

Review Article

The Nanotechnological Revolution and the Complexity of Waste: The Possibility of Using the OECD Protocol as an Alternative to *Nanowaste* Risk Management

Wilson Engelmann^{*}, Daniele Weber S Leal and Raquel Von Hohendorff

Department of Public Law, University of the Sinos River Valley, UNISINOS/RS, São Leopoldo, Brazil

*Corresponding author: Wilson Engelmann, Department of Public Law, University of the Sinos River Valley, UNISINOS/RS, Brazil, Tel: 55 51 3591-1122; E-mail: wengelmann@unisinos.br

Received date: June 17, 2017; Accepted date: June 25, 2017; Published date: July 13, 2017

Copyright: © 2017 Engelman W, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Abstract

Nanotechnologies are in the process of increasing their development in research and in industries. Thus, there is also an increase in the production of waste in nanoscale. There is an alert point: as the challenges brought by nanotechnologies are not yet completely known, given the different physicochemical characteristics of the nano scale, the same will happen in the production of nano waste. Can garbage containing nano particles be added to waste with larger particles? What are the risks and how to establish the regulation? The paper intends to show that the documents already produced by the OECD-The Organization for Economic Co-operation and Development (OECD) since the year 2006, in the series of studies entitled "Series on the Safety of Manufactured Nanomaterials", focusing on the safety assessment of nanomaterials, could be an alternative for the lack of regulation. In fact, 80 specific documents have already been published in this regard, and one study, specifically, entitled "Nanomaterials in Waste Streams: Current Knowledge on Risks and Impacts", handling waste. These documents may serve to develop a non-legislative regulatory framework through Dialogue between the sources of Law, anchored in legal pluralism (Gunther Teubner) in order to organize flexible legal rules, but in conditions of disciplining the safe treatment of nano waste.

Keywords: Nanotechnology; Waste's final disposal; Nanowaste; Regulation; OECD; Legal pluralism

Introduction

The world of the nano scale has always existed, that means, it integrates nature. However, only by the middle to the end of the 22nd century the human being was able to access this order of greatness, due to the development of the nanoscopes, visualizing the billionth part of a meter. Probably, the "admiration of creativity" [1] led the scientists to develop technical conditions to research in this scale, unravelling a "new world" with possibilities and risks still greatly unknown. Despite this fact, the industrial use of the nanometer scale is advancing rapidly, increasing the nanoscale developed products, without having a scientific certainty about nanoparticle safety and without the legal area having built a specific regulatory framework.

It is observed in the daily routine of human life the increasing consumption of innumerable new products with nanotechnology in the most diverse areas. Examples include sunscreens, footwear, cell phones, fabrics, cosmetics, automobiles, human medicines, agricultural products, veterinary drugs, water treatment products, building materials, plastics and polymers, products for Aerospace industries, naval and automotive, iron and steel, among others. This role is unfinished, since nanotechnologies are in the process of development. Thus, they cease to be only futuristic promises and are incorporated into the daily routine of society at the beginning of the 21st century, thus requiring attention of the Law.

However, while observing such a promise of evolution beneficial to mankind, nanotechnologies are accompanied by scientific

uncertainties as to their effects and (possible?) future harm to the environment and human life. In the current state of the art, it is uncertain what damage nanomaterials can entail to the ecosystem. For this reason, several researches are being conducted in order to verify which are the (possible or not) impacts of nanos in human life and environment.

Consequently, the consumption of those creations at nano scale have been increasing, and as a result of this use of nanoproducts there is greater disposal of nanomaterials to the environment. In this context, the final destination of nanomaterials raises a huge uncertainty and calls for a necessary implementation of rules, given the current lack of knowledge, especially regarding their deposit and disposal, considering the possibility of damages. It is raised the incognito of the *Nanowaste*. How should the final nanotechnological residue be disposal? Is there a difference in disposal on a macro scale?

Furthermore, considering the inexistence of specific regulation for nanotechnologies, also about *nanowaste*, it is necessary to seek for an alternative to implement instruments with potential regulation (they could be elaborated outside of the juridical context). Many researches about nanotechnologies are in development worldwide, in places such as United States, Europe in general, Asia and even in Latin America. In international organizations such as ISO, NIOSH, FDA, NANOREG (Europe), British Standars Institution (BSI), the European Commission and European Parliament, and finally the OECD (which is focused on this study), a series of studies, protocols and instruments with regulatory potential, could act as regulatory frameworks, with the objective of remedy the legislative gap and state omission.

The bibliographical research will be used to review the publications in books, scientific articles and official websites, aligned with the

Page 2 of 17

systemic-constructivist methodology, using bases that do not compound the traditional Law, allowing the connection and application of other institutes which interconnect other areas of science. To do so, it is necessary to start with a previous knowledge about nanotechnologies and their debate at international level, as well as the issue of risk; in addition, the life cycle of the nanomaterials and necessary attention to *nanowaste* will be analyzed; and finally, know the specific study on *nanowaste* of the OECD, and how it might be feasible to use such instrument with regulatory potential, performing risk management.

Therefore, the problem that is intended to be faced in this article can be thus circumscribed: since there is no specific regulation on *nanowaste*, in what way would it be possible to use the OECD protocol? What theories make feasible the validation and adoption of instruments with regulatory potential that deal with nanotechnological wastes? Based on caution, an appropriate response would be to use some regulatory instrument, even if it is unknown to the Law, respecting the precaution required in this context, seeking to avoid possible damages to the environment and to future generations, providing adequate responses to the presented complexity.

The provisional hypothesis that was structured from the bibliographical review is based on the understanding of the nanotechnological complexity and its life cycle, together with the understanding of the potential risk presented (seeking to conduct its management), possible and necessary adoption of an instrument with regulatory potential, in the case of the specific protocol of *nanowaste* of the OECD, made possible through the "dialogue" of appropriate theories, thus providing a suitable regulation for nanotechnologies, while respecting the fundamental rights and the precaution required in this context.

Understanding the nanotechnologies: what is it and how is its development inserted in society?

The discussion about nanotechnologies has been developing more steadily in the last decade. Nanoscale production gained momentum at the beginning of the 21st century, entering the context of innovation, presenting a range of new products, which bring numerous promises of advances in the most diverse areas of society. Thus, in the panorama of innovations are the nanotechnologies, which would be the set of actions of research, development and novelty, obtained due to the special properties of matter organized from structures of nanometric dimensions [2].

This scale of technology is equal one billionth of a meter, about ten times the size of an individual atom. Its conceptualization has imprecise terminology, lacking internationally standardized definitions [3].

Nano is the name that comes from Greek, it means dwarf, a term fused with the word technology that emerged in 1974, resulting in the famous term nanotechnology. It is a transdisciplinary science difficult to explain because it is part of the complexity sciences, i.e., it is not a pure science like physics, chemistry and mathematics, but rather a heterogeneous science, and in its core there is the combination of many disciplines. Therefore, there can be in a single product made with this science, traces of engineering using chemistry, physics, biology, mathematics, among other new sciences [4]. From this characterization, one can gauge all the complexity involved in this technology, and because of this there is also the inconsistency to conceptualize and define it (Figure 1). It was the American physicist Richard Feynman [5] considered the prophet of nanotechnology, whose prophecy was announced in his lecture There is plenty of room at the bottom, held at the annual meeting of the American Society of Physics at the California Institute of Technology in December 1959. At that occasion, the scientist approached practically all the important concepts of nanotechnology, although without naming it in that form. One of the ideas defended was that it would be possible to condense, at the head of a pin, all 24 volumes of the Britannica Encyclopedia, glimpsing the future discoveries in the manufacture of systems at atomic and molecular scale [6].

Until the prophecy was later confirmed: Feynman's predictions, however premature and audacious, came to be confirmed two decades later. The scientist Eric Drexler was responsible for popularizing the term nanotechnology in the 1980s, when referring to the construction of machines so small that they would have molecular scale with a few nanometers in size [7].

The "nano" era enters in the concept of innovation, however, there has not yet been a repercussion on human life. They could be considered an invisible discovery, given the metric level in which they enable the operation and manipulation of atoms and molecules. It is at this point that the discoveries on this scale allows humans to enter the nooks of nature, already existing but untouched [1].

The nanometer is equal a billionth part of a meter, to exemplify it, according to the ABDI primer, this size is approximately one hundred times smaller than the diameter of a hair, thirty thousand times smaller than the wire of a spider's net or seventy hundred times smaller than a red globule [1].

Nanotechnologies are in almost all productive sectors, which are available today. What is contained in this word? The manipulation and the production in atomic scale, i.e., in the billionth part of the meter, equivalent to the scientific notation 10⁻⁹. According to the Technician committee 229 from ISO (International Organization for Standardization), the utilization of the nanometer scale can be found in the following sectors, here exemplified: fabrics, agriculture [2], construction materials, medicines, disease diagnosis [3], sunscreens, medical [4] and odontology equipment, energy, sporting equipment, warlike and electronic equipment [5], application in food [6] and cosmetics [7] industry, plastic industry [8] and biofuel [9].

Therefore, nanotechnologies are present in almost all branches of industry, even in the most common household appliances, as can be seen in the guide published by an American online magazine-The Conversation-entitled "A guide to the nanotechnology used in the average home" [10].

In order to illustrate, it is presented the nanos by the National Research Program NPR 64, Switzerland [11]: The Technical Committee 229 (Nanotechnologies) of the International Organization for Standardization ISO is developing a globally recognized nomenclature and terminology for nanomaterials. According to the ISO / TS 27687: 2008, nano-object is defined as a material with one, two or three external dimensions in the approximate size of 1-100 nm [11].

The Technical Committee 229 (Nanotechnologies) of the International Organization for Standardization ISO is developing a globally recognized nomenclature and terminology for nanomaterials. According to the ISO/TS 27687: 2008, nano-object is defined as a

material with one, two or three external dimensions in the approximate size of 1-100 nm [12].

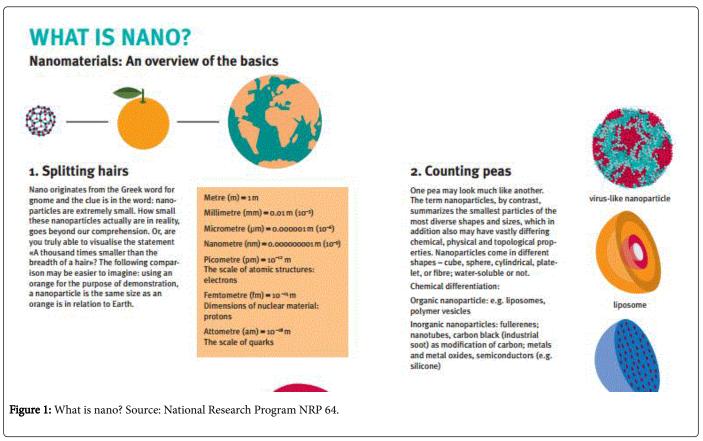
ISO TC 229

Nanotechnology: Standardization in the field of nanotechnologies, which includes one or both of the following procedures:

- 1. Understanding and controlling of matter and processes at a nano scale, typically but not exclusively, below 100 nanometers in one or more dimensions, where the appearance of phenomena that depends on their size usually allows new applications.
- 2. Utilization of the properties of the materials in nanoscale that differ from the properties of the individual atoms, molecules, in

bulk in order to create better materials, devices and systems which explore these new properties. (author's translation) [13].

In the other hand, there is the definition of the Danish Agency of Protection of the Environment, in the proposed study "Better Control of nanomaterials: summary of the 4-year Danish iniciative on nanomaterials": A nanometer (nm) is a billionth (10⁻⁹) part of a meter and a millesimal part of a micrometer. Nano-sizes usually refer to objects having a size of 1-100 nm. A human hair is about 50,000 nm thick. The wavelength of visible light is 400-700 nm. Particles smaller than this interact differently with visible light than larger particles. Nanoparticles are so small that they are not possible to be seen with a regular optic microscope. (Author's translation) [14].



It is verified the discussion and imprecision towards those definitions, considering that various international organizations have been diverging on the topic, given its particularities. In Figure 2, presented below, it is possible to observe the important parameters to the characterization of the nanoparticles, in order to obtain a definition [15], from this, it is understandable the difficulty in finding a unique characterization.

Given the particularities of the nanoparticles, it is difficult to reach a consensus regarding their safety, but countless studies seeking an indepth analysis on those aspects have been conducted. It is emphasized the mapping on Figure 3 of the "Hierarchy of the relevant properties of security for nanoparticles", developed by a German industry [16] TÜV SÜD, private regulatory agency which promotes specific studies about nanosecutiry [17].

Despite the lack of definition in the characterization, the production and consumption of nanomaterials and products is large. By demonstrating this diversity, at a global level, it is possible to present the general numbers registered by *Nanotechnology Products Database* (NPD)-Nanotechnology Products Database, created in January 2016. In order to become a reliable, accredited and updated source of information for the analysis and characterization of nanotechnology products (i.e., nanoproducts) introduced in global markets, it catalogs and records all nanotechnology production capacity developed in the world. Based on the NPD, it can be stated that there are currently 7819 products with nanotechnologies, produced by 1352 companies, from 52 countries [17].

Therefore, the wider the use of nanoscale in industry, the greater the number of products made available to the consumer. Why the concern? By means of specialized equipment, in conditions of interacting with the atomic level, products with physicochemical characteristics different from those found in the macro scale are generated. Allied to this aspect, there is no specific regulation for nanotechnologies throughout the life cycle of a nanomaterial. The Exact Sciences, among which it is underlined: Engineering, Chemistry,

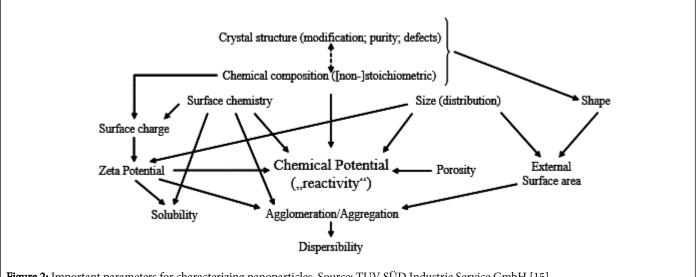
Page 3 of 17

Page 4 of 17

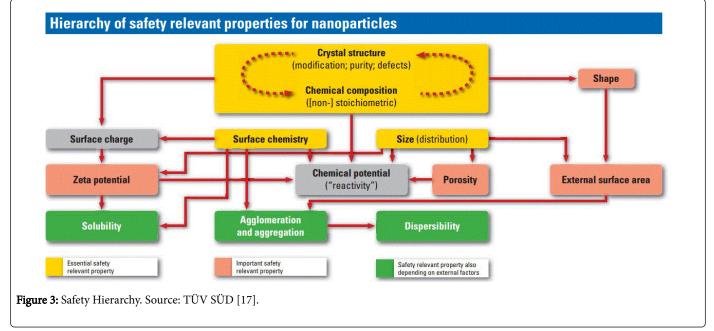
Physics, Biology and others, have not yet been able to calibrate the methodology for the evaluation of safety of products developed based on the nano scale; the number of nanoparticles already produced by human action, the so-called engineered nanoparticles, is unknown. Despite this fact, there are already many products developed from the nano scale-which is equivalent to the measurement between approximately 1 and 100 nanometers (nm).

toxicology, which provided the arisen of a new discipline, the nanotoxicology [19], which for still being a new discipline, has not stablished parameters capable to generate the toxic effect which emerges when the nanoparticles interact with the environment and the human organism. Therefore, there is still research to be done to know the tolerable levels, especially for humans, of exposure, how to manage and evaluate the risks. It is evident the importance of designing the necessary elements for the systems of tests, from each application of the nano scale.

The diversity of alternatives created from the access of humans to the nanometric scale is large and diverse [18]. Issues related to







This set will require a great deal of attention from the Law, which is responsible for regulation. It seems interesting to observe how to operationalize the so-called "normative self-regulation and Law in globalization", because, according to M. Mercè Darnaculleta i Gardella: "... in the global risk society, however, increasing complexity, the specialization and the technification of the issues on which the Law has to be pronounced are completely transforming these institutions (the State, the Law and the institutions with the power to adopt legally binding decisions). [...]"[20]. The novelties are generated in the scope of the Exact Sciences, but are promoting reflections and transformations in the Law and in the conception about its sources of expression.

The importance of the debate on the nanotechnology era: A discussion at the international level: Considering the evolution of this new technology the necessity for a greater debate about them is raised, especially regarding the possibility of future damage to the environment and human life, given the complexity and particularity of the materials in such a small scale. It is then inserted in the Risk scenario. In this context, therefore, it is inserted the world's concern with nanos. It is possible to observe that debate and studies have been taking place globally, in developed countries, and progressively in developing countries, such as Brazil.

Regulating and the regulation of nanotechnology use, research, development and innovation (P, D and I) has topped the agenda of both governments and the scientific and technological community, as legal uncertainty is a major factor of repression of the investments in new technologies. Several international organizations have been holding discussions, forums and meetings to establish definitions of nanomaterials and methods for characterizing and evaluating their safety. However, to date, there is no specific regulatory framework for the subject, with products registered in different countries, including Brazil, by their respective Regulatory Agencies, in case-by-case analyzes [20].

In the Brazilian conjuncture, the study conducted in 2015, through the Institute of Applied Economic Research (IPEA)-where they discussed the world Megatrends for 2030, with the current questions about what the world entities and personalities think about the worldit was verified the growth of the investments and application in the field of nanotechnology and biotechnology [21].

It is also possible to follow the initial Brazilian movement, through initiatives in regulatory agencies such as ABDI and ANVISA (but in a very precarious way), as well as some legislative procedures [21].

Such actions regarding nanotechnology are only incipient, but there is a concern about the still nebulous facet of nanoproducts, which caused the Brazilian government, through the Secretary of Technological Development and Innovation of MCTIC, Álvaro Prata, to discuss the regulation of these products: He also noted that the definition of objective criteria facilitates not only the work of the regulator, which needs to check the action and adverse effects of each evaluated item, but also the innovative agent. "The producer will know exactly what information he will have to submit for his invention to be approved. This will accelerate the whole process, which will bring many benefits to the country, especially from the economic point of view, since we want the innovations to become commercial products," he explained. According to Granjeiro, the main concern is related to the chronic effects of nanotechnology. "Further research is still needed into the consequences for people and the environment of continued use of these materials" [22].

Finally, in the legal aspect of nanos, it is presented the initiatives of the regulatory frameworks, which, to date, are four: a) proposition of the bill n.º 19/2014 [22], in Rio Grande do Sul; b) two bills in the federal level (House of Representatives), under the n.º 5133/2013 [23] and 6741/2013 [24]; and c)bill n.º 1456/2014 [25], in the state of São Paulo.

Already in the European, American and Asian international scene, the discussion is in a much more advanced *scale*, presenting several studies, research, guidelines and protocols on nanotechnologies.

In Europe, the theme of nanotechnologies is part of the EU's "Horizon 2020" Framework Program Strategy, expressly stating: "[...] Key enabling technologies, such as cutting-edge and advanced materials industry, biotechnology and nanotechnologies, are at the heart of innovative products: smart phones, high-performance batteries, light vehicles, nanomedicines, smart fabrics and more. European manufacturing is the largest employer, with 31 million workers across Europe" [25].

In addition, it is worth mentioning the June 2015 revision of the document entitled: High-Level Expert Group on Key Enabling Technologies [26], referring to a communicate from the European Commission dated 2009, entitled: Preparing for our future: developing the Common Strategy for Key Enabling Technologies in the EU. In this paper six Key Enabling Technologies have been identified and one of them is nanotechnology.

Still on the European scene, Germany stands out, almost one step further in terms of regulations and nanotechnologies. Through various federal agencies, many protocols for the evaluation of nanotechnologies and the environment have already been published, with the purpose of exposing precautionary measures, in compliance with the Precautionary Principles. It is mentioned as an example, the action plan developed in its own interdisciplinary department in the federal government, called Action Plan Nanotechnology 2020 [26]. Another study calls attention, inserted in the proposal of the plan of action previously mentioned, and still being part of Horizon 2020 entitled "Review of joint research strategy of senior federal authorities. Nanomaterials and other advanced materials: Application safety and Environmental compatibility" [27], developed by the union of several German federal agencies, such as the German Environment Agency (UBA), the National Institute of Metrology (PTB), the Federal Institute for Risk Assessment (BfR), the Federal Institute for Occupational Health and Safety (BAuA), And the Federal Institute for Materials Research and Testing (BAM).

The European Commission (EU), by the JRC (*Joint Research Center*) in 2015, has also been making great efforts in the field of nanotechnologies, according to the general report presented, which reports on activities, achievements and resources related to the work developed by the commission in 2015. It is the presentation of a panorama of achievements and scientific activities. The document outlines the contribution to the ongoing review of the definition of nanomaterials and reinforces the industrial base with two new cutting-edge technologies from nuclear research [27].

Furthermore, it is affirmed that the exact definition of a nanomaterial represents the gateway to its production, use and safety of health and environmental assessment. The Commission is reviewing its definitions and the result was expected for 2016. In addition, future collaboration in the fields of energy, transport, nanotechnology, materials reference, health and environment, innovation and growth was established. This commission and the authorities of the Academy of Sciences have already successfully collaborated on a number of scientific projects under the Framework Strategy for Research and Innovation Programs as well as on international scientific networks such as the Danube Academies of Science [28]: The exact definition of a nanomaterial represents the gateway to its wider production, use and safety assessment for human health and the environment. [...]. This sets the framework for future collaboration in the fields of energy, transport, nanotechnology, reference materials, health and environment, innovation and growth. The JRC and the Slovak Academy of Sciences have already cooperated successfully on several scientific projects under the EU Frameworks for research and

innovation, as well as within international scientific networks, such as the Academies of Sciences of the Danube region.

In Europe, the work of NANoREG, which elaborates protocols and studies on nanomaterials testing, is seeking for appropriate regulation, evaluating and creation methods to analyze the effects on human life and the environment, through the joint effort of the entire European Union and even of Brazil and Korea: The NANoREG project is aimed at developing and evaluating methods of testing the effects of nanomaterials on the Environment, Health and Safety (EHS), methods to assess the related risks and methods and concepts to take EHS aspects into account in an early stage of the development of new nanomaterials or new applications. In the project more than 85 partners from EU member states, associated states, the Republic of Korea and Brazil collaborate. The Dutch Ministry of Infrastructure and the Environment coordinates the project. The total budget of the project is 50 million euro of which 10 million euro is provided by the EU (FP7 program) and 40 million by member states, regions, partners and other parties. According to the original planning most of the R & D work of the project has been finalized before 1 September 2016. The process of reporting and approving the deliverables is still ongoing [28].

The European Commission has published a safety and security guide entitled "Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work: Guidance for employers and health and safety practitioners" [29]. The European Nanosafety Cluster-a group of scientists from the European Union-has published the study "Nanosafety in Europe 2015-2025: Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations" [30].

In the United States is also strong the development of this area of research. Considering the numerous products launched with nanotechnology, a range of studies were started to investigate this new technology, and several internal organs have reached important warnings. For example, NIOSH [31], The American Occupational Health Protection Agency, has identified 10 critical topics in which it is currently conducting research to guide the resolution of gaps and to provide recommendations on the applications and implications of nanomaterials in the workplace [32] (A) toxicology and internal dose, (b) risk assessment, (c) epidemiology and surveillance, (d) engineering controls and PPE, (e) measurement methods, (f) exposure assessment, (g) safety fire and explosion, h) recommendations and guidelines, i) communication and information, j) applications.

In order to glimpse the importance of the nanos in the USA, through the economic investment in these studies, the budget presented for 2017, in the National Program of the United States, NNI, "*National Nanotechnology Initiative*", was voted in 2016, proposing the 2017 budget of \$1.4 billion dollars, distributed in several institutes, such as NIOSH [33], NASA [34], EPA [35], among many other public entities, according to the Figure 4.

As seen, the vast debate about nanotechnologies is inserted globally, from the largest developed nations, like Germany, that owns a plan of action, in its own interdisciplinary department and in the federal government, called Action Plan Nanotechnology 2020 [37] and the United States (with the National Nanotechnology Plan)-to developing countries (such as Brazil) which are engaged in numerous researches, as well as in developing large-scale products using nanotechnology.

These are just a few references of discussion at the global and Brazilian level on nanotechnologies and regulation, being necessary

the selection in this moment, considering the high number of other institutions and international organizations that also publish studies, protocols and documents on the topic.

Therefore, the greater the production and consumption of nanoproducts and nanomaterials, the greater the disposal of these elements in the environment after the end of their life cycle. There are many uncertainties as to their effects on the environment and human life, thus how to deal with nanotech waste, or nanowaste? The concern has been gaining even greater importance in the surveys, there is a specific study on nanowaste in the OECD-The Organization for Economic Co-operation and Development (OECD) [37], which has been developing since 2006 a series of studies entitled "Series on the Safety of Manufactured Nanomaterials", focused on the safety assessment of nanomaterials. In fact, 80 specific documents have already been published in this regard. The objective of the OECD series on the safety of manufactured nanomaterials is to provide up-to-date information on OECD activities related to human health and environmental safety. Thus, highlighting the nanowaste, it was elaborated the specific study called "Nanomaterials in Waste Streams: Current Knowledge on risks and impacts" [38], in which they present at the end a conclusion as an adequate protocol to the final destination of the Nanowaste.

NNI Budget, by Agency, 2015–2017 (dollars in millions)			
Agency	2015 Actual	2016 Estimated*	2017 Proposed
CPSC	2.0	2.0	4.0
DHS	28.4	21.0	1.5
DOC/NIST	83.6	79.5	81.8
DOD	143.0	133.8	131.3
DOE**	312.5	330.4	361.7
DOT/FHWA	0.8	1.5	1.5
EPA	15.1	13.9	15.3
DHHS (total)	385.8	405.0	404.4
FDA	10.8	12.0	11.4
NIH	364.0	382.0	382.0
NIOSH	11.0	11.0	11.0
NASA	14.3	11.0	6.1
NSF	489.8	415.1	414.9
USDA (total)	21.1	21.5	21.0
ARS	3.0	3.0	3.0
FS	4.6	4.5	4.0
NIFA	13.5	14.0	14.0
TOTAL***	1496.3	1434.7	1443.4

* 2016 numbers are based on 2016 enacted levels and may shift as operating plans are finalized.

Funding levels for DOE include the combined budgets of the Office of Science, the Office of Energy Efficiency and Renewable Energy (DOE-EERE), the Office of Fossil Energy, and the Advanced Research Projects Agency for Energy (ARPA-E).

*** In Tables 2–6, totals may not add, due to rounding.

Figure 4: 2015 budgets, 2016 estimate, 2017 proposal. Source: NNI, 2016 [36].

In view of the risk scenario involving nanotechnologies, it is necessary to deepen the discussion about the final destination of nanomaterials, reaching for an alternative for nanowaste management, due to the absence of specific regulation on the matter, once that the

risk involving this waste requires precautionary action. Hence, it is important first to know about the interesting life cycle of nanomaterials and the risk.

The intrigant life cycle of nanomaterials and the (necessary) concern for the management of nanowaste risks: How to deal with final destination of nanotechnological waste?

In order to develop an effective risk management of nanotechnology products, it is necessary to analyze the life cycle of nanomaterials, more precisely the final destination. As the growth of nanoscale products is verified, a nanotechnological waste (residue) will advance in the same direction, being dispersed without any precautionary measure, disregarding the risks already presented in the previous moment. However, these nanomaterials can have harmful effects when released into the environment [39]. As previously indicated, it is important to take risks.

Programs and procedural obligations to define programs are important for the Law of risks. These have a discretionary directing function and thus resembles regulations that set standards. Here it is evident how the practice generates new forms of rationalization of the margins of decision to which the dogmatics and the controls can be connected. [...] [40].

As a result of this possibility, the nanoscale development in the risk society is located, according to Beck. The author explains that the world of unquantifiable uncertainty, created by ourselves, can greatly expand following the pace of technological development. Therefore, decisions made in the past with regard to nuclear and current energy, such as engineering and exploration of genetic engineering, nanotechnology, information technology and so on, is a trigger of unpredictable, uncontrollable and even incommunicable consequences, threating life on our planet: In the modern world, the gap between language of quantifiable risks, according to What we think and do, and the world of uncertainty that cannot be quantified, That we have created ourselves, is expanding more and more, following the rhythm of the Technological development. The decisions that we have taken in the past of nuclear power and the current ones regarding the exploitation of engineering and genetic manipulation, nanotechnology, information technology and so on They unleash unpredictable, uncontrollable consequences and even Incommunicable, threatening life on our planet [41].

Therefore, inserting the nanos in a Society of Risk, its existence is observed as well as its prominence given by scientific researches published in qualified magazines of diverse areas, related to diverse nanomaterials.

In Brazil, the National Council for Scientific and Technological Development (CNPq), together with the Ministry of Science, Technology and Innovation (MCTI), launched in 2011 a call for the formation of the first nanotoxicology networks in Brazil. To date, there was still no specific promotion for the development of this area of research. The research project entitled "Occupational and environmental nanotoxicology: scientific subsidies to establish regulatory frameworks and risk assessment" (MCTI / CNPq process 552131/2011-3) was presented, which has already produced some results, pointing to toxic effects of some investigated nanoparticles, such as confirmation of evidence that the carbon nanotubes are potentially hazardous in aquatic environments, and that the mechanism of toxicity is complex and insufficiently understood so far [42]. Another study shows possible brain effects (neurotoxicity) of

Zebrafish (Danio rerio) fish exposed to this same material at nano scale [43].

In the same sense, it has been demonstrated that the nanotechnology industry, such as carbon nanomaterials, are strong candidates to contaminate aquatic environments, since its production and disposal have grown exponentially in a few years, without conclusive studies on its effective interaction with the environment. Recent study has shown that fullerene C60 decreased the viability of the cells and impaired the detoxification of enzymes, evidencing toxicological interactions [44].

Other engineered nanomaterials (those produced from human action) most commonly used in products for the consumer market are nanoparticles. It has a relevant antibacterial activity and low production cost. The nano silver [45], for example, is used in the white line of home appliances, drinking fountains, air conditioners and other items of daily consumer use and contact. However, such is the potential for risk, which the US EPA has agreed to regulate it as a new pesticide.

Increased use of zinc nanoparticles, incorporated into a growing number of products, also leads to enlargement of disposal and packaging, food waste and other types of waste, increasing the possibility of environmental risks [46]. Considering its antibacterial properties, the ability of nanoparticulate zinc to fight bacteria increases with the reduction of the size of the particles. Nanotoxicological studies on zinc are still poorly understood, increasing the need for greater care in their incorporation of products and equipment that come into contact with food, given the possibility of migration of the particles into packaged or transported food. Therefore, considering the doubts about the effect of nanoparticles in biological systems and the possible impact of these materials on human health, a perspective arises, above all, ethical focusing on "the necessity of exhaustively exploring the possible toxicological effects of nanoparticles [...], specially in the case of food-related applications" [47].

In the same vein, the NIOSH (National Institute for Occupational Safety and Health) alerts: When it comes to nanotechnologies, ensuring the health and safety at the work place of your company and employees is paramount for the success and future growth of your business. This responsibility for companies dealing with engineered nanomaterials has become even more challenging by research, showing that some nanomaterials cause respiratory and cardiovascular risks in laboratory animals. Your employees may be at risk of exposure through inhalation, absorption of the skin or ingestion. A number of factors can affect its potential for exposure, the pathway, concentration, duration and frequency of any exposure. The nanomaterial's ability can be easily dispersed (such as a dust or aerosol). The implemented control measures aim to reduce or limit exposures [48].

In Switzerland, a research of the National Program called "*Opportunities and Risks of Nanomaterials*" (Environmental Science & Technology, *Dynamic Probabilistic Modeling of Environmental Emissions of Engineered Nanomaterials*", Led by Bernd Nowack (EMPA), analyzed how nanoparticles flow through the environment, and alarmingly concluded that, atleast in the case of nanozinc (among many others in abundance) its concentration in the environment approaches the critical level. That is why such research emphasizes the priority to be given in this particular nanomaterial in future ecotoxicological studies-even though nanozinc is produced in smaller amounts than titanium nano-dioxide. In addition, ecotoxicological tests have so far been conducted mainly with freshwater organisms.

Page 8 of 17

The researchers conclude that further investigations using soil organisms is a priority [49].

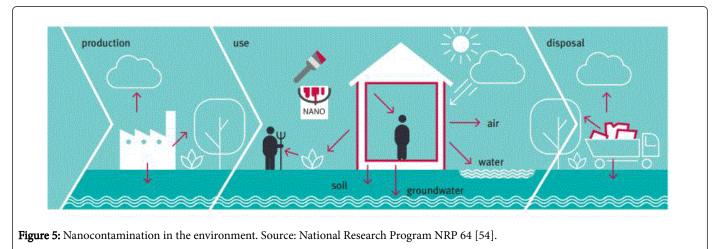
Furthermore, nanos present mechanisms of toxicity [50], an aspect that is not receiving due attention by the manufacturers or at least this "detail" does not appear on any labels or publicity materials.

Those studies confirm the necessity for increased care with the health and safety of the human being and with the environment. The answers obtained from the Exact Sciences, which may also be denominated as Sciences Production [51], to date, are provisional, unconclusive and often contradictory, but with evidence of risks, deserving the attention of Impact Sciences [52]. Here, an interesting field for regulation exists, which must be occupied with creativity by the Law, mobilizing the dialogue between the sources of Law, as a way of inserting the legal in the scenario of the Nanotechnological Revolution.

It is also important to remember the balance of the development of nanos to the foundations of bioethics, and it is impossible to preserve its foundations, seeking protection of human life. All the attention to future generations, in order to protect human dignity, imposing minimum bioethical limits on these technological innovations, such as the case of nanotechnologies, is an imposition for (possible) damages management, while also respecting the precautionary principle. As Honas teaches, fear is healthy in the interaction with the new technologies, in order to hold the respective agents accountable, so as not to cease development, only cherishing the current and future wellbeing (Figure 5). And as Douglas claims, "doubting is always a healthy exercise." Therefore, the application of bioethics in nanoscale production is essential [53].

Therefore, all nanowaste (residues) can be a source of contamination to the environment, and returning to the human being. It is also observed that the contamination can occur by several routes, as in the residues water (from nanotechnology clothes that are washed), in the soil, when the nanowaste is discarded in the landfill, or in the air, when it is incinerated.

By the following illustration, it is possible to analyze the forms of contamination of nanos in the environment:



Generally, the concept of nanowaste can be understood as those materials generated from a productive process whose order is the size of nanometers. Or, the residues of the nanoproducts, whose useful life has come to an end and have been discarded. Thus, the generation of nanowastes encompasses two chains: a) the industries in the manipulation of nanomaterials and nanoproducts deriving from their productive system; B) and consumers who are also responsible for the generation of nanowastes when consuming the nanoproducts [55].

Very little is known today about environmental behavior and the effects of nanoparticle release, although these are materials that are already effectively present in the environment. Further research is necessary to determine whether release and transformation processes result in a similar or more diverse set of nanoparticles and ultimately how this affects environmental behavior [56].

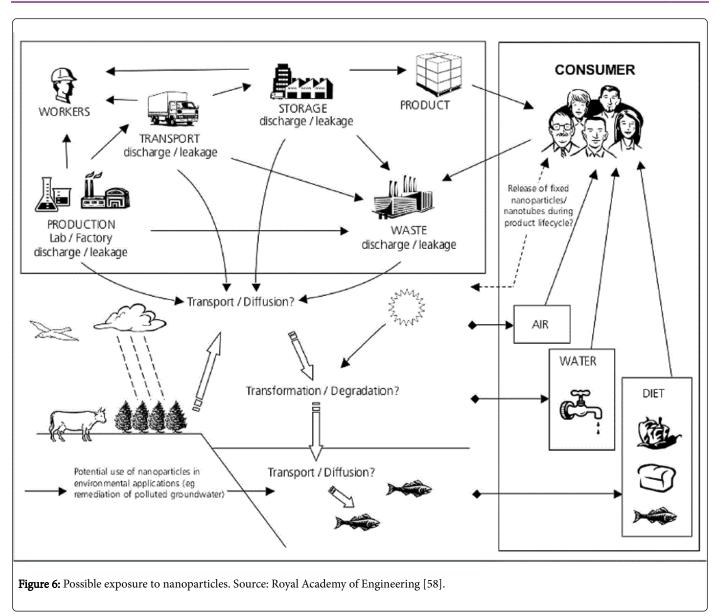
In recent years, despite numerous publications and articles on the exponential growth of global nanotechnology and its particularities, these publications contain little scientific evidence and feasible approaches to dealing with *Nanowaste* generated at various stages in

the material life cycle. The lack of scientific publications for the management of Nanowaste is evidence of limited or concerted limited effort by researchers in this field [57].

About the exposure of the consumer and producer public of nanoparticles, Figure 6 demonstrates the different possibilities of exposure.

The various possibilities of impacts that these new technologies can cause throughout the product life cycle are observed. Therefore, it is relevant to consider the potential processes of transformation and nanowaste which may occur during the various waste treatment options. Only scarce information is available in published literature on how [59] ENMs may be altered or transformed during waste treatment processes. Moreover, the coating of persistent particles and their potential transformation of the residues are of high relevance because the surface properties of the NMS predominantly influence their fate and behavior. In addition, scarce study focused on the degradation or persistence of nanowaste surface coatings. Thus, this issue is a challenging task for future research [60].

Page 9 of 17

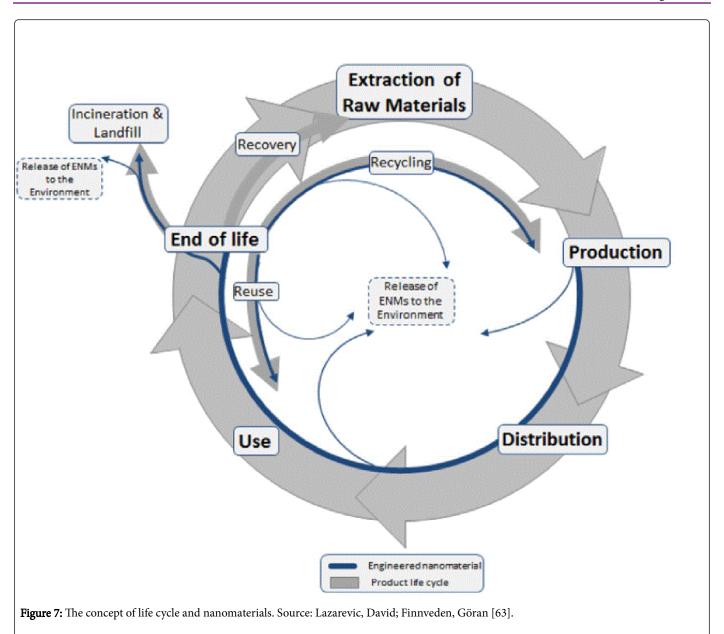


The development of techniques for the monitoring and diagnosis of nanomaterials (in order to increase knowledge in the nanotoxicological area and the life cycle of these materials) and to determine appropriate, sustainable and safe forms of production (including waste management) is essential so that the benefits of nanotechnologies can be safely enjoyed and aimed at protecting [61] the environment for the present and future generations [62]. Images are typically useful for conveying the life cycle perspective, however, an important aspect related to products containing nanoparticles and what should be considered is the release of these particles into the environment during the different phases of the life cycle. Figure 7 highlights the fluxes and potential launches of nanoparticles as a result of their incorporation into product life cycles. The blue line represents the nanoparticles in the product life cycle and also the potential emissions of nanoparticles during the product life cycle [63].

The final destination of these materials with nanotechnology preoccupies, as those materials may not be biodegradable and consequently remain in the ecosystem. This potential risk already causes alerts to the developing countries, which may be receiving residues containing nanomaterials via exportation [64].

The life cycle assessment is directly linked, and vice versa, to the nanoparticle risk assessment. The presence of nanomaterials in dry or powder form and the composting of sewage sludge that is often disseminated on agricultural land as fertilizer is a particular concern. In France, the national half of sewage sludge is used for agricultural fertilization. The potential transformation of artificial nanomaterials in the soil, their interactions with plants and bacteria and their transfer to surface water has never been studied in depth [65].

Page 10 of 17



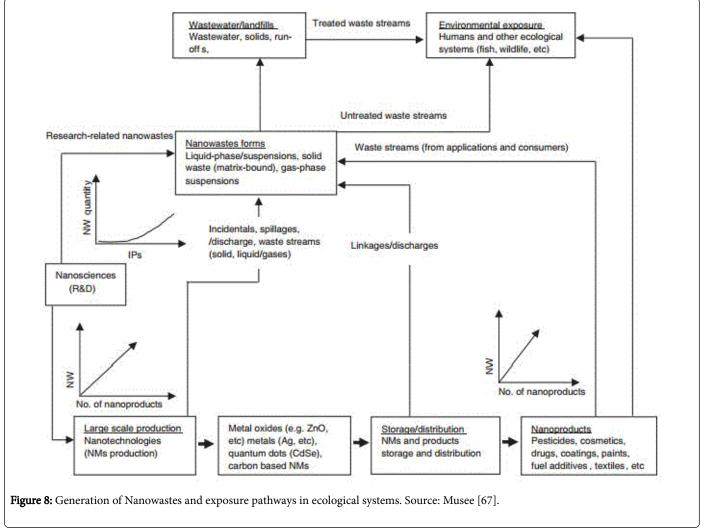
An assessment of the waste generated by nanotechnology production processes is necessary and should include attention to waste from installations producing nanomaterials that may impose new pressures on environmental systems [65]. Nanowaste risk analysis is essential, specially considering the postulation by specific regulation for the final destination, which will be demonstrated at the end, when presented the protocol and specific study of the OECD, which exposed the effects of the four types of treatment with nanotechnology [66].

Therefore, nanowaste demands greater attention to its particularities. The complex bonds of these parameters are likely to trigger increasing amounts of nanowaste released into the environment, with several exposure pathways, as illustrated in the Figure 8.

Given the absence of specific studies and regulation on nanotechnological wastes, their dispersion in the environment becomes more insecure and increases the risk, since there are several channels of introduction of nanowaste in the ecosystem: Nanowastes are potentially the most particular and unique way of introducing NMs into environmental systems. Lack of response to these concerns continues to disrupt the release of NMs into the environment (example: water, air and soil)-which can cause contamination of soils, as well as surface and subsurface water resources. In the long run, this not only threatens the safety of water resources, but may be impossible to remedy due to: the shear size of the problems due to the dispersion of NMs in the environment, high cleaning costs, lack of adequate technologies for remediation and lack of monitoring tools to identify contaminated areas. For example, there is a growing global demand for additives for fuels, lubricants and catalysts, due to the performance through the infusion of nanoscale particles of cerium oxide. Generally, these fuels additives, lubricants and nanotechnology catalysts are susceptible to emission through various wastes, fluids into the air, water or soil. Ultimately, they will end in aquatic and terrestrial environments through surface runoff, spills during use and vehicle

leaks, or through sewage drainage. This raises serious concerns about dealing with *Nanowastes*, from ponctual and unpunctual sources. Furthermore, it is important to emphasize that nanotechnology and its

products are present in several areas of industry. Therefore, there are studies related to this topic, which brings us relevant news more often [68].

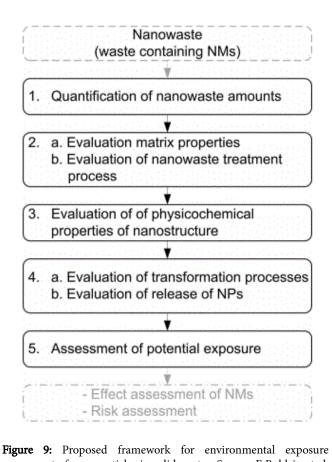


It is also important that the focus is directed to evaluate the environmental exposure related to the management of nanowaste, which requires knowledge about handling, as well as processing and eliminating nanowaste, not forgetting related environmental emissions. In relation to waste management, specific aspects can influence the emission of *nanowaste* in the environment, for example the physico-chemical properties of the waste, as well as any *nanowaste* during handling/treatment/disposal in the waste management system. It is the scheme presented in the illustration, as a step-by-step for analysis, proposed for environmental exposure and evaluation of nanoparticles in solid waste. The Figure 9 includes steps 1-5. When combined with results of an effect assessment, the results of the exposure assessment can be a contribution to the evaluation of environmental risks and emissions of nanoparticles waste [69].

Thus, specifically, the implementation of responsible risk management practices by regulators, nongovernmental organizations, scientists, insurance companies and perhaps most importantly, companies in all phases of the nanotechnology lifecycle will be critical to Governance and ensure the safety of research, development, manufacturing, distribution, use and disposal of nanotechnology products [71].

The issue/risk management of nanotechnologies continues to be discussed in the most different areas of knowledge, a recent document from the North American Congress, prepared by a specialist in science and technology policies, mentions that potential environmental, health and safety risks of nanoparticles in humans and animals depend in part on their potential to accumulate, especially in vital organs such as the lungs and brain, which can injure or kill, and diffuse into the environment and potentially harm ecosystems [72].

The development of techniques for the monitoring and diagnosis of nanomaterials (in order to increase knowledge in the nanotoxicological area and the life cycle of these materials) and to determine appropriate, sustainable and safe forms of production (including waste management) is essential for the benefits of nanotechnologies to be safely enjoyed aiming at the protection of future generations [73].



assessment of nanoparticles in solid wastes. Source: F Boldrin et al. [70].

Hence, it is demonstrated the necessary adoption of measures for the proper disposal of nanowaste. In the next section of this study, it will be analyzed the treatment processes of residues with nanotechnology from the OECD perspective, in the specific research about nanotechnological waste. In addition, it will be demonstrated the viability of the usage of the protocol to the correct management of nanowaste.

The specific nanowaste study developed by the OECD: An alternative for the understanding and adoption of precautionary measures adequate to nanotechnological Residues: Since the nanotechnology waste brings the risk potential, and may cause future damages to the present and next generations, it is necessary for the Law to seek for an alternative for the correct management of the nanowaste, so that, at a minimum, occurs the adoption of minimally precautionary measures, once regulatory framework for both nanos and nanowaste are inexistent.

Even if a standard norm would be elaborated by the State power, would it be effective given the dynamics and complexity of nanotechnologies? It is believed that it would not, because the temporal lapse would be very large between the drafting of the bill, promulgation of the norm, validity, and when dealing with the speed of scientific discoveries of this new technology, probably at the moment of the law enforcement, this would already be obsolete. The nanotechnology movement is very fast, the discoveries about them are daily, and a tight, closed law would not be able to account for this complexity.

However, there are a number of other instruments with potential for (self) regulation by international agencies, both governmental and private, that would assist in the delivery of specific protocols and regulations. These documents are the result of extensive and profound studies related to nanotechnology, safety and nanoresidue (which will be the focus of this research).

The point is to adopt an alternative, even if it is not legislative, seeking for an adequate response to nanotechnologies, more precisely on waste, which is disposed into the environment on a daily basis, after its life cycle, without any minimal care. In this sense, one of the most universal methods to approach the problem might be the application of a comparative legal method to develop a legislation, just as suggested by Belokrylova [74], in relation to Russia: Questions of guaranteeing safety on nano products and nano materials have been a wide object of discussion in the international, European, and national levels of countries. In the Russian Federation, there is an urgent challenge in developing the aspects of political, legal, supervisory, social, and economic spheres connected to nano activities. A number of international documents have noted a lack of legal regulation in the sphere of nanotechnologies in the Russian Federation. One of the most universal methods of addressing the problem might be applying a comparative legal method for developing legislation in the nano industry in the Russian Federation. This would foster a useful regulation of stakeholder relationships and formulate a full theoretical legal concept of nanotechnology's safety in the Russian Federation, based on the recommendations of the inter-national and European consortiums.

As discussed above, a large number of regulations are already found, produced by various agencies and international bodies on this new technology and its risk management, such as the National Institute for Health (NIH) in the United States, National Science Foundation (NSF) ISO, OECD, British Standars Institution (BSI) in the European Union, from the European Commission and European Parliament, European Medicines Agency, Conanomet, European Agency for Safety and Health at work, among others. Those regulations, risk evaluations and recommendations might be used for the creation of an internal legal framework [75].

The specific study that is highlighted about nanowaste and its treatment is the protocol from the OECD, *Nanomaterials in Waste Streams: Current Knowledge on Risks and Impacts* [75].

Awaken by this questioning together with the Precaution Principle, the OECD performed a series of specific researches and studies in the field of nanotechnology, focusing on the seek for adequate answers in relation to the residues of the nanoscale production, i.e., the final disposal of nanomaterials, considering the large production without any concern to the disposal [76]. Thus, the research was justified in the face of increasing nanoscale production, in order to evaluate waste treatment processes, relating them to nanomaterials, in order to minimize existing risks, taking literary evidence of specific waste treatments (residues), such as recycling, incineration, disposal of landfills and water treatment: This raises the question as to whether existing waste treatment processes are able to effectively minimize the risks that may be linked to ENMs. This report surveys the evidence from the literature for four specific waste treatment processes: recycling, incineration, landfilling and wastewater treatment, and

Page 13 of 17

identifies the current state of knowledge on the fate and possible impacts of ENMs in these processes [77].

possible destiny and impacts of the products in nano scale in those processes.

With this objective, the research provided a review of literature of the four specific processes of the waste treatment: (a) recycling, (b) incineration, (c) disposal of landfills and (d) treatment of residual water, aiming at demystify the current scenario of knowledge about the Aiming at inform the aspects of treatment specifically directed to the nanomaterials, it is presented below a explicative Table 1 in which are exposed the main characteristics and results of each procedure presented by the previously mentioned organization:

Category of waste treatment containing nanomaterials	ng Explanation of the respective waste treatments with nanomaterials and results	
Recycling	In this process, it would be possible to separate materials at nanoscale. The problem is the identification of those that are (and are not) produced in nano-scale. It is observed in this procedure that dust can occur in the handling of the residues with nanoparticles, and this would require specific work safety conditions, both to prevent human contact and contact with the environment.	
	Result: The destiny of nanomaterials in the process of recycling is unclear due to the challenges in the exposure of nanoscale products to the real working environment.	
Incinerate	The wastes are mixed and thermic treated in incineration plants. It occurs that the flammable parts are destroyed, which leaves particles undestroyed in the combustion chamber. This would require modern filters and specific cleaning procedures. It could reduce the amount of hazardous waste. However, there is not much information on the influence of cleaning on the nanoparticles that persist in the chimneys. And this would be the worst case, where the undissolved particles persist, which would remain in the environment.	
	As a result, the study reveals that a significant portion of nanoparticles could be trapped, diverting them into flyer ash and ash. But the removal of the remaining particles and their efficiency was reported in various ways in several studies. Still, even with this treatment, 20% of the total material would not be reached and would go through the method, which would require additional preventive mechanisms.	
Sewage treatment works	Products with nanomaterials can release particles during use as well as in contact with water. An example of this is washing clothes on machines. Thus, nanomaterials can be found in wastewater treatment, including sludge incinerated and used as fertilizer for agriculture. Therefore, the absence of knowledge exists regarding the environmental impacts resulting from the use of this sludge as fertilizer.	
	Results: In the investigation of some types of nanoscale products at pilot water stations, it was found that they were able to divert and capture 80% of bulk nanomaterials in solid sludge, but the remainder of the nanoparticle residues would remain in the surface waters.	
Deposition in landfills	Landfilling of waste with untreated (biodegradable) nanomaterials is the main waste, as it is the most commonly used management technique in the countries. Depending on how and where the landfill is the nanoparticles can leave the landfill by emitting in the atmosphere, water and still on the ground.	
	Result: here it is similar to the case of water treatment, where the capture would occur before the aggregation or agglomeration with organic matter and bacteria. But in the specific case of the effectiveness of landfill linings in maintaining nanomaterials for the environment, the results are contradictory, and the extent to which landfill or release gas surfaces have not been studied in depth.	

Table 1: Main waste treatments and results with nanowaste.

Therefore, the study presented a clear concern to verify the amount of residues of nanotechnology in the main treatment techniques, as well as their impact on the effectiveness of such processes. There are a set of practical guidelines that should guide the process of destination and treatment of waste generated from the nanoscale. The knowledge process is not restricted only to the research and industrial sector, but it must reach the consumer, promoting an adequate organization of the generated domestic waste. Finally, even with these treatment procedures implemented, there is still a certain degree of uncertainty associated with its final disposition, requiring further research in the area.

Although there is knowledge about the destiny of residues containing nanomaterials and the treatment stations being capable to collect, diverge or eliminate most of the nanomaterials another great share, frequently the ones more susceptible to the contact with the environment, is not reached by the control of those processes and might be released as emissions [77].

However, it should be noted that such a protocol had the purpose of minimizing the effects on the environment, and it was noticed that

there was at least a minimal containment and protection of the environment against nanomaterials and their emissions. Allied with this orientation, it is highlighted the Precaution Principle, mechanism widely adopted in environmental causes in which the risk to the environment is inaccurate, but imminent, and the absence of the precaution measure might entail inestimable damages to humankind [77].

The success of the protocols cannot be disregarded, as they certainly minimize the potential damages and risks to the environment. It is clear from the presented framework that a great concern is faced, and it is urgent to adopt some instrument with regulatory potential, in this case the OECD protocol, because even the most elaborate protocols are not enough considering the enormous risk that nanotechnologies have.

Once there is agreement in the use of this OECD regulatory mechanism, or in the case of other instruments, would it be possible within the legal framework of each country? How to validate or adopt these regulatory instruments? This discussion will be seen in the following section.

The use of the OECD protocol as a possibility of nanowaste management: Perphasizing the dialogue between the sources of law, Luhmann's communication and teubner's legal pluralism: In order to provide adequate responses to new nanotechnological demands, it should be emphasized that the necessity of opening legal production on the subject is due to the fact that it generates, from nanotechnologies, the risk of damages (severe or not), which requires decisions in the present, even though there are no examples related to the past, but with irreversible and serious impacts to the future. Such a combination of those temporal lapses challenges legal science. This happens because since the beginning of this century the society generates risks with new formats and impacts, consequently reaching the necessity of security. Therefore, the complexity of nanotechnology will demand from the risk management a new and updated configuration of the structure of the subjective law as well [78].

To make feasible the utilization of the protocol from OECD, as a form of validation or coupling, providing apt answers to the adequate management of nanowaste, and with the appropriate risk management, three theories in the Law, beginning with the Dialogue between the Sources of Law, from Engelmann [79].

As no methodology has been achieved so far to provide adequate answers to our questions regarding the possible effects of nanomaterials on the environment and human health, it is essential to collate and relate other areas of science, promoting a true "Dialogue between the Sources of Law", as it promotes the author's lesson, in which he claims that: The doctrine needs to reassume its role of promoting orderly transformation in the meanings of legal models; redetermination. Because of these predicates of the Doctrine, it is thought that it will be in a position to assume the role of conduction of the nanotechnological point through the different sources of Law. The dialogue between the aforementioned sources of Law, since it is not intended to make an exhaustive presentation, should be led by the Doctrine, traversing other sources of Law-both national and international (see the table of agencies and countries outlined above) before plunging the answer into two filters: The Federal Constitution and the International Human Rights Documents [80].

In other words: In order to operate the innovation of Law, it is necessary to open the juridical to the transdisciplinary methodological structure, expressly recognizing that the Law is not alone in the world, requiring other areas of knowledge to generate legal responses appropriate to the times of new (nano) technologies [81].

In the context of new nanotechnological demands, in order to provide adequate answers to the new demands, it is necessary to face the old positivist paradigm, seeking for the facilitation of the closed norms, guaranteeing the dialogue with other areas of knowledge. Below what the dialogue proposes: Thus, it will be possible to place the law in the route of building a society where the human being and the environment are effectively protected, through a modern normative set, flexible and capable to enable the communication of national Law with its international face and vice versa, increasingly important, especially in the case of the construction of regulatory frameworks for nanotechnologies. For this enterprise, the "Dialogue between the Sources of Law" will be of great value, where the hierarchical and vertical arrangement, in the style of Hans Kelsen's pyramid, it will be replaced by the scenario in which all sources of Law will be arranged horizontally, without hierarchy, with the central role assured to the Constitution, responsible for filtering constitutionality the constructed legal responses. Therefore, the Constitution will occupy the central place in conducting the dialogue between all sources of Law. With this

change, the Law will be represented by the plurality of legal manifestations, decentralizing its production, no longer focused on the State and the Legislative Branch, but moved by the creative and creator activity of jurists. This will be fundamental to ensure a new approach and contextualization of intellectual property rights [82].

Furthermore: Moreover, the entry of the principles into the dialogue between the sources of Law is decisive for such a change, which thus provides a reconstruction of the contours of the "subjective right". It is necessary for categories that provide the dynamic and genesis of rights from vague expressions that assume and enable new positions [...] the Law must be seen beyond the legal text, radiating the possibilities of building the legal in a plural and flexible scenario, guided by the principles backed by the human being, which are embodied in human rights-internationally-and in Fundamental rights and in human dignity, internally [83].

For this reason, the dialogue or structure or various fields and sciences, it will be promoted the inter relation between the agents involved in the generation of a new model of innovation, based on the scientific production but focusing in the sustainability of the State and the result of the industrial production.

The perspective of dialogue between the sources of the Law are adequate mechanisms for the production of legal answers, fomenting the plurality of truths. Therefore, it is necessary to deal with the interconnected plurality of sources, in imprecise and insecure ways, with new subjective features of Law, constructed from the content involved between subjects based on constitutional principles. Furthermore, this set will be among several areas of knowledgeincluding the Law [83]. As discussed above, a large number of regulations are already found in nanos, produced by various agencies and international institutions. Those frameworks, evaluations of risk and recommendations can be used to the generation of an internal normative framework. In the present case, the possibility of using the OECD in this specific study on nanowaste is defended.

In addition to the Dialogue between the sources of Law, there is the possibility of communication between different systems, according to Luhmann.

Niklas Luhmann, in the structuring of systems theory, considers that communication is the elementary operation for what is constructed in a social complexity. The author develops a communication theory that allows the understanding of the processes which happen in interactions, in the organizations and in the society [84]. It explains that social systems can arise within other social systems, generating its own meaning. Therefore the communication between both systems is possible, separated by a specific communication of each of them, creating an unique meaning [85]. Thus, the Theory of Systems would be a viable form of communication between diverse systems, which would develop a shared connection, making possible the coupling of subsidies from one system to another, when necessary, which means, "Structural co-ordination consists of a permanent adaptation between different systems, which maintain their specificity" [85]. Considering the nanotechnology demand the idea would be interesting, because there would be a viable the adoption of frameworks from other systems-outside the legal-such as Science, for example, once that its complexity hampers its adaptation to the social modern systems [86].

By another perspective, according to Gunther Teubner, there is the Legal Pluralism System. It is interesting and compatible with the legal loophole of nanotechnologies, and that would enable the response and

Page 15 of 17

use of appropriate instruments to the demands of the nanotechnology era. In the "Law, System and Policontexturality" lesson, the importance and use of informal norms from other spheres and organizations is reinforced, thus solving the problem of the absence of state norms, which in today's postmodern society would not even solve the demands endowed with complexity: Legal pluralism fascinates postmodern jurists, who no longer care about the official law of the centralized state and its aspirations of abstraction, generality, and universality. It is in the "asphalt law" of large American cities or in the "near right" of the favelas of Brazil, in the informal norms of alternative political cultures, in the quilt of minority rights, in the norms of ethnic, cultural and religious groups, In the disciplinary techniques of "private justice", and also in the internal regulations of formal organizations and informal networks that find all the ingredients of postmodernity: the local, the plural, the subversive. The diversity of fragmented and hermeneutically closed discourses can be identified through numerous informal types of rules, generated almost independently of the state and operating in various informal spheres. Legal pluralism thus discovers, on the "dark side" of sovereign right, the subversive potential of repressed discourses. The most diverse informal and local quasinorms are considered as supllément to the modern official, formal, centralized legal order. Exactly this ambivalence, duble character, is whats makes the juridical pluralism attractive to the eyes of the postmodern jurists [87].

Through this system it would be possible the utilization in the internal ambit of the "almost Law" norms, by the acceptance of informal norms from the alternative political cultures of the norms from the ethnic group, cultural and religious, in the disciplinary techniques from the "private justice" and of the internal regulation of the formal and informal networks [88].

According to Engelmann [89], it is the "moment of creativity for the Law through the valorization of multidimensionality". Soon, the dialogue or structure of several areas and sciences will promote the interrelation between the actors involved in the generation of a new model of innovation.

Edgar Morin warns, "We must know that science has no providential mission to save mankind, but it has absolutely ambivalent powers over the future development of mankind" [90], and the role of Law is this. It may not be able to achieve full answers to nanotechnological complexities, however, at least it must seek regulatory alternatives, even if the instruments are foreign to the legal environment, since these means may be the only ones able to manage demands never faced in a risk scenario before.

In this sense, the research proposed in this study demonstrates the possibility of using the OECD protocol as an instrument with regulatory potential as a way of risk management, correctly handling the nanotechnological wastes, and at least adopting minimally precautionary measures in order to preserve the present and future generations, as well as the environment of possible damages. This feasibility of adopting this protocol stems from the "dialogue" between three important theories of the legal world, any of which allows the coupling of the OECD instrument, promoting effective response to the management of the nanowaste, as well as taking precautionary measures necessary in the context of uncertainty and risk of nanos.

Conclusion

The recent paradigm shift of the power of new technologies has been raising imminent concern for environmental protection,

including (possible) harm to present and future generations. As can be seen from the large bibliography presented in the study and in recent scientific news, nanoscale production is in great growth, which consequently generates an increase in the deposit and disposal of residues with nanomaterials. There is no certainty about the (possible) damages that the disposal of these nanomaterials in the environment can cause, which reflects in the existence of the Risk, thus requiring a more effective precautionary measure in order to protect every ecosystem.

In this sense, we highlight the existence of recommendations and guidelines provided by the OECD, which conducted a large study on various forms of waste treatment, linking them directly to nanotechnologies, specifically nanowaste. However, even such research was not decisive enough to give scientific certainty about the efficacy of these treatments-such as recycling, incineration, water treatment and landfill-with the nanomaterials, since they were not 100% efficient at containing and filtering these nanomaterials. Particles in the environment.

It should be emphasized that such guidance proposes auxiliary preventive mechanisms. However, it should be notice that such a protocol had the purpose of minimizing the effects on the environment, and it was found that at least there was minimal containment and protection of the environment against nanomaterials and their emissions. Together with this orientation the Principle of Precaution is emphasized, which is a principological mechanism widely used in environmental causes in which the environmental risk of damage is imprecise but imminent and the absence of a precaution measure may cause inestimable damages to humankind.

Legislative abstention and government policies regarding nanotechnology regulation are absent and in the meantime nanomaterial discards are occurring by default, without any precautionary measures being taken to protect the environment. Thus, the guidance provided by the OECD shows a minimum regulatory framework that could be inserted in the national scenario, although the treatments do not contain absolute certainty of effectiveness, they corroborate with the minimization of the impacts of nanotechnologies on the environment.

Considering the context presented, there is an urgent need for the adoption of instruments with regulatory potential, which currently would be viable through the dialogue of the pertinent ideas in Legal Pluralism defended by Gunther Teubner in Luhmann's communication, as well as in the Dialogue Between the Sources of Law, advocated by Engelmann, which becomes more appropriate to the complexities and demands generated by nanotechnologies. Through this system, it would be possible to use "*almost law*" standards at the internal level [91], through the acceptance of informal norms of alternative political cultures, norms of ethnic, cultural and religious groups, disciplinary techniques of "private justice" and, internal regulations of formal organizations and informal networks [92].

References

- 1. Sebastian A (2015) The stakes of Robotics. Destination Science Themes. Naintré.
- 2. Abbott KW (2008) Soft Law Oversight Mechanisms for Nanotechnology. Jurimetrics J 52: 279-312.
- 3. Bowman D, Hodge G (2008) Governing Nanotechnology without Government. Sci Public Pol 35: 476, 479-484.

Page 16 of 17

- 4. http://www.desenvolvimento.gov.br/arquivos/dwnl_1296148052.pdf.
- 5. http://www.abdi.com.br/Estudo/GUTERRES%20EPOHLMANN %20APRSENTACAO%20FINAL%20corrigida.pdf
- 6. https://www.bmbf.de/pub/Action_Plan_Nanotechnology.pdf
- Sydneia Abel AA (2017) The governance of labor risks of nanotechnology and the legal framework of science, technology and innovation of Brazil-The governance of social and environmental risks of nanotechnology and the legal framework of science, technology and innovation in Brazil. pp: 26-40.
- 8. Ulrich B (2003) A world at risk-Translation by Laura Castoldi. Giulio Einaudi Publisher Sps Torino.
- Belokrylova EA (2011) The Legal Problems of Nanotechnology Environmental Safety Provision in the Russian Federation: The Foreign Country's Experience. Nanotech L Bus 8: 203.
- Boldrin A, Hansen SF, Baun A, Hartmann NI, Astrup TF (2014) Environmental exposure assessment framework for nanoparticles in solid waste. J Nanoparti Res 16: 2394.
- 11. http://www.camara.gov.br/proposicoesWeb/fichadetramitacao? idProposicao=567257
- 12. http://www.camara.gov.br/proposicoesWeb/fichadetramitacao? idProposicao=600333
- Britto RS, Garcia ML, Da Rocha AM, Flores JA, Pinheiro MV, et al. (2012) Effects of carbon nanomaterials fullerene C-60 and fullerol C-60 (OH) 18-22 on gills of fish Cyprinus carpio (Cyprinidae) exposed to ultraviolet radiation. Aqua Toxicol 114: 80-87.
- 14. http://www.lqes.iqm.unicamp.br/canal_cientifico/lqes_news/ lqes_news_cit/lqes_news_2014 /lqes_news_novidades_1844.html
- 15. Comissão E (2013) On the protection of the health and safety of workers from the potential risks related to nanomaterials at work: Guidance for employers and health and safety practitioners.
- 16. https://www.iso.org/committee/381983.html
- Wilson E (2017) Nanotechnologies and the management of risks generated during the biofuel production. Nanotechnology Solutions for Bioenery and Biofuel production. New York.
- Wilson E (2014) Nanotechnologies applied to food and Biofuels: building legal Models Founded on the precautionary principle. Nanotech, Food Biof 1: 49-98.
- 19. Wilson E (2015) The use of zinc nanoparticles in the plastic industry: will the consumer be safe? J Consum Law 102: 355-385.
- 20. Wilson E (2015) Nanotechnology as a factor of democratic approach of the countries of Latin America: searching for regulatory molds. Democratic Constitutionalism in Latin America: Challenges of the Century XXI. Curitiba: Multideia, pp: 105-122.
- Wilson E (2015) Nanotechnologies and the transdisciplinary management of innovation. Human Rights and New technologies. Jundiaí, Paco, pp: 49-78.
- 22. Wilson E (2011) Nanotechnologies and intellectual property: challenges and possibilities to the transdisciplinary Innovation Management. The Legal Protection of Technological Innovation. pp: 25-44.
- 23. Wilson E (2015) Nanocosmetics and the Right to Information: building Elements and the conditions to approximate the techno scientific development in the nano scale of Need to inform the consuming public.
- 24. Wilson E (2010) Nanotechnologies, regulatory frameworks and environmental law.
- 25. Wilson E (2014) Nanotechnology law and the (required) reconstruction of the structuring elements of category of "entitlement". Constitution, social systems and hermeneutics. Port Alegre: Lawyer Publisher, São Leopoldo: UNISINOS, pp: 339-359.
- 26. Wilson E (2011) The precautionary principle as a Fundamental right: the human challenges of research with the use of Nanotechnology. Fundamental Rights and State, Public policies & democratic practices, UNESC.
- 27. Wilson E, Cristina Port BI, Taís Ferraz G (2014) Civil liability and nanotechnologies. São Paulo: Atlas.

- 28. Wilson E, Machado VS (2013) The precautionary principle the Precautionary principle: building the Foundation for nano-compatible with the environment. Magazine of Environmental Law.
- 29. EPA-United States Environmental Protection Agency [https:// www.epa.gov/]
- EPA Agrees-to-regulate-novel nanotechnology-pesticides-after-legalchallenge. [http://www.centerforfoodsafety.org/press-releases/3817/epaagrees-to-regulate-novel]
- 31. European Union The European Commission's Science and Knowledge Service.
- FAO/WHO (2012) Food and Agriculture Organization of the United Nations/World Health Organization, Seminar on Nanotechnologies in food and agriculture Roma.
- 33. Faria Costa J (2005) Lines of criminal law and philosophy: some reflective crosses.
- Jonsecler F, Ribas I (2014) Co-exposure of the organic nanomaterial fullerene C60withbenzo[a]pyrene in Danio rerio (zebrafish) hepatocytes. Eviden Toxicol Intera Aqua Toxicol 147: 76-83.
- 35. Richard PF (2002) An invitation to penetrate a New field of Physics. SBPC Labjor / Brazil.
- European Union Nanosafety in Europe 2015-2025 (2013) Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovations. Finnish Institute of Occupational Health. European Cluster Nanosafety.
- Claudio F (2015) Self-regulation. Strategies of Law before Uncertainty and Globalization. Cambridge, Cambridge University Press.
- Mercè Darnaculleta GM (2015) Self-regulation and Law in Legislation. Strategies of Law before Uncertainty and Globalization. Cambridge, Cambridge University Press.
- Kenneth G (2012) Unsustainable Science in the Treadmill of Production: The declining Salience of Impact Science in environmental conflicts. Denver, American Sociological Association.
- Hatzigrigoriou NB, Papaspyrides CD (2011) Nanotechnology in plastic food-contact materials. J App Poly Sci 122: 3719-3738.
- High-Level Expert Group on Key Enabling Technologies, Final Report, June 2015 Kets: Time To Act, European Commission.
- 42. Raquel Von H (2015) Nanotechnology Revolution, risks and reflections in the law: the necessary contributions of transdisciplinarity. Human Rights and New Technologies. Jundiaí, Paco Publisher.
- HORIZON 2020 in short words: The Research and Innovation Framework Program I.
- 44. World Megatrends 2030 What international entities and personalities think about the future of the world? Contribution for a long-term debate for Brazil / organizer. Institute of Applied Economic Research.
- 45. ISO ISO/TC 229 Nanotechnologies (2005).
- 46. Sheila K (2013) Nanotech Innovation high, but playing catch-up on health and safety.
- 47. Shana K (2015) Disease Detector. Scientific American 313: 5.
- Harald KF (2014) Nanosafety Research-Are we on the right track? Angewandte Chemie International Edition, Wiley 53: 12304-12319.
- David L, Göran F (2013) Life cycle aspects of nanomaterials. Environmental Strategies Research KTH-Royal Institute of Technology.
- 50. Daniele Weber SL, Wilson E (2016) The final destination of nanomaterials: the precautionary principle as a basis for the standardization of nanotechnologies and their final waste. Environmental and Socioenvironmental Law II.
- 51. Daniele Weber SL, Wilson E (2017) Nanotechnology and the environment: The Initial movement of national regulatory framework in the context of (possibility) risks. Constitutionalism, economics and development Sustainable, IV Congress of Environmental Law.
- 52. Daniele Weber SL, Von Hohendorff R (2016) Development of nanotechnologies and the necessary application of bioethics as a guarantee of respect for human dignity. Biodiversity and animal rights II, XXV Congress Of (Shackles)-Curitiba.

Page 17 of 17

- Kerry JL (2007) In vivo imaging of transport and biocompatibility of single silver nanoparticles in early development of zebrafish embryos. American Chemical Society Nano 1: 133-143.
- 54. Gomes de Lima E (2014) Nanotechnology: Biotechnology and New sciences. 1st edn, River of January-Interciencia.
- 55. LQES News Bulletin (2016) How nanoparticles flow through the environment.
- 56. LQES News (2017) Newsletter Ministry discusses the regulation of products from nanotechnology.
- 57. Niklas L (2005) The Right of Society. 2nd edn, Herder-University Iberoamericana, Mexico.
- 58. Bianca Fell M (2013) Toxicological effects induced by the fullerene nanomaterials and nanosilver in the polychaete Laeonereis acuta (Nereididae) and in the bacterial communities living at their surface. Mari Environ Res 89: 53-62.
- Jonathan SM, Andrew MS (2014) Whole-cell-based assay bio-sensor Escherichia coli is dual zinc oxide nanoparticle toxicity mechanisms. Biosens and Bioeletron 51: 274-279.
- 60. MCTI (2013) Ministry of Science, Technology, and Innovation Dialogues for the regulation of nanotechnology-based products.
- Carlos Felipe M, Laura Meraz C (2012) Towards green nanoscience Nanomaterials and green nanoresidues. UNAM-Mexico University, Advan Mater, pp: 39-42.
- 62. Edgar M (2010) Science with Consciousness. 13th edn, Rio de Janeiro, Bertrand Brazil.
- 63. Musee N (2011) Nanowastes and the environment: Potential new waste management paradigm. Environ Intern 37: 112-128.
- 64. Nanoreg (2015) The Common European Approach to the regulatory testing of nanomaterials. 7th Progress Report Executive Summary.
- 65. Nanosciences and Nanotechnologies (2004) Opportunities and Uncertainties. Royal Academy of Engineering.
- 66. Nanotechnology Products Database (NPD).
- 67. https://www.nasa.gov/
- Roco Mihail C, Mirkin Chad A, Hersam Mark C (2011) Nanotechnology Research Directions for Societal Needs in 2020.
- 69. NIOSH-The National Institute for Occupational Safety and Health.
- 70. NIOSH (2016) Building a safety program to protect the nanotechnology workforce: a guide for small to medium-sized enterprises, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication.
- 71. Approaches to Safe Nanotechnology-Managing the Health and Safety Concerns Associated with Engineered Nanomaterials.
- 72. Bernd N, James FR, Stephen D, Julian AG, Chris M, et al. (2012) Potential scenarios for nanomaterial release and alteration by the company in the environmental. Environ Toxicol Chem 31: 2-15.

- 73. Oberdörster G (2014) Paper presented in the 7th International Nanotoxicology Congress, NanoTox, Antalya-Turkey.
- 74. OECD (2016) Nanomaterials in Waste Streams: Current Knowledge on Risks and Impacts, OECD. Paris.
- 75. https://issuu.com/oecd.publishing/docs/oecdobserver_306_q2_2016_lowres
- 76. OECD. The Organisation for Economic Co-operation and Development.
- Gonzalo OF (2013) Intraperitoneal Exposure to Nano/Microparticles of Fullerene (C60) Increases Acetylcholinesterase Activity and Lipid Peroxidation in Adult Zebrafish (Danio rerio) Brain. BioMed Res Intern 5: 20-50.
- 78. Part F (2015) Current limitations and challenges in nanowaste detection, characterization and monitoring. Waste Manag 43: 407-420.
- Matheus P, Glauciene PM, Jardim S, Wilson F (2010) The Nanomaterials and the Environmental issue. New Chem 22: 10.
- 80. Review of the Joint Research Strategy of the Higher Federal Authorities-Nanomaterials and other advanced materials-Application safety and environmental compatibility, Germany.
- 81. Rio Grande Do Sul. Legislative Assembly Proposed bill 19/2014. Makes mandatory and regulating the labelling of products of nanotechnologies and products that make use of nanotechnologies.
- Sao Paulo. Legislative Assembly Proposed bill 1456/2015 and makes mandatory labelling of products of nanotechnology and products use.
- 83. John S (2016) Nanotechnology: A Policy Primer. Congressional Research Service.
- 84. Steve S (2015) No Small Task-Generating Robust Nano Data.
- Swiss National Science Foundation (2017) National Research Programme NRP 64. Opportunities and Risks of Nanomaterials Results, Outcome and Perspectives-Final Brochure.
- 86. Gunther T (2005) Right, System and Polycanxturality.
- 87. The Conversation (2016) A guide to the nanotechnology used in the average home.
- Danish Environmental Protection Agency, Ministry of Environment and Food of Denmark (2015) Better Control of nanomaterials-Summary of the 4-year Danish initiative on Nanomaterials.
- The National Nanotechnology Initiative (2017) Supplement to the President's Budget 2017. Executive office of the President's National Science and Technology Council Washington, DC.
- 90. Klein G (2008) TUV SÜD Industry Service GmbH. Safety-relevant properties of Nanoparticles.
- 91. Klein G, Weidl T, Zöllner R. TÜV SÜD Industrie Service GmbH, Applying Nanotoxicology-A non-toxicologist's point of view, Germany.
- 92. http://www.tuv-sud.com.br/br-pt/sobre-a-tuev-sued/grupo-tuev-sued/ historia