

# ENVIRONMENTAL LAW AND NANOTECHNOLOGIES: CHALLENGES TO THE NEW RISKS OF INNOVATION

**Juliane Altmann Berwig<sup>1</sup>**

Universidade Feevale

**Wilson Engelmann<sup>2</sup>**

Universidade do Vale do Rio dos Sinos (UNISINOS)

**André Rafael Weyermuller<sup>3</sup>**

Universidade FEEVALE / Universidade do Vale do Rio dos Sinos (UNISINOS)

## ABSTRACT

We intend to assess the complexity posed by new technologies, especially in the use of nanotechnologies in numerous products that were first developed to bring in improvements, and not to cause future damages. Through a descriptive and bibliographical research, we aim at learning the traditional instruments of Environmental Law and assessing the possibility of new ways to reconcile the necessary technological evolution with prudence in relation to the possible unpredictable result of the use of elements developed at the “nano” scale. The protection provided by the Environmental Law system was developed on an

<sup>1</sup> Doctor in Law by UNISINOS. Master in Law by UNISINOS. Specialist in Brazilian and International Environmental Law by Universidade Federal do Estado do Rio Grande do Sul (UFRGS). Undergraduate in Law by Universidade de Santa Cruz do Sul (UNISC). Professor of FEEVALE Law course and researcher in the project “The human-environmental impacts caused by nanotechnologies: redesigning the structuring elements of Environmental Law”. Chairperson of the Rio Grande do Sul Association of Business Environmental Law Attorneys – AGAAE. Author of the book “Direito dos Desastres na Exploração offshore do petróleo”. Owner shareholder of Berwig Advocacia law firm. ORCID: <http://orcid.org/0000-0002-9050-8531> / e-mail: [julianeberwig@feevale.br](mailto:julianeberwig@feevale.br)

<sup>2</sup> Post-Doctoral student in los Retos Actuales del Derecho Público by Centro de Estudios de Seguridad de la Universidad de Santiago de Compostela (CESEG/USC). Doctorate and Master’s in Public Law by UNISINOS. Undergraduate in Law by UNISINOS. Executive Coordinator of the Professional Master’s Course in Company and Business Law of UNISINOS. Professor and researcher in the Law Graduation Program of UNISINOS. Visiting Professor at Universidad Católica del Uruguay, research collaborator for the Latin American Nanotechnology & Society Network, associate researcher – Portucalense Institute for Legal Research, associate researcher of Centro de I&D sobre Direito e Sociedade. ORCID: <http://orcid.org/0000-0002-0012-3559> / e-mail: [wengelmann@unisinis.br](mailto:wengelmann@unisinis.br)

<sup>3</sup> Post-Doctor in Law by Pontificia Universidade Católica do Rio de Janeiro (PUC-RIO). Doctor in Law by UNISINOS. Master in Public Law by UNISINOS. Specialist in Environmental Law by FEEVALE. Bachelor in Law and Social Sciences by UNISINOS. Researcher of the FEEVALE graduation program. Permanent professor of the Vocational Master’s Course in Creative Industry and Academic Master’s Course in Environmental Quality of FEEVALE. Permanent Professor of the Professional Master’s Course in Company and Business Law of UNISINOS. Undergraduate Law Professor for FEEVALE and UNISINOS. Professor of UNISINOS PRASJUR. Attorney. Member of ACI-Novio Hamburgo Legal Committee. Member of OAB Sapiranga (Brazilian Bar Association) Sub-section board ORCID: <https://orcid.org/0000-0001-5714-6906> / e-mail: [andrerrw@feevale.br](mailto:andrerrw@feevale.br)

anthropocentric basis and presents a series of mechanisms classified within the three levels of protection, namely, administrative, criminal and civil. With the advent of new demands, especially nanotechnology and its possible future repercussions, it is necessary to find alternatives to avoid technological development from being hampered and, at the same time, provide security. It is possible to conclude that the lack of a specific standard to protect the use of nanotechnology products cannot justify the use of new instruments capable of performing this complex task. Despite the need for a specific rule, the application of Environmental Law principles such as precaution, prevention, polluter pays and other Law sources represents a viable path.

**Keywords:** Environmental Law; nanotechnologies; new risks; principles.

*DIREITO AMBIENTAL E NANOTECNOLOGIAS: DESAFIOS  
AOS NOVOS RISCOS DA INOVAÇÃO*

*RESUMO*

*Propõe-se avaliar a complexidade que as novas tecnologias representam, sobretudo na utilização das nanotecnologias em inúmeros produtos que, a priori, foram desenvolvidos para proporcionar melhorias e não para causar danos futuros. Por meio de uma pesquisa descritiva e bibliográfica, objetiva-se conhecer os instrumentos tradicionais do Direito Ambiental e avaliar as possibilidades de novos caminhos com a finalidade de conciliar a necessária evolução tecnológica com a prudência em relação às possíveis resultantes imprevisíveis da utilização de elementos desenvolvidos na escala nano. A tutela pelo sistema do Direito Ambiental se desenvolveu sobre uma base antropocêntrica e apresenta uma série de mecanismos classificados dentro das três esferas de tutela: a administrativa, a penal e a civil. Com o advento de novas demandas, sobretudo a nanotecnologia e suas possíveis utilizações no futuro, alternativas precisam ser construídas para evitar o impedimento do desenvolvimento tecnológico e, ao mesmo tempo, proporcionar-lhe segurança. É possível concluir que a ausência de norma específica para tutelar a utilização de produtos com nanotecnologia não pode ser justificativa para frear o desenvolvimento de novos instrumentos capazes de realizar essa complexa tarefa. Não obstante a necessidade de uma regra específica, a aplicação de princípios de Direito Ambiental, como precaução, prevenção, poluidor-pagador e outras fontes do Direito, representam um caminho viável.*

**Palavras-chave:** *Direito Ambiental; nanotecnologias; novos riscos; princípios.*

## FOREWORD

The environmental theme is increasingly reverberating in society, since there are several demands arising from the complex relationship that has been established between society and the environment from which it withdraws its existence. From the more predictable reality and more predictable consequences of the past, we have moved to another level of uncertainty about the future consequences of decisions made today.

Law, an important social system, has as its main scope to lay down the rules that allow a minimally organized coexistence between so many possibilities and interests. These consist of rules of a more specific and objective nature, and also of principles of a more general and guiding nature throughout the system. Environmental Law, as a specialized field of the Law system, is precisely focused on this complex relationship between society and its needs and the environment and its limitations.

The traditional structures of Environmental Law are applicable to a wide range of factual possibilities, which seek to prevent, restrain, recompose, organize, indemnify, and punish human conduct in relation to the environment. Civil, criminal and administrative liability are the three major branches or paths that are thus structured to account for all the possibilities assumed in this complex relationship.

More and more possibilities of damage and unknown future consequences are adding up. Such novelties are produced in a context commonly called innovation, where there is a constant technological evolution that seeks to meet new demands and needs of society. However, innovations such as those developed at the nanoscopic scale open new frontiers and cast possible future consequences unknown to the present. This is the problem we face: Given the normative gap, based on what instruments could the Brazilian Environmental Law System pose responses to nanotechnological risks?

Nanotechnologies will therefore be the technology dealt with in this article; for a better understanding, it is necessary to explain its concept. Nanotechnologies can be understood primarily by the meaning of the word. The prefix “nano” comes from the Greek word “nanos”, which means dwarf, very small (MARANHÃO, 2008). Thus, the “area of knowledge that studies the fundamental principles of molecules and structures, where at least one of the dimensions is between about 1 and 100 nanometers, is called nanotechnology. A nanometer – represented by the abbreviation

“nm” – is the billionth part of a meter, i.e.  $10^{-9}$  of a meter. It can also be explained by dividing the number 1/1,000,000,000, or 0.000000001m; so, a nanometer is nine orders of magnitude smaller than a meter. Therefore, nanotechnologies are the application of these nanostructures in usable nanoscale devices (ALVES, 2004). Nanotechnologies have numerous practical applications that are already being marketed, and today some 8,794 nanotechnology products are estimated to exist worldwide (NPD, 2019).

Future outlooks are still under research, but they already corroborate the fascination with this revolutionary technology that is and will be applied in agriculture, the automotive industry, construction, cosmetics, electronics, the environment, food, and medicine, and many other sectors. But at the same time, nanotechnologies pose serious risks, and environmental effects related to nanoparticles can be due to their higher permeability, scattering power, persistence, absorption and potential to be transformed or interact with other contaminants that may have effects on aquatic and terrestrial ecosystems, when released into the environment. Therefore, on a nano scale, physicochemical characteristics tend to undergo modifications that can even generate toxic effects. At this point, the question arises of unwanted effects, many of which are still completely unknown. Thus, there is considerable scientific uncertainty about the risks of environmental damage from nanotechnologies, especially nanoparticles.

Different events must be expected, new types of effects, and new possibilities as their results. Because of this, an element developed with a positive objective may have environmentally negative consequences, if disposed of in an unpremeditated environment at the time of its creation, as made clear by toxicological studies. As a hypothesis of the problem, we understood that in order to deal with this reality, new instruments are needed in addition to all other situations protected by Environmental Law, so as to quickly adapt to this new context of risks and uncertainties. And there is also the need to take into account the required prudence regarding restrictions or estoppels that can become obstacles to science and development, something that cannot be done without taking the future into account.

Starting from the realization that we live in a complex situation where nanotechnologies are presented as a solution to many demands of current society, it is necessary for the Law system, especially Environmental Law, to determine new possibilities to overcome these protection difficulties we are faced with when we utilize only traditional Law structures.

## 1 ENVIRONMENTAL LAW AND ITS TRADITIONAL PROTECTION STRUCTURES

Law and its traditional structures are faced with a complex and dynamic situation requiring innovating contributions, also because the technology environment is characterized by rapid evolution. There is a clear interconnection between the risks of new technologies, rights in the broader sense, and the difficulties along the way to finding adequate solutions. Environmental Law and its specific aspects have a significant role in that, including because its origin is closely linked to Human Rights. Thus, on an international level, Environmental Law evolved toward heated discussions among countries aimed at protecting and improving the human environment, which was warned of the environmental degradation dangers brought about by the Industrial Revolution (NAZO; MUKAI, 2002). Countless changes have taken place, needs were met and created, and consumption became yet another social complexity element.

In this situation, the age when humanity finds themselves now is that called the *Anthropocene*, that is, the “Age of Man,” where the subject is at the center of the universe, so all that all thought and done is “by themselves and for themselves”. The human acts as “observer and manipulator in a large laboratory, having two elements for mutational and technological experiences: the Planet and people” (PELLIN; ENGELMANN, 2018, p. 132).

This situation had consequences. So much so that in Europe, since the early 1970s, industrialized countries started to acknowledge that they had pollution problems. Severe ecological accidents, with serious environmental, economic and human impacts, show the importance of the environment matter. These circumstances forced governments to take measures to control environmental damage, with the awareness that when “environmental problems taken on severe proportions, *a posteriori* state intervention to repair damages, compensate victims, or hold polluters responsible for acts of pollution is not the most appropriate and efficient way to deal with these problems” (ARAGÃO, 2011, p. 36). Aragão also highlights the economic aspect of international discussions on environmental protection:

[...] the disparity between high production costs of companies located in countries with strict environmental policies based on the polluter pays principle and the lower

production costs of their competitors based in countries which have not developed any environmental protection policy (or otherwise developed them on the basis of the opposite principle of public financing of environmental protection measures) generates inequalities in competitiveness among businesses, which simply stem from a lack of equivalence in the conditions of the markets they are inserted in (ARAGÃO, 2011, p. 37).

Development systems were only based on a classic view of development and economic growth founded on a kind of industrialism where the rule is the accumulation of capital and the production of wealth, and ignoring the preservation of natural resources, as they are limited and finite. Leite, in turn, agrees when he says that the environmental issue questions economic and technological processes that are subject to a market rationale, resulting in environmental degradation and impaired quality of life (LEITE; AYALA, 2011, p. 26-27).

In the 70s and 80s, this situation justified the adoption of environmental protection measures by means of international instruments. Thus, the Stockholm Declaration, adopted at the United Nations Conference on the Human Environment (1972) and the publication, at that time, of the “Club of Rome” report on the limits of growth, served as an ethical model for the international community, paving the way for national constitutions to posit an ecologically balanced environment as a fundamental human right (KRELL, 2013, p. 2079).

Brazil participated in these international law movements, and in 1981 – inspired by the 1972 Stockholm Convention – the National Environmental Policy Act (PNMA) was enacted (BRAZIL, 1981). Before PNMA, the Special Secretariat for the Environment (SEMA) was established in 1973, geared at the conservation of the environment and the rational use of natural resources (BRAZIL, 1973). SEMA was extinguished by Law 7,735/1989, which established the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) (BRAZIL, 1989).

PNMA aims at preserving, improving and restoring the quality of the environment for social and economic development purposes, as well as at protecting human dignity. In its Art. 2 paragraphs, PNMA lists the principles that must be followed to achieve the objectives provided for in its heading. Items I, IV and VI are especially related to the risks presented by nanotechnologies, given their potential for damage if they should violate these environmental protection principles (BRAZIL, 1981).

Likewise, Art. 4 of PNMA provides for the compatibility of economic

development with environmental preservation, a reality that is relevant for discussions about the development of nanotechnologies, where economic incentive is present, but there is an unconscious lack of concern with the environmental risks of new products using nanotechnologies, because they are already being marketed, while their possible negative effects are not yet fully known (BRAZIL, 1981).

Even with all its breadth, PNMA was not enough to provide the necessary protection for the environment, and thus the wealth of “land and groves” that surprised and enchanted Pero Vaz de Caminha in 1500 had its protection strongly acknowledged and given sufficient importance only in the Brazilian Constitution of 1988 (BENJAMIN, 2011, p. 77). This constitutional provision was a leap from “a traditional rule-of-law state to a state that is aware of the need to preserve the environment for future generations, as the right and duty of all” (LEITE; AYALA, 2011, p. 34).

Antunes points out that the Constitution brought important innovations to the environmental issue, given that in previous Constitutions, environmental resources were not dealt with in a systematic way, as the existence of a constitutional system of environmental protection could not be said to really exist. This resulted from the lack of concern for the conservation of natural resources or their rational use, and the environment at the time did not have a legal concept deserving autonomous protection (ANTUNES, 2016, p. 65).

Among the articles of the 1988 Federal Constitution, the article that refers especially to environmental issues is Art. 225, which states that “Everyone is entitled to an ecologically balanced environment, a common good for the use of the people and vital to a healthy quality of life; so, the Government and the collectivity have the duty of defending and preserving it for both the present and future generations” (BRAZIL, 1988). Therefore, the legal nature of an “ecologically balanced environment” is a common asset for the use of the people. Consequently, “the individual realization of this fundamental right is intrinsically linked to its social realization” (DERANI, 2008, p. 245). It is therefore one of the fundamental human rights (ANTUNES, 2016, p. 18).

It is important to keep in mind that international movements are concerned with controlling pollution and establishing environmental law as a fundamental human right. Thus, the norms ruling on first-generation environmental problems are at the anthropocentric level, placing the dignity of the human individual at the center of environmental morality (LEITE;

AYALA, 2011, p. 34). This search for dignity supported these movements in search of better living conditions in the face of pollution, lack of basic sanitation, and other essential conditions (ANTUNES, 2016, p. 17).

Moreover, the very inclusion of the environment in the constitution comes up in a strictly anthropocentric formula as a kind of broader component of human life and dignity, with ownership granted also to future generations. Benjamin points out that biocentric components are already scattered along the constitutional text (second generation) or in its interpretation. Especially when the normative bond is not connected to strictly utilitarian, but rather protectionist interests. He also mentions that “the constitutional legislator did not hesitate in acknowledging its intrinsic value, establishing duties to be demanded from human subjects in favor of the biotic and abiotic elements that make up the foundations of life.” But, the author points out that in one way or another, “the paradigm of man as *prius* is irreversibly cracked” (BENJAMIN, 2011, p. 130-131).

From Antunes’ perspective, the center of gravity of Environmental Law is the “Human Being.” Thus, despite the attempt to break with anthropocentrism when Environmental Law aims at protecting animal and plant life, the “Human Being” as center of gravity for new legal subjects (animals and plants) does not change. Positive Law is a human construct to serve human purposes, so even though Law is evolving in respect of other life forms, that is not enough to shift the axis around which the legal order gravitates – the Human Being (ANTUNES, 2016, p. 19).

Leite, adopting an intermediate position, notes that first-generation environmental problems are not watertight. This means that, although they are assumptions for anthropically-centered (first generation) control norms, they are not restricted to a certain time period. This means that the environmental problems and the interpretation of these problems, whether they are first or second generation, are not mutually exclusive, but coexist today, requiring a legal system including compatibility mechanisms (LEITE; AYALA, 2011, p. 36). Accordingly, Ayala refers to the risks of the second generation, which require protection for the present and future society, but also for the desired future:

Second generation risks require responses on a reinforced protection plan for present and future generations, but also for differentiated existential projects integrated into a new constitutional culture that gains importance in this morally open and plural scenario capable of integrating moral communities and meeting demands for protection hitherto unknown or only timidly considered before, at least by the Brazilian legal community (AYALA, 2013, p. 244).

In addition to the protection provided for in Art. 225, CF/88 (1988 Federal Constitution) includes harmonization between the different provisions aimed at the protection of the environment; it also systematized said protection among the other federated entities (Union, States, Municipalities and the Federal District) in its Articles 23 et seq. (BRAZIL, 1988). Given the common jurisdiction provided for in said Article, Complementary Law 140/2011 laid down cooperation between the Union, the States, the Federal District and the Municipalities in administrative actions arising from the exercise of their common powers regarding the protection of remarkable natural landscapes, protection of the environment, fight against pollution in all its forms, and the preservation of forests, fauna and flora (BRAZIL, 1981). With the enactment of CF/88, Art. 225 allowed the drafting of specific laws to include provisions laid down in the sections of that Article (BRAZIL, 1988).

It appears that the Brazilian Environmental Law System aims at preventing the occurrence of environmental damage and recovering from negative consequences caused by these damaging events. Thus “environmental damage should be understood as any intolerable damage directly caused by any human action (whether in tort or not) to the environment as a macro-asset of interest of the community, in a totalizing conception and, indirectly, to third parties” (MILK; AYALA, 2011, p. 104).

Environmental licensing is an important environmental control instrument for activities that, due to their characteristics and dimensions, are potentially capable of causing environmental degradation (ANTUNES, 2016, p. 205). Environmental licensing procedures apply to Complementary Law 140 (BRAZIL, 2011), CONAMA Resolution 237/1997 (BRAZIL, 1997) and other CONAMA, as well as state and municipal resolutions, according to the powers laid down in CF/88 and Complementary Law 140/2010 (BRAZIL, 1988; 2010).

Given the importance of this instrument, when violating the conditions of environmental licensing (BRAZIL, 1997) or committing acts or activities considered as harmful to the environment, offenders, whether individuals or legal entities, are subject to criminal and administrative sanctions, and the obligation to repair the damage caused on a civil level, according to Art. 14, § 1 of PNMA (BRAZIL, 1981), which was confirmed in the constitution by § 3 of Art. 225 (BRAZIL, 1988). That is, CF/88 determines triple liability in cases of environmental violations/damages. In the Environmental Crimes Law, sanctions range from penalties to

incarceration and restrictions on rights (BRAZIL, 1998). Environmental administrative violations, according to Art. 3 of Decree Law 6,514/2008 are also punished with various sanctions (BRAZIL, 2008). As a third part of this set, environmental liability is applied as an instrument of reparation, without the need to prove guilt to have the duty to indemnify established, i.e. it follows the theory of strict liability in tort (MACHADO, 2014, p. 403).

As it turns out, despite a complex Environmental Law System, the environmental risks of new technologies, including nanotechnologies, are not part of the legal facts. And neither are the activities that employ nanotechnology required to have environmental licensing or to meet special requirements for the control of environmental damage risks. This proves to be an important problem to overcome in order to have greater security, predictability and control over the use of products containing that technology. It is appropriate to highlight some regulatory advances already under development; however, we still do not have a specific standard for nanotechnology that addresses the risk outlook.

We can highlight an initiative launched in 2013, called the Brazilian Nanotechnology Initiative (IBN), which aims at “integrating governmental actions to promote increased competitiveness of Brazilian industry”; it is linked to the Ministry of Science, Technology, Innovation and Communications. The initiative is connected to “research and development activities in the National System of Nanotechnology Laboratories (SisNANO)”; it aims at improving “infrastructures and opening of laboratories for users in the academic and business sectors, thus promoting interaction and knowledge transfer between the academia and businesses”. The implementation strategies are: i) support to SisNANO; ii) promotion of the RD&I Thematic Networks system; iii) stimulating applied research in nanotechnology; iv) proposition, follow-up and assessment of a nanosefety pilot model; v) incentive to internationalization actions of public and private nanotechnology players; vi) fostering of models and programs that promote interaction between the productive sector and CTIs in the field of nanotechnology (BRAZIL, 2019).

In addition to the participation of Brazil in NanoReg, Ordinances and Normative Instructions on the subject were issued. Ordinance 245/2012 establishes SisNANO as one of the elements of the National Nanotechnology Program, within the scope of the National Science, Technology and Innovation Strategy and associated with Brazil Maior Plan

(BRAZIL, 2012a). Normative Instruction 2/2012, which establishes the Technical Regulation for the integration of the Strategic Laboratories and SisNANO Associated Laboratories (BRAZIL, 2012b). Ordinance 03/2015 establishes the Nanotechnology Technical Assistance Committee (CAT NANOTECNOLOGIA) with the objective of providing technical support to the Department of Technological Development and Innovation staff in the drafting of an expert opinion on the performance of technical and administrative activities and proposals for improvement of SIBRATEC Networks of Innovation Centers in Nanomaterials, Nanocomposites, Nanodevices and Nanosensors, and of the Modernit-SisNANO initiative (BRAZIL, 2015). Ordinance 2,228/2017 (BRAZIL, 2017) extends the work of CAT Nanotechnology for 24 (twenty-four) months from the expiration of SETEC Ordinance 3/2015 (BRAZIL, 2015).

Also noteworthy is the Protocol for Establishment of the Brazilian-Argentine Center for Nanotechnology (CBAN), between the Governments of Brazil and the Republic of Argentina, signed on November 30, 2005, together with Ordinance 259/2016, which provides for the National Coordination of the Brazilian Section of CBAN (BRAZIL, 2016). In the same vein, The Brazil-China Center for Nanotechnology Research and Innovation was created by Ordinance 117/2012, and aims to: i) coordinate activities involving a Brazil-China cooperation in nanotechnology areas; ii) promote the scientific and technological advance of research and applications of nanostructured materials; consolidate and extend nanotechnology research, expanding scientific capacity to explore the benefits of developments associated with technological implications; iii) develop expansion programs for companies located in Brazil for possible developments in the field of nanomaterials (BRAZIL, 2019).

There are legislative initiatives underway. There are two bills pending, filed with the Federal Chamber of Deputies: One of them is Bill 5,133/2013 that aims to regulate the labeling of nanotechnology products and products that make use of nanotechnology (BRAZIL, 2013a). The other is Bill 6,741/2013, which provides for the National Nanotechnology Policy, research, production, waste disposal, and the use of nanotechnology in Brazil, among other measures (BRAZIL, 2013b).

Together with the Brazilian Association of Technical Standards (ABNT) there is a Special Study Committee on Nanotechnology (ABNT/CEE-089) whose scope of action is: i) standardization in the field of nanotechnology, including: understanding and controlling of materials and processes at the

nanometric scale, typically, but not exclusively, below 100 nanometers, in one or more aspects where the emergence of size-dependent phenomena usually leads to new applications; using the properties of nanoscale materials that differ from the properties of individual atoms, molecules and bulk matter to create better materials, devices and systems that exploit these new properties. ii) as regards terminology and nomenclature, metrology and instrumentation, including specifications for reference materials, test methods, modeling and simulations, and science-based health, safety and environmental practices (ABNT, 2019).

As can be seen from the description above, the Brazilian Environmental Law System has a gap, since nanotechnological facts are not included in any standard, especially regarding the control of environmental risks and damages. Therefore, these risks present themselves as a real challenge for Law, since it cannot match the speed of technological development.

## **2 SUPERVISION OF NANOTECHNOLOGIES BY THE ENVIRONMENTAL LAW SYSTEM: DIFFICULTIES AND POSSIBILITIES**

Due to the legal gap displayed by the system, a deeper look on the difficulties faced by the Brazilian Environmental Law System to incorporate nanotechnological risks is required. Given the lack of a specific legal norm on nanotechnologies, we will try to show a possible path of empirical applicability using the principles of the Brazilian Environmental Law System.

Mota's approach to the subject reveals an important retrospective for understanding the current scenario in relation to liability in the face of technological risks. He explains that during the nineteenth century, the moral obligation of each citizen to themselves and others was more important than legal obligations. Citizens were responsible with and prudent about their freedom, which meant taking steps to protect themselves and their family. Thus, the victims of misfortune were always regarded as the sole authors of their fate, and should act with prudence. In the twentieth century, with the social security system, "legal obligations tended to become more important than moral obligations." New social rights emerged from the feeling that every citizen had a right to be compensated for the damage resulting from events in his or her life. This new approach to thinking has largely resulted in a Utopian feeling about the ability of science and

technology to predict and control all risks. This has allowed for social protection systems to be put together, which are based on the assumption that all risks are measurable. “In this way, a sense of social solidarity based on measurable risks replaced the individual’s sense of moral obligation” (MOTA, 2008, p. 180-211).

In this way, the system was structured under the sign of an economic equality where everyone had the right to be protected, a generalized measurement of risks, the consequent possibility of full compensation of damages and the unrestricted attribution of causality. Today, however, this institutional structure has become inadequate in view of the new risks of complex industrial societies, which, especially when related to the environment, are impossible for science to measure. “The notion of uncertainty has replaced the notion of probability, which means an admission of society’s inability to predict irreversible catastrophic losses” (MOTA, 2008, p. 180-211). Although modern society is committed to the continuous acquisition of knowledge, a paradoxical situation emerges: “New and greater knowledge often reveal new and greater lack of knowledge” (HOFFMANN-RIEM, 2015, p. 17).

The risks associated with technology or processes permeated by high degrees of scientific uncertainty become part of national and international debates and discussions regarding their ability to put the existence of all life forms at risk (AYALA, 2013, p. 244). However, there is the awareness that the so-called risks of ignorance or uncertainty cannot be avoided. “The expected benefit is not yet certain; similarly, it is not known whether the risks to the common good or the pursuit of individual interests will be surpassed. Law has to take such uncertainty into account” (HOFFMANN-RIEM, 2015, p. 27).

The management of ecological risks begins with being a scientific and technical problem, starting with the identification of the situation and developed through the creation of strategies or alternatives of action available, “when”, “how” and “to what extent” the effects presumed risks obtain. Therefore, it is necessary to incorporate uncertainty into Law, implying in its reinterpretation and a search for more flexible ways to express, from the outset, the general principles and the use of general clauses (GARCIA, 2015, p. 421).

It is clear that legal science is reluctant to explore the role of Law in the prevention, control and monitoring of innovations; it is content to point out the conditions that legitimize a judicial decision; however, in the face

of nanotechnology this is not enough (HOFFMANN-RIEM, 2015, p. 12). Therefore, this view of Law in the face of the uncertainties of technological risks, especially nanotechnology, requires a closer consideration of the new configuration of environmental problems (AYALA, 2013, p. 244). Thus, while Law tends to be conservative, on the other hand, this conservatism is challenged by the accelerated speed of knowledge diffusion promoted by technologies (SILVA, 2017, p. 160).

One issue deserves further consideration: the understanding one must have about the new configuration of environmental problems (AYALA, 2013, p. 244). In this sense, the term “disruption” mentioned by Harvard University professor Clayton Christensen means breaking or overcoming something that already exists, giving rise to a new, more efficient and easily accessible solution, either economically or from the operational point of view (SILVA, 2017, p. 159). With a critical view, Garcia talks about the position of Law in the face of technological challenges:

The alliance between ecology as a science, in its current evolving stage, and the reality of community, particularly technical and industrial action, has given rise to *know-how*, actions directed and appropriate to preserve the quality of the natural heritage and life cycles on earth. [...] If the “being” of Law, as a normative system, is in the law – an ontological problem – and if it, by its general and abstract structure, proves inadequate to face the situation of ignorance and scientific uncertainty, then the ontological problem of Law renews itself in a relevant way. Keeping up the technical and legal discourse based on the general and abstract norm, and its interpretation and application to actual cases, and teaching it uncritically at universities reminds us of the story of the ship that was sinking while the captain and his crew were taking navigation lessons (GARCIA, 2015, p. 66; 419)

Innovation processes show that the assumptions of legal instruments are no longer based on traditional law (HOFFMANN-RIEM, 2015, p. 25). This is largely because legal rules do not contain alternatives for action. Garcia argues that ecological risk management cannot be part of the system of legal norms because the internal coherence of the system does not produce a predictable framework for orderly action for its recipients, as required by ecological risk management. “The norm can give decision-making power to experts. But it cannot presuppose the result of the exercise of that power at the time it is exercised and with the knowledge available at that time” (GARCIA, 2015, p. 428).

As an example for understanding the difference between the legal system and technical rules in the face of new technologies, Garcia mentions that a rule is questioned when scientific development has surpassed it or

a contrast between the experience derived from its application and the empirical knowledge of parallel situations is made evident. Therefore, a revision of the rule is a consequence of this challenge and the evidence produced as a result of that challenge. It follows that technical rules deal with scientific uncertainty as a natural phenomenon, because this change does not involve a rupture, does not call for a pathological movement, as it happens in legal norms (GARCIA, 2015, p. 399).

Therefore, the Brazilian Environmental Law system must be ready to adapt itself (WEYERMÜLLER, 2014) to the practical needs imposed by nanotechnologies, to aim for the best possibilities available today to control the risks of serious environmental damage. The extent to which Law can include this potential is uncertain and will always be under discussion regarding the methods of interpretation of Law and the correct application of laws, since technologies and knowledge about them are always changing (HOFFMANN-RIEM, 2015, p. 27).

In short, within the framework of the normative legal system, it is impossible to conclude what is the meaning, relevance and legal effects of knowledge transformations and technical-scientific developments. Considered as a normative system, Law allows the community to rely on predictability, as a result of its completeness, coherence and non-contradictory nature, but it cannot, without losing its characteristics, incorporate risk management. Thus, the notion that absorbing risk management into the legal system means establishing not only knowledge gaps in the legal system, but also ambiguities and uncertainties that would replace its completeness, coherence and non-contradiction. Therefore, the loss of the autonomy of Law and the sense of order of validity would be the consequence of that (GARCIA, 2015, p. 428).

Therefore, it is verified that the nanotechnological facts are not incorporated in any norm belonging to the Brazilian Environmental Law System. Therefore, what are the answers to Law in case of environmental damage from nanotechnology? How to deal with this uncertainty when reality should impose the need to investigate damages, responsibilities and reparations?

This uncertainty situation is based on the fact that nanotechnological damage to the environment is still unknown. In addition, we find that there is a range of products that are already on the market (as mentioned in the Introduction) that include nanotechnologies. So, the unanswered question still remains: what would the Brazilian Environmental Law System standing

in case of damage caused by nanotechnologies to the environment?

It is well-known that it is the Law system that defines “the problems that the Law system can observe and decide upon. Problems that are not part of the Law system are not problems, they do not exist” (ROCHA, 2017, p. 180). But are nanotechnological risk problems not real problems that require a response from the Brazilian Environmental Law System?

Furthermore, it should be noted that in the case of nanotechnologies, the risks presented are closely related to the risks associated with other chemicals and manufacturing methods. The risks differ according to their specifics. For example, nano-silver has different properties from standard silver. Thus, a law applicable to nanotechnology must acknowledge that size can affect properties. Therefore, more diagnoses are required on how products whose risks are still being investigated are managed (MOSES, 2013).

It can be said that a law applicable to nanotechnology needs to be constantly updated or adapted (WEYERMÜLLER, 2014, p. 402), given technological discoveries of both new products and greater or lesser risks than previously known ones. Moses refers to the critique of the progress mismatch in the relationship between Law and technology, where “technology changes like a hare and the regulatory framework, like a tortoise.” Thus, a regulation targeting nanotechnology will almost inevitably become obsolete (MOSES, 2013).

Technological innovation makes production processes more complex and speeds up the pace of their changes (FRYDMAN, 2016, p. 32-35). These changes belong and are linked to the rationales of each social subsystem, and the more inaccurate the system is built, the stronger the normativity arising from an analysis of the system’s relationship to a given empirical reality. This normativity is even more pronounced in systems associated with the laws of nature. Phenomena such as gravity, thermodynamics, photosynthesis, and others, create knowledge systems on how nature operates in various areas. Such norms are invisible and unknown before they are explained by science (HYDÉN, 2015, p. 86).

In the early stages, however, little is known about the new technology, its inherent risks and the damage it can cause. Thus, the “uncertainty” paradox comes up. Also, even in the face of a lack of knowledge about the risks of each nanotechnology product, the government cannot take full responsibility for its safety. For that reason, private players – producers, distributors and industrial users – are being burdened with responsibilities.

That is why these players “along the value chain” must be linked through common communication as well as information sharing in order to take greater responsibility for risk control. In this scenario, it is private players who should help identify potential risks in advance by means of innovative solutions. This leads to a process of knowledge generation among stakeholders under the stimulating threat that a ban on the use of chemicals is possible, if risk control is not achieved (HOFFMANN-RIEM, 2015, p. 16).

Engelmann suggests that civil liability anchored in “Damage Law – which projects into the future – and the uncertainties of damage relating to actual effects that nanotechnology can actually produce” is being advocated. The “Damage Law” expression is useful because of the statement of precaution as a connecting bridge in a probable way of stabilizing cognitive expectations by means of the Law system (ENGELMANN, 2018, p. 245). “Damage Law” would thus change the interpreter’s perspective by shifting the scope of investigation from the harm-causing agent’s conduct to the harm itself (*in dubio pro victim*) (FROTA, 2008, p. 158).

It must be admitted that where there is technology there is risk. So, from the perspective of civil liability, a new outlook on liability in relation to Damage Law is appropriate with the relaxation of the causal link. This is especially due to the serious and irreversible nature of the potential damage that nanotechnologies may cause (ENGELMANN; PORTO BORJES; GOMES, 2014).

Frydman agrees that the private sector needs to take care of how its products and services are being manufactured and delivered. It must provide acceptable environmental and working conditions, without violating or abetting violations of people’s fundamental rights and with regard to their activities (FRYDMAN, 2016, p. 63). This responsibility is related to the emergence of governance through assessment: technological assessments to predict social developments and negative impacts of new technologies. These assessments must be carried out *ex ante*, before the decision to adopt a new technology, and that is an important step. However, it is clear that there has been little empirical investigation on the actual impacts of new technologies, as several products about which little is known, are already being marketed (WIENER, 2004, p. 483-500). Engelmann also adds that “we must think of an ethics of responsibility for the future that aims at a “new” responsibility, not only directed to past facts, but especially to future damages, a requirement for prevention and precaution” (ENGELMANN;

PORTO BORJES; GOMES, 2014).

Concerning the regulatory situation, it is important to consider the impact of regulation on technological innovation, so we need to look beyond the regulation of technology. Problems are encountered in all historical, doctrinal, and technological aspects, as technology changes. Thus, one wonders about the effectiveness of prevention. Still, one can consider how lawmakers should approach a new technology that changes rapidly in the face of the uncertainty about both known and unknown risks. It is necessary to consider institutional design matters, in particular, how existing institutions – such as agencies of specialized institutions – can help policy makers and regulators manage technology change in general or in specific contexts. All of these issues are tied to the idea of technological change. Thus, the study of the impact of a change in legal and regulatory design presents important problems (MOSES, 2013).

In the field of nanotechnology, it is not surprising to find specific technology laws being proposed and enacted. Several cities and states in the United States are adopting nanotechnology as a regulatory category. In Europe, cosmetics containing nanomaterials are already subject to specific provisions (EUR-LEX.EUROPA. REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products), including safety and labeling requirements (MOSES, 2013). Diloreto, founder of Nanoreg, said that “the slow wheels of the federal government have evolved to be more reactive than proactive [sic], which is why important issues often need to reach a critical stage before any action is taken” (DILORETO, 2010).

Along the same lines, Brownsword and Yeung understand that the “regulatory connection challenge” is a novelty dilemma. They talk about the mismatch between current laws and regulatory approaches that are designed for the technological landscape of the past, requiring a constant “reconnection”. This becomes clear when “new” technologies (such as nanotechnology) enter a “regulatory void” and when older technologies – such as *in vitro* fertilization – become previous regulatory regimes. The authors’ concept of regulatory disconnection is useful in that it allows observing this disconnection, even when there is no “legal” disconnection (BROWNSWORD; YEUNG, 2008).

While it is a duty to try to develop tried and trusted action responses to challenges, “simply transplanting a particular regulatory response from one technology to another is not always appropriate” (BROWNSWORD;

YEUNG, 2008). This is because spaces are dynamic. Even if there is public concern about a new technology, with increasing acceptance, a counter-judgment can shift from safety, precaution and legitimacy issues to compliance and effectiveness issues (MOSES, 2013). Therefore, a new technology raises the question: Do we need to develop specific regulation for nanotechnology? Does this regulation or need fit into a preexisting legal and regulatory scenario?

This is explained in the sense that the challenge of regulatory connection/progress is continuous. Good mechanisms of continuous and dynamic adaptation are essential. "Technology will not always be new, but it will always change, posing new legal and regulatory problems" (MOSES, 2013). Well, it is clear that legal evolutions went from stages of formal/autonomous law to substantive/material law and then to something Nonet and Selznick called "responsive law" and Teubner "reflexive law", that is, ones with greater flexibility and openness to face the challenges of contemporary society (HYDÉN, 2015, p. 80). Ecology occupies a prominent place, as it extends the notion of a legal system. In addition to norms, it is also made up of rules and principles. Law, then, can no longer avoid a contact – which has always existed as part of the complexity of the matter – with other systems, notably the political and economic system, which also manifest other kinds of problems, especially by virtue of their own and discrete rationales (ROCHA, 2017, p. 175).

Therefore, in this scenario, the chaos and crisis faced by human beings, the instrumental technique combined with capital, has proven to be the perfect marriage. Law has not been able to address this, as it is trapped in an institutional gridlock because of the contrast between the high globalization level of social subsystems and the inadequacy of the globalization of politics. And to manage this unbalanced advance, the precautionary principle presents itself as a possibility of tracing the limits of action spaces, but it must suffer irritations to become an active principle (PELLIN; ENGELMANN, 2018, p. 135).

Pontes de Miranda (apud ENGELMANN, 2012, p. 319-344) helps here by describing the legal world on three Planes: existence, validity and effectiveness. The entry of a social fact into the legal world occurs through its entry into the Plane of Existence, broken down into: a) an abstract moment, which takes place by the description of a factual hypothesis by the legal norm; b) a moment of actualization, the incidence of a normative hypothesis on the fact or set of facts of life; c) the moment when the legal

fact is born, which is the subordination of the fact or set of facts to the preliminary designs abstractly inserted beforehand within the legal norm.

With this interpretation, Engelmann proposes a revision of Pontes de Miranda's theory of legal fact to answer the nanotechnology questions. He clarifies that he is not proposing to replace the theory, but rather a creative realignment to give more flexibility and openness to Pontes' theory by enhancing its power to produce legal effects in the face of nanotechnological challenges. In this sense, the author argues that when the Pontes and Kelsen Theory came about, the benchmark was the application of natural sciences, which did not comply with the specificities of law and the humanities. Today, the scenario is also challenging, since hard sciences are in the forefront of the formulation of scientific assumptions (ENGELMANN, 2011).

Thus, a review of the legal fact theory does not mean these are necessarily provided for in law. But they can be so in other Law sources: in the law theory of costumes, negotiations (mediation and arbitration), International Treaties, and general international law principles, among others. Thus, it is necessary to "overcome the Positivist paradigm – of a notably legalistic origin – which still dominates Law and supports the Pontes' Theory of Legal Fact" (ENGELMANN, 2011).

Therefore, an approach to the Brazilian Environmental Law System based on these principles seems to be adequate to the challenges posed by nanotechnological risks. Even the realization of environmental law by means of legal principles has two effects: shortening the distance between Law and reality, and producing changes in the understanding of the action of jurists and legal technicians. The new Law paradigm raised by the question as a legal question states that the jurist's role is not so much to shorten the distance between the norm and the facts, but to lead the creative rational process of finding the just solution, inscribed in the principle or principles the facts call for, all of which is understood in the complex framework of conflicting interests where rights and duties are embedded (GARCIA, 2015, p. 480).

Even though the Environmental Law System does not have internal codes capable of identifying and rationalizing nanotechnological risks, there are Principle commands within the system that can serve as tools for managing nanotechnological risks. To this end, the Principle of Prevention/Precaution, Polluter Pays and Environmental Adaptation are called into play to provide responses for the Law System to control nanotechnological

risks. In addition, support by other sources of Law, such as law theory, customs, negotiations (mediation and arbitration), international treaties, and general international law principles, among others, should serve to impart greater flexibility to the Legal System, allowing for a dynamic monitoring of the evolution and transformation of technology. Therefore, we propose that one should not fully deviate from legal positivism, but to undertake a creative realignment of the Legal System to give it more flexibility and openness to technological novelties, and thus enhance the production of legal effects on the challenges of nanotechnological risks.

## CONCLUSION

The possibilities posed by nanotechnologies cannot be ignored, as they point to a new technological paradigm for the future. Humanity has already experienced several technological revolutions, but nanotechnologies mean crossing into a new frontier without possibility of return.

Not only are nanotechnologies a new stage in human evolution, they are also a clear novelty in terms of future risks. Many other innovations cannot yet be considered safe as in the case of GMOs for example. However, the breadth of nanotechnology applications surpasses any other in terms of number and multiplicity of applications. That is precisely why the issue is urgent and of great importance to the system of Environmental Law.

The absence of a legal norm, more precisely a rule, indicates that, even under the outlook we here called traditional Law, there is adequate response to the future possibilities of damage that may arise from the widespread use of this technology. Traditional protection instruments also find it difficult to properly reconcile the needs of society with the environmental burden they represent. Thus, even if there were already an objective response from Environmental Law by means of a Law, for example, this would probably be provide security, either.

From this perspective, it is necessary to adapt legal instruments that can cope with such complexity, at least by greatly reducing the chances of future damage. Within the set of elements available to Law, we find that the principles are possibly the most appropriate and structured answer that can be used in supervising nanotechnologies. Damage that may arise from possible as-yet unknown effects of nanoscale products cannot be controlled by the traditional and positivist notion of Civil Law, for example. Thus, analyzing the broad context of nanotechnology risks is

the first point to consider. This complexity cannot simply be countered by a restrictive rule. An Environmental Law adapted to these new demands must effectively consider the application of the founding principles of the environmental legal order, with special emphasis on precaution. Not just a formal precaution but, above all, a truly anticipatory stance based on the premise of scientific uncertainty.

In the end, we should remind ourselves of the problem detailed at the beginning of this paper: Given the normative gap, based on what instruments could the Brazilian Environmental Law System pose responses to nanotechnological risks?

The solution hypothesis we outlined at first came from the understanding that, in order to cope with the reality of nanotechnology, we need new creative tools capable of quickly adapting to novelties and a situation of risks and uncertainties. For these risks, the application of the Prevention/Precaution and Pollution Pays Principles is required, which are based on an Environmental Adaptation outlook, as well as other sources of Law (law theory, customs, International Treaties, general principles of international law) aiming at answering nanotechnological risks. When adapted to each reality of nanotechnological risks, these instruments provide an adaptive flexibility to the Legal System, allowing it to follow the evolutionary dynamics of nanotechnologies. Therefore, it can be concluded that the hypothesis of the solution envisaged at first is confirmed.

It is necessary to reformulate the role of environmental law; also, a wide application of flexible instruments (principles, law theory, treaties) can be an important step forward in tackling the inexorable advance of nanotechnology. Achieving an optimal level of reconciliation between defending the right to a safer future in environmental terms and the benefits of technology seems to be the biggest challenge facing environmental law today.

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Juliane Altmann Berwig & Wilson Engelmann & André Rafael Weyermuller

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