditions in which interactions occur and new nanotoxicological effects emerge. Environmental assessment should begin with the product's life cycle, taking into consideration its potential interactions with raw materials. The assessment should also cover research and the industrial production process; commercialization; consumption; and disposal, including recycling. In addition, product exposure, transportation, and transformation are important to effectively evaluate the impact on humans and the environment. The development of the production process poses new challenges and risks, with the workers being particularly exposed to them. This leads to the inauguration of a new management phase.

Regulation and risk management is thus required. The regulation of nanotechnologies has given rise to a new form of

i Translated freely by the authors.

ii A recent study published in June 2012, conducted by researchers of Duke University, described how silver nanoparticles behave after they are released into the ecosystem, by simulating a miniature ecosystem. The particles accumulated in the plants, insects, and fish, which were a part of this miniature ecosystem. Interestingly, silver nanoparticles are already used as antimicrobial agents in various goods, such as clothes (in particular socks), containers for storing food, and pharmaceutical, cosmetic, electronic, and optical products.

iii According to a recent study by NIOSH researchers, carbon nanotubes can cause lung tumors.

iv One example is nano-scale cerium oxide, which is used in vehicle catalysts. There are no conclusive studies on the safety of this substance, and risk assessments conducted until now have been considered inadequate.

regulation: a multicentered set of rules and principles to guide the safe and clean implementation of new nanoscale products.

The term regulation has various meanings depending on the area of knowledge, which include cybernetics, economics, politics, and law. In social sciences, regulation traditionally refers to the state activity of producing legal regulations such as laws and other legally binding instruments (administrative acts such as decrees, ordinances, and regulatory instructions). Regulation is mainly used in the context of regulatory law, to denote the activity of regulatory agencies.

In recent years, regulation has assumed a wider meaning and includes instruments of meta-regulation. Although there are no universal definitions of self-regulation and meta-regulation, in general terms, the former is a process of voluntary regulation, independent from state regulation and created by non-state stakeholders. Furthermore, it includes its own addressees, as is the case with companies. On the other hand, the latter results from the interaction between state regulation and self-regulation. Meta-regulation is a monitoring strategy of the state for the mechanisms of self-regulation. It refers to a multilayered regulation in which "each layer regulates the following layer's regulation through various combinations of horizontal and vertical influence"[25].

The regulatory scenario: Innovation and uncertainties due to nanoscale

In this dynamic and uncertain situation, debates regarding how and whether to regulate nanotechnology are common on the Internet, in groups within organized civil society, in scientific literature, in conferences (meetings of researchers, government agencies, company representatives, etc.), and in public hearings. However, the mainstream press does not pay due attention to the topic.

Conversely, researchers and representatives of the business sector criticize the possibility of legal solutions arising from conventional command-and-control instruments, as they would not adequately address the rapid technological changes owing to difficulties in adapting to uncertain and complex situations. Through voluntary regulations, these professionals propose strategies for the governance of risks posed by cutting-edge science and emerging technologies, particularly those based on instruments of self-regulation established and applied either individually or by a set of professional organizations, technical regulation institutions, transnational corporations, or NGOs.

In 2005, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars in the United States released a report, "Managing the Effects of Na-

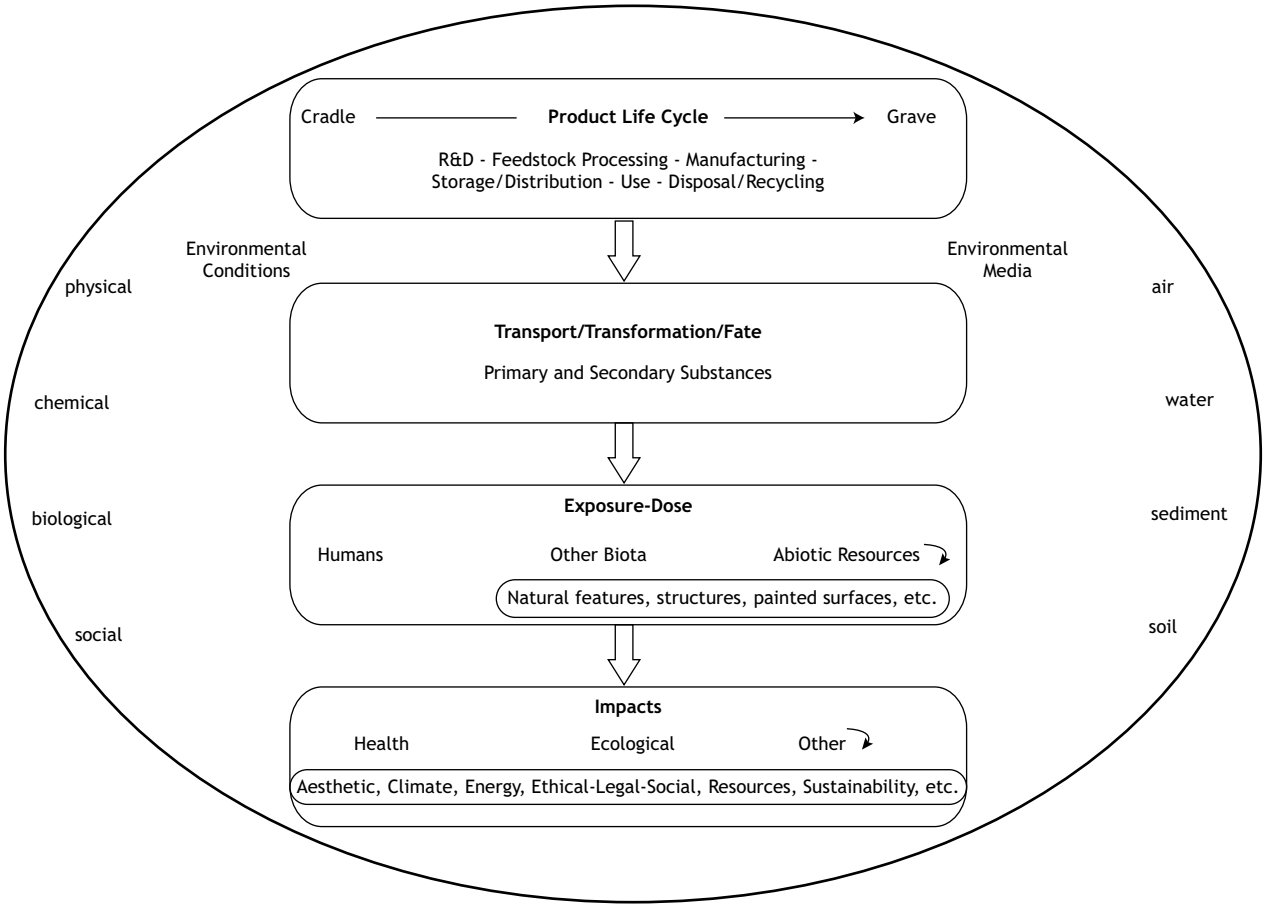

Figure 1.Comprehensive Environmental Assessment's schematic summary.

notechnology," authored by J. Clarence Davies. In the study, based on the legislation of the United States, Davies observed the inadequacy of the country's legislation to address the unique characteristics and risks of nanomaterials, concluding that a new regulatory framework was necessary[26].

The Communication of the European Commission of June 17, 2008, titled "Regulatory aspects of nanomaterials"[27], concluded the following: a) current legislation covers the risks associated with nanomaterials and (b) the protection of health, safety, and the environment needs to be reinforced, mainly by improving current legislation implementation when it is unable to effectively manage its risks owing to lack of adequate data and methodology for assessing risks related to nanomaterials.

To address this, in 2009, the European Parliament approved the "Resolution on Regulatory Aspects of Nanomaterials"[28], presented by the Commission for the Environment, Public Health and Food Safety. It highlights both the inadequacy of the current community legislation and the need to a) review all relevant legislation within two years to ensure the safety of all applications of nanomaterials that may impact health, the environment, or safety during its life-cycle, and b) ensure that the legal provisions and implementation instruments reflect the specificities of nanomaterials that workers, consumers, and the environment could be exposed to.

On October 3, 2012 the European Commission (EC) released an analysis on nanomaterials regulation, the "Second regulatory review on nanomaterials"[v,29,30]; however, its conclusions were criticized by organized civil society. A coalition of NGOs wrote an open letter to those responsible for the conclusions, criticizing them for not consistently considering the available scientific information on potential risks of exposure to nanomaterials, e.g., in the document titled "Staff Working Paper (SWP)"[31], prepared by scientists at the request of the EC. This letter deemed the changes limited to the REACH annexes as insufficient, considering it inadequate to fill existing gaps and address the lack of information on nanomaterials in products. Moreover, it accused the analysis of "putting the interests of industry before the well-being of society" as it rejected "the implementation of a precautious approach" [32].

Therefore, there is high tension regarding this issue between the EC and the European Parliament, due to the interests represented by both institutions, with the Green Party exerting considerable influence on the latter.

Next, we present the options for regulation of nanotechnologies applied to foods and biofuels[33].

a) Non-regulation:

The first option is immediate non-regulation due to the lack of scientific confirmation of the risks and hazards associated with nanotechnologies. This is the current situation in most states, as their legal systems do not include regulations on any form of labeling, monitoring, and information on the risks posed by nanotechnology. Furthermore, in many states, there is no public debate on this topic. However, awaiting scientific proof of the negative effects of nanotechnology before establishing legal frameworks or reviewing current laws does not seem to be an adequate decision. The various stakeholders should at least discuss the necessary measures to address the risks associated with nanotechnologies.

Regarding the release of nanoparticles into the environment, several studies have recommended that direct state intervention is urgently needed to create risk management instruments that include research on the undesired effects of nanoparticle residues; risk monitoring; limitation of activities; and depending on the conditions of uncertainty and the seriousness of potential risks, a ban on sales of nanoparticles or the release of nanoparticles into the environment.

b) A general moratorium on the research, development, and commercialization of nanotechnologies and/or nanomaterials:

This option opposes non-regulation and is supported mainly by environmental NGOs. The NGOs Friends of the Earth Australia[34] and Grupo ETC[35] are seeking a moratorium on the use of nanotechnology in agriculture and the production of foods. The moratorium on nanotechnology would be an extreme example of an application of the precautionary principle, which demands that no substance is released without evidence that it is not dangerous to the environment. However, this is not the only application of the precautionary principle.

Therefore, both non-regulation and a general moratorium do not adequately address the uncertain risks posed by nanotechnology. The precautionary principle highlights that something should be done. However, considering both the complexity associated with the wide spectrum of innovations in the fields of nanotechnology application as well as the resulting potential risks, comprehensive solutions must be developed by modifying/complementing current regulations, constructing new regulatory frameworks, or adopting/acknowledging voluntary state and private regulations as being complementary.

c) An incremental process using existing legal structures:

A mid-point between both the above positions would be to use existing legal structures, train state bodies and agencies to enforce regulations to the specificities of nanotechnology, and review and alter the regulations to adapt to new requirements of nanotechnological risks. As this process focuses on politically consensual selective modifications in the current legislation, it is not as radical and represents a shorter path than launching a comprehensive and profound regulatory process specific to nanotechnologies.

As previously mentioned, most national and international legal structures do not include specific protection against risks

v Among the main conclusions of the European Commission in the "Second regulatory review on nanomaterials," the following idea stands out: "Nanomaterials require an evaluation. In light of current knowledge and opinions of the European Union's scientific and advisory committees as well as of independent risk evaluators, nanomaterials are similar to chemical products or normal substances, i.e., some may be toxic and others may not. The possible hazards are related to specific nanomaterials and their uses. Therefore, nanomaterials require risk assessment, which should be performed on a case-by-case basis using relevant information. The current methods of risk assessment are applicable, even if certain aspects need to be worked upon…"

posed by nanotechnologies. However, considering the various legal regulations aimed at protecting the environment and human health as well as the wide range of legal approaches to risk, applying existing laws or adapting them to the specificities of nanotechnology should not be ruled out. Regulations regarding toxic substances, biotechnology, foods, medications, consumer rights laws, civil laws, penal laws, and environmental laws should not be ignored, although they are not currently aimed at the risks and specificities of nanotechnologies. The current regulation network related to the risks associated with consumers as well as environmental and human health issues is clear on important principles such as precaution, prevention, and the right to information, and although it does not directly mention nanotechnology, it cannot be neglected. In addition, regardless of the solution for the regulation of nanotechnology—modification or creation of regulatory frameworks—it is important to analyze current regulations, because a new regulation will not be included in a parallel, autonomous system specifically created for nanotechnologies.

It is essential to set the current legal context as the point of departure and identify situations in which it is appropriate to make minor or major changes to incorporate new criteria and requirements. Thus, it is important to study comparative law as a way of "prospecting" different realities in order to make decisions regarding when and how to legislate within a national context.

d) A comprehensive and profound regulatory process aimed at nanotechnologies:

The French legal system includes an example of the control of specific information about nanoproducts. Articles L523-1–L-523-3 of the French Environmental Code foresee the obligation to declare the quantities and uses of all produced, distributed, or imported nanoparticles in France. This exercise will enhance knowledge about these substances and their uses, enable the control of the areas of use and commercialized quantities, and contribute to the collection of information on the toxicological and ecotoxicological properties of these substances. To regulate the instruments of the French Environmental Code that are related to the subject, Decree no. 2012-232 of February 17, 2012 was enacted in January 2013. It foresees the annual declaration of "substances in the state of nanoparticles."

Regarding nanomaterials in foods, the regulation regarding the availability of information for consumers in the European Union (EU Regulation 1169/2011) was approved by the EC in July 2011 and will be enforced in December 2014, combining two previous directives: regarding "labeling, presentation and advertising of foodstuffs" (2000/13/EC) and "nutritional labeling of foodstuffs" (90/496/EEC). This regulation requires the labeling of ingredients that are in the form of nanomaterials in food products. According to the regulation, "All ingredients present in the form of artificial nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets"[vi].

In Brazil, four bills have been proposed at the National Congress, Bill nos. 5,076/2005, 131/2010, (brought to a close in 2007 and 2013, respectively), 5,133 and 6,741 of 2013, which is still in Congress.

The first project, Bill no. 5,076/2005, proposed by the Member of Parliament Edson Duarte to create legal provisions on "nanosafety," was brought to a close in January 2007 owing to the unanimous approval of the statement by rapporteur Léo Alcântara representing the Commission on Economic Development, Industry and Commerce of the Chamber of Deputies. According to the Commission's understanding, Brazil is not currently conducive to enacting laws on nanotechnology, because "in the country's current stage of nanotechnological development, the scope of the object of analysis that it proposes to regulate is not clear." According to Alcântara, "to enact laws on something whose processes and products are still somewhat unknown creates a high risk of increasing the investors' uncertainty and inhibits the flow of investments in that activity." According to the rapporteur, the concerns of the project's author are covered by current regulations. In the same statement, the rapporteur declares that "the proposal would add a series of bureaucracies that would mean the increase of the so-called *'custo Brasil'* in relation to that activity, which is only now starting to assert itself in the country." According to the text, approving the proposal would "mean the difference between businessmen investing and not investing in this new area of knowledge"[36].

The second rejected project, Bill no. 131 of 2010, aimed at altering Decree-Law no. 986 of October 21, 1969, which instituted basic regulations on foods, and Law no. 6,360 of September 23, 1976, with regard to health surveillance regarding medication, drugs, pharmaceutical ingredients and related substances, cosmetics, and sanitizing products. If approved, it would promote the alteration of Decree-Law no. 986 of October 21, 1969 to determine that the following clearly state information about this fact: labels; leaflets; printed materials; tags; packaging; prospectuses; as well as advertising materials for products, medication, drugs, pharmaceutical ingredients and related substances, cosmetics, and sanitizing products that are developed using nanotechnology. The project's justification highlights the importance of nanotechnology in the development of new products and of the growth of nanoproducts already in the market.

The proposal was submitted for analysis to the Commission for Social Affairs and Commission for the Environment, Consumer Protection, Control and Surveillance. Both commissions were in favor of rejecting Bill no. 131 of 2010 because they regarded it as a proposal for unnecessary legal intervention with regard to food and the other mentioned products. According

vi The text of Regulation 1169/2011 of the European Union includes the concept of an "artificial nanomaterial," which refers to intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates, or aggregates, which may have a size above the order of 100 nm but which retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include (i) those related to the large specific surface area of the materials considered and/or (ii) physicochemical properties that differ from those of the non-nanoform of the same material.."

to the report, there is no scientific foundation for the requirement of this information. In addition, the project may cause unnecessary confusion and alarm among consumers and economic losses to businesses. Moreover, the members of the commissions believed that because the ANVISA has the authority to regulate on this matter via a non-statutory regulation, such requirements should not be included in common law.

Currently, Bill no. 5,133 of 2013, authored by Sarney Filho, Federal Deputy of the Partido Verde (PV), is in Congress. This proposal aims to make compulsory the labeling of products that use nanotechnology. This is justified by citing the consumer's right to information about the potential risks of products "obtained via the nanotechnological process."

The abovementioned proposal states that information should be placed on labels of products that are obtained or produced via nanotechnological processes, that contain nanoparticles (nanotechnological ingredients) in their composition, or that are or that include ingredients produced using animals which were fed nanoproducts. This information applies to cosmetics, pharmaceuticals, and foods.

Bill no. 6,741 of 2013, also authored by Sarney Filho, proposes the creation of a national public policy of risk management regarding nanotechnological development under the principles of information, transparency, social participation, precaution, prevention, and social responsibility. To implement the National Policy on Nanotechnology, this bill indicates four instruments: a) national registration to control and monitor research projects, technological development, creation, commercialization, and introduction in the nanoproducts market; b) state authorization in relation to human and animal health as well as environmental protection for the research, production, and commercialization of nanoproducts or products derived from nanotechnological processes; c) the requirement of studies on the environmental impact of the release of nanoproducts; and d) the promotion of studies on the effects of nanoproducts on human and animal health as well as on the environment. Moreover, when the state authority decides that nanotechnological processes and products can damage the environment or human or animal health, the bill enables the establishment of specific monitoring plans for them. The same legislative proposal also mentions the following: a) the possibility of rejection, suspension, and registration of a nanotechnology process or product, or of a product containing nanotechnological ingredients; b) the adequate disposal of nanotechnology rejects, establishing the need for residue plans based on the National Policy for Solid Residues (Law no. 12,305 of August 2, 2010); c) an obligation for notification of accidents involving nanoproducts (Law no. 12,608 of 10 April 2012 of the National Policy on Civil Protection and Defense); d) the use of public resources in nanoscience and nanotechnology; e) the prohibition of patenting nanotechnological products or processes obtained from living organisms as well as that of research, use, commercialization, registration, patenting, and licensing of nanotechnologies; and f) responsibilities and sanctions regarding non-compliance with the necessary measures in order to prevent drawbacks and damage caused by activities derived from nanotechnology.

Because nanotechnologies have applications in distinct areas of science, technology, and economy, and because legal interests are involved (safety, environment, property, health, life, freedom), future actions in terms of regulation should involve the participation of society, including stakeholder organizations, as well as wide dissemination of information on the process of the development of regulation.

However, the challenge of establishing "official" state legal regulations for the development of nanotechnologies shows that there are "blank pages," i.e., the existence of various paths that can be chosen and the incapacity of the political system to address in a conventional manner the creation of mandatory legal frameworks regarding risks and uncertainties as technologies advance.

The inertia of states with regard to establishing regulations to address the risks associated with nanotechnologies is the result of the general uncertainty in relation to this technology and the pressure from the private sector, which regards state regulation as an obstacle to its interests. This indicates that state initiatives are limited to the issuance of recommendations, good practice guidelines, or referendums of such initiatives once they are developed and applied by private organization networks. Direct regulation on nanotechnologies involves two major problems: a) a lack of consensus within the scientific community regarding the methodology to measure the toxicological effects of nanoparticles and b) a lack of knowledge about the exact number of nanoparticles already produced as a result of human activities. In the short term, these difficulties hinder any attempt to create a specific nanotechnological regulatory framework. In addition, it should be noted that the creation of specific regulations without adequate alignment with the various relevant areas of knowledge could exacerbate problems as compared to during the absence of regulations.

e) Voluntary measures (soft law, self-regulation, and metaregulation):

The expression soft law emerged as the contrast to hard law in the context of international law; it represents regulations that are not of an explicit sanctionary nature. Most soft law initiatives are conceived in the context of international organizations involving economic and financial activities as well as of emerging topics related to society as a whole, such as environmental protection, human rights, and regulation of new technologies.

Soft law has been strongly criticized for its doctrinal difficulties and terminological contradictions. It is not a legal regulation in the positivist sense, because there are no clear criteria that distinguish between and law and non-law. Moreover, soft law is considered a threat to state sovereignty due to the easing of international regulations in favor of economic and market globalization.

The positivist duality between law and non-law does not determine the importance of soft law and its influence on

the various addressees of the regulation. Soft law draws its strength not from a supposed legal nature but from social practices, as László Blutman observes: "It is not certain that these regulations require a legal form to effectively fulfill their regulatory functions. However, the academic reflections on soft law usually make the mistake of attributing some kind of legal nature to these regulations, at all costs, to explain their regulatory functions. However, in most cases, the answer to the efficacy or inefficacy of these regulations is not found in the coordinates of their relation to formal legal regulations, but rather in the detailed analyses of the international sociological relations"[37].

The current scenario of governance of risks associated with nanotechnological innovation is based on regulations that lack a sanctionary nature, at least in two major soft law categories: a) voluntary "public regulations," which serve as guidelines for good scientific and business practices, programs and voluntary governmental guidelines (e.g., EPA's Nanoscale Materials Stewardship Program, DEFRA's Voluntary Reporting Scheme for Manufactured Nanomaterials, and the European Union Code of Conduct on responsible research in the area of nanosciences and nanotechnologies), and b) self-regulation "private regulations," good practice guidelines developed and implemented within companies (e.g., BASF's Nanotechnology Code of Conduct) or in collaboration with NGOs (e.g., DuPont & Environmental Defense's Nano Risk Framework) for the safe handling of nanomaterials, codes of conduct established together with various stakeholders, multi-stakeholder codes of conduct (e.g., Responsible NanoCode), standards and technical regulations based on scientific expertise (regulations of the International Standards Organisation (ISO), American Society for Testing and Materials (ASTM), European Committee on Standardization (CEN), Organization for Economic Cooperation and Development (OECD), and British Standard Institute (BSI))[38].

Owing to the difficulties in legal regulation on the matter, i.e., financial costs and obstacles for research associated with the creation of new institutions to monitor and regulate nanotechnologies, the advocates of self-regulation are in favor of capitalizing on the existing regulations to assess the safety of new products and substances and abandoning the search for new state regulatory frameworks. Moreover, they promote the development of regulatory activities of private organizations (research institutes, businesses, NGOs, and institutions responsible for establishing technical regulations and certifying conformity with the required standards). Others, however, believe that voluntary codes can play an important role in a "first attempt at new governance" by quickly regulating emerging areas; however, they argue that governments should also play a central role in the governance of risks associated with nanotechnologies through "nano-specific" regulations, thus gradually creating a "regulatory web in evolution"[39].

Considering the uncertain future of nanotechnologies, which involves a complex mix of expected benefits and feared risks, soft law regulatory approaches could offer important advantages to experimentation and learning in a gradual regulatory action, which begins with voluntary regulations and progresses to decisions regarding the incorporation of more formal and binding regulations (hard law)[40].

Furthermore, soft law facilitates a consensus with regard to cooperation commitments between the various social participants. The need to address opposing interests and values of non-state stakeholders such as transnational corporations (TNCs) and NGOs is one reason why states are interested in promoting soft law strategies[41].

In this context, soft law, in particular private self-regulation, should be considered as complementary to state legislation in order to anticipate future obligations, generate information, stimulate behaviors, clarify and encourage good practices, and create opportunities. However, soft law, in particular self-regulation, should not be used as an instrument of opposition to state external control in order to "restrain the development of laws" regarding public demands brought on by nanotechnology. Therefore, governance initiatives based on soft law should be transparent and open to control by the state and civil society. This can be enabled through ample access to information; otherwise, such initiatives tend to function more as greenwashing aimed at misleading consumers, demobilizing state authority, and alienating society from risk management.

A study conducted in the United States between 2008 and 2012 reinforces previous analyses, including governmental studies, which indicate the lack of transparency on this issue[15]. The study, conducted by "*As You Sow,*" concluded that companies are not aware of the presence of nanomaterials in their production chain. In this study 2,500 questionnaires were distributed among food industry companies, including the largest food industries, distributors, fillers, retailers, and fast food and nutritional supplements companies. Only 26 companies responded to the survey[15]. How can the consumer's right to information be respected if manufacturers and retailers are either unaware of or refusing to provide information about the use of nanotechnology in their products? How can agencies and other institutions to do their part—estimating, systematizing, and studying possible toxic effects—if companies withhold this important information? Can we expect companies, when they make voluntary commitments, to present all their data, especially those that may lead to their research, technological developments, and products being interpreted as risk warnings?

Considering the difficulties in conventional state regulation, established through command-and-control instruments, to adequately address the uncertainties resulting from technological development as well as the common flaws of self-regulation strategies (lack of transparency and legitimacy), we highlight the relevance of the debate on new instruments of meta-regulation. This enables the aggregation of better communication between the civil society, the state, companies, and scientists with the strategies of governance of risks associated with nanotechnology[25]. In meta-regulation, the state neither delegates all regulation to the private sector nor bestows all control upon itself; meta-regulation involves monitoring strategies on the part of the state regarding private self-regulation mechanisms.

Conventional command-and-control instruments usually require information on the risks posed by certain products or production methods. Regulators need to know the magnitude of the potential damage as well as the likelihood of damage. With regard to the development of nanotechnologies, state regulation organizations, as compared to the industries they supervise, tend to be at a disadvantage when it comes to obtaining significant information. According to Coglianese and Mendelson[25], in complex cases or when there is emerging risk, self-regulation and meta-regulation can offer advantages in terms of the necessary resources and information for regulation, but this does not imply that they are flawless solutions. That is, meta-regulation can be the optimal option, or the available if not ideal option, in circumstances that involve accelerated development and scientific uncertainties regarding risks. According to Coglianese and Mendelson[25], the main problem with self-regulation and meta-regulation is that, even in situations in which companies have the best information, which allows them to find solutions to problems concerning public interest, they are not always encouraged to do so[25]. After all, "If those incentives were sufficient, no regulation would be necessary." In practical terms, a great challenge for them, with regard to self-regulation and meta-regulation, is to ensure that the goals established for the use of companies' discretionary power are consistently implemented, aiming for public regulation rather than their private individual interests[25].

Nanotechnological development raises the important question of whether meta-regulation effectively represents a mid-point between state command-and-control instruments and private self-regulation, as it is more flexible and adaptable to scientific uncertainties than the former and more reliable and transparent than the latter.

Results and Discussion

As observed in this study, uncertainty about the effects of nanotechnologies involves the participation of various social stakeholders (businesses, NGOs, international organizations, scientists, and states), and a series of non-official texts such as reports, good practice guidelines, and recommendations have been produced on the subject. Conversely, state official regulatory solutions, via the promulgation of legislation on the risks associated with nanotechnology, are the exception.

In this study, we observed that in the case of nanotechnology, there are a variety of complex regulation networks (including self-regulation and meta-regulation) that structure distinct forms of risk governance and involve different social, governmental, state and non-state stakeholders.

As a preliminary result of the assessment of options regarding the regulation of risks posed by nanotechnologies, including foods and biofuels, the conventional forms of state regulation based on command-and-control instruments are the exception; they are limited to initiatives that demand supply of information via the legal requirement to label food products or register substances and products containing nanoparticles. These are important initiatives to ensure the consumer's right to information. In this sense, the rejection of Bill no. 131 of 2010 represented a lost opportunity to establish a regulation that was pertinent to the protection of the consumer's informed right of choice.

Moreover, the use of soft law, namely, the voluntary measures of self-regulation and meta-regulation, may be beneficial when they are developed and applied as a complement to state regulations that protect the basic rights of citizens and consumers, with the following goals: a) promote compliance with obligations in addition to those imposed by current legislation, b) create and disseminate information, c) stimulate preventive behaviors (risk management) among private stakeholders.

References

1. Kerchove MV, Ost F. De la pyramide au réseau? Pour une théorie dialectique du droit. Bruxelles: Publications des Facultés universitaires Saint-Louis; 2000.
2. Kelsen H. Teoria Pura do Direito. 5. ed. São Paulo: Martins Fontes; 1996.
3. Echeverría J. Interdisciplinariedad y convergencia tecnocientífica nano-bio-info-cogno. Sociologias. 2009;11(22):22-53.
4. Maldonado CE. Filosofia de la Ciencia y Nanotecnociencia. In: Gallo JG, González E, Baquero-Gómez F (editores). Nanotecnociencia: nociones preliminares sobre el universo nanoscópico. Bogotá: Ediciones Buinaima; 2007. p. 70-1.
5. Engelmann W. A nanotecnociência como uma revolução científica: os direitos humanos e uma (nova) filosofia na Ciência. In: Streck L, Morais JLB (organizadores). Constituição, Sistemas Sociais e Hermenêutica: Anuário do Programa de Pós-Graduação em Direito da UNISINOS: Mestrado e Doutorado. Porto Alegre: Livraria do Advogado; 2010. p. 249-65.
6. Drexler E. Os nanossistemas: possibilidades e limites para o planeta e para a sociedade. In: Neutzling I, Andrade PFC (organizadores). Uma sociedade pós-humana: possibilidades e limites das nanotecnologias. São Leopoldo: Unisinos; 2009. p. 42.
7. Engelmann W, Flores AS, Weyermüller AR. Nanotecnologias, marcos regulatórios e direito ambiental. Curitiba: Honoris Causa; 2010.
8. Guimarães AS. O Corpo Expandido. Filosofia Ciência & Vida. 2008;3(28):16-25.
9. Pittella JE. Construindo o saber da Ciência. Belo Horizonte: COOPMED; 2012. p. 63.
10. Gray KA. Five myths about nanotechnology in the current public policy debate: a science and engineering perspective. In: Dana DA (editor). The nanotechnology challenge: creating legal institutions for uncertain risks. New York: Cambridge University Press; 2012. p. 11-60.
11. Malloy TF. Soft law and nanotechnology: a functional perspective. Jurimetrics. 2012;52(3):1-12.

12. Shatkin JA. Assessing nanotecnology health and environmental Risks. In: Nanotechnology: health and environmental risks. 2. ed. New York: CRC Press; 2013. p.25-8.
13. Shatkin JA. Defining risk assessment and how it is used for environmental protection and its potencial role for managing nanotecnology risks. In: Nanotechnology: health and environmental risks. 2. ed. New York: CRC Press; 2013. p. 32-5.
14. Keller KH. Nanotechnology and society. In: Maynard AD, Pui DYH (editores). Nanoparticles and occupational health. New York: Springer; 2007. p. 5-6.
15. Behar A, Fugere D, Passoff M. Slipping through the cracks: an issue briefs on nanomaterials in food [Internet]. Oakland, CA: As You Sow; 2013. [cited 20 July 2013]. Available from: http://www.corporatecrimereporter.com/wp-content/uploads/2013/02/SlippingThroughTheCracks-2013.pdf
16. Lowry GV, Espinasse BP, Badireddy AR, Richardson CJ, Reinsch BC, Bryant LD, Bone AJ, Deonarine A, Chae S, Therezien M, Colman BP, Hsu-Kim H, Bernhardt ES, Matson CW, Wiesner MR. Long-term transformation and fate of manufactured ag nanoparticles in a simulated large scale freshwater emergent wetland. Environ Sci Technol. 2012;46(13):7027-36.
17. Food and Agriculture Organization of The United Nations, World Health Organization. Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications [Internet]. Rome: FAO/WHO; 2010. [cited 28 July 2013]. Available from: http://whqlibdoc.who.int/publications/2010/9789241563932_eng.pdf
18. Castranova VG, Charles L, Schulte P. New Findings on Lung Tumor Formation in Laboratory Mice Exposed to Multi-Walled Carbon Nanotubes [Internet]. NIOSH; 2013. [cited 28 July 2013]. Available from: http://blogs.cdc.gov/niosh-science-blog/2013/03/11/mwcnt/
19. Khodakovskaya M, Dervishi E, Mahmood M, Xu Y, LI Z, Watanabe F, Birit AS. Carbon nanotubes are able to penetrate plant seed coat and dramatically affect seed germination and plant growth. ACS Nano. 2009;3(10):3221-7.
20. Organisation for Economic Co-Operation and Development. Small sizes that matter: oportunities and risks of nanotechnologies [Internet]. Paris: OECD; 2005. [cited 29 July 2013]. Available from: http://www.oecd.org/chemicalsafety/nanosafety/44108334.pdf
21. Duailibe AK. A Realidade dos Biocombustíveis no Brasil. Scientific America Brasil. 2012;11(21):32-9.
22. Basha JS, Anand RB. Role of nano additive blended biodiesel emulsion fuel on the working characteristics of a diesel engine. J Renew Sust Energ Rev. 2011;3(2):1-17.
23. Shatkin JA. Sustainable nanotechnology development using risk assessment and applying life cycle thinking. In: Nanotechnology: health and environmental risks. 2. ed. New York: CRC Press; 2013. p. 61-66.
24. United States Enrivonmental Protection Agency. Comprehensive environmental assessment: a meta-assessment approach to increase effectiveness of risk management and research planning [Internet]. United States: EPA; 2013. [cited 29 July 2013]. Available from: http://www.epa.gov/nanoscience/files/CEAPrecis.pdf
25. Coglianese C, Mendelson E. Meta-Regulation and Self-Regulation. In: Baldwin R, Cave M, Lodge M (editores). The Oxford Handbook of Regulation. Oxford: 2010. p. 146-68.
26. Davies JC. Managing the effects of nanotechnology [Internet]. Washington DC: Woodrow Wilson International Center for Scholars; 2006. [cited 20 July 2013]. Available from: http://www.nanotechproject.org/process/files/2708/30_pen2_mngeffects.pdf
27. Comissão Europeia. Parecer do Comitê Econômico e Social Europeu sobre a Comunicação da Comissão ao Parlamento Europeu, ao Conselho e ao Comitê Econômico e Social Europeu: aspectos regulamentares dos nanomateriais [Internet]. Jornal Oficial da União Europeia C 218/21, 11 set. 2009. 6 p. [cited 14 June 2013]. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:218:0021:0026:PT:PDF
28. Parlamento Europeu. Comissão do Ambiente da Saúde Pública e da Segurança Alimentar. Relatório sobre aspectos regulamentares dos nanomateriais (2008/2208(INI) [Internet]. 2009. [cited 15 May 2013]. Available from: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A6-2009-0255+0+DOC+XML+V0//PT#title1
29. Comissão Europeia. Comunicação da Comissão ao Parlamento Europeu, ao Conselho e ao Comitê Econômico e Social Europeu: segunda revisão regulamentar relativa a "nanomateriais" [Internet]. Bruxelas: Comissão Europeia; 2012. (n. 572 final). [cited 14 June 2013]. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:PT:PDF
30. Comissão Europeia. Nanomateriais: Abordagem de segurança caso a caso para tecnologias inovadoras [Internet]. Bruxelas: Comissão Europeia; 2012. [cited 13 July 2013]. Available from: http://europa.eu/rapid/press-release_IP-12-1050_pt.htm
31. European Commission. Types and uses of nanomaterials, including safety aspects [Internet]. Brussels: European Comission; 2012. (n. 288 final). [cited 18 May 2013]. Available from: http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_staff_working_paper_accompanying_com(2012)_572.pdf
32. Stakeholders' Response to the Communication on the Second Regulatory Review on Nanomaterials [Internet]. Brussels: European Environmental Citizens Organisation for Standardisation; 2012. [cited 19 July 2013]. Available from: http://www.ecostandard.org/wp-content/uploads/Nanomaterials-joint-letter-23-10-2012-logos.pdf
33. European Commission. Nanotechnologies: a preliminary risk analysis on the basis of a preliminary workshop organized in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission [Internet]. 2004. [cited 10 July 2013]. Avai-

lable from: http://ec.europa.eu/health/ph_risk/documents/ev_20040301_en.pdf
34. Friends of the Earth. Out of the Laboratory and on to our Plates. Nanotechnology in Food & Agriculture [Internet]. United States; 2008. [cited 29 July 2013]. Available from: http://nano.foe.org.au/sites/default/files/Nanotechnology%20in%20food%20and%20agriculture%20-%20text%20only%20version_0.pdf
35. Grupo ETC. Manual de Bolso das Tecnologias em Nanoescala ... e a teoria do "little bang" [Internet]. Canada: Etcgroup; 2005. [cited 15 July 2013]. Available from: http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/57/01/tinyp_portuguesfinal.pdf
36. Brasil, Câmara dos Deputados. Comissão de Desenvolvimento Econômico, Indústria e Comércio. Projeto de Lei nº 5.076-C, de 2005. Dispõe sobre a pesquisa e o uso da nanotecnologia no País, cria Comissão Técnica Nacional de Nanossegurança - CTNano, institui Fundo de Desenvolvimento de Nanotecnologia - FDNano, e dá outras providências [Internet]. Brasília: Câmara dos Deputados; 2005. [cited 02 Mar 2013]. Available from: www.camara.gov.br/sileg/integras/337343.doc
37. Blutman L. In the trap of a legal metaphor: international soft law. Int Comp. Law Qual. 2010;59(3): 605-24.
38. Shatkin JA. Ongoing International Efforts to Address Risk Issues for Nanotechnology. In: Nanotechnology: health and environmental risks. 2. ed. New York: CRC Press, 2013.
39. Bowman DM, Hodge GA. Governing Nanotechnology without Government? Sci Public Policy. 2008;35(7):475–87.
40. Marchant G, Sylvester D, Abbott K. A new soft law approach to nanotechnology oversight: a voluntary product certification scheme [Internet]. UCLA J. Envtl. L. & Pol'y. 2009 [cited 30 July 2013]; 28 (123). Available from: http://papers.ssrn.com/sol3/Delivery.cfm/SSRN_ID1483910_code336250.pdf?abstractid=1483910&mirid=1
41. Abbott K, Snidal D. Hard and soft law in international governance. Int Org. 2000;54:421-56.

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