

The promises and risks of nanotechnologies: regulation in Mexico

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Abstract

Nanotechnologies have been placed at the forefront of scientific knowledge. Their uses and applications have generated a wide range of technoscientific advances with impacts in different industrial fields. Research and development achieve unprecedented investment figures around the world. From the Optics, materials science and Biotechnology, to Medicine, the food industry and the military industry, the fact is that this new technological package has placed at the table of discussion the social repercussions that will bring with it. In addition, various organizations have raised their voices to discuss the consequences for human health and the environment that are already beginning to be seen. For this reason, the regulation of its use and its possible applications in the different stages of the value chain of products is playing a fundamental role in this debate, so this article seeks to present a panorama of the regulation of nanotechnologies in Mexico .

Nanotechnologies, regulation, value chain, environmental impacts, human health

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Introduction

The nanosciences and nanotechnologies have revolutionized the way in which the human being has made use of matter until a few years ago. The potential of the use and applications of this new technological package is, in fact, still uncertain.

Nanosciences are understood as that set of sciences that study, understand and manipulate matter at the nanoscale (10⁻⁹). At this scale, the material acquires novel characteristics and that it does not possess on a larger scale (hardness, adsorption, flexibility, conductivity, etc.), a fact that made them immediately attractive for an endless number of industrial spheres. Around the world these new sciences began to receive unprecedented amounts of investment from governments, private capital, international organizations and public-private investors. One part of the discussion focuses on this point, since each of these different actors have particular interests, interests that give a certain direction to the direction of research and the possible applications of this new knowledge.

Nanotechnologies, meanwhile, are the applications that these new sciences began to develop in different industrial spheres, either by manufacturing new components with nanoparticles, or by incorporating them into some materials to enhance their properties or make them more efficient (nano-polyporation). At this point, the debate has been presented by the few studies that have been developed around the effects of the use of nanoparticles, since some of these materials on a normal scale are toxic and highly toxic, so it is thought that their use can have serious repercussions for both human health and the environment.

Some organisms have raised their voices to stop their use before the investigations that conclude that the toxicological science does not possess the necessary knowledge or the sufficient technology to determine still in what way the nanoparticles, the nanomaterials or the nanoincorporations will impact.

These voices direct their attention, then, to the need to establish strict regulatory frameworks that balance the applied research of nanotechnologies with the pertinent nanotoxicological studies, in such a way as to ensure that from their manipulation in research centers, universities and laboratories until its commercialization it has under control the risks and impacts of those who manipulate them and potential consumers. We are talking, then, of safety and hygiene controls in those who study them, up to a control and surveillance in the labeling of those articles that contain nanoparticles, nanomaterials and nanoincorporations.

In this research, current issues regarding the state of regulation around nanotechnologies in Mexico will be presented, under the idea that in our country there is no government agency that manages the course of nanotechnologies.

Context: the promises and risks of nanotechnologies

In 2010, Stephen McGrail (2010) ensured that nanotechnologies (NT) could simultaneously project techno-scientific advances in the field of science fiction, or become scientific nightmares due to the scenario of potential risks that lie behind them. In his article, McGrail debates about the position of the "nano-optimists" and the "nano-pessimists", concluding that the development of these technologies would be marked, on the one hand, by the political-economic weight of the investors and, on the other hand, for the debate on the controls that can be established and their regulatory frameworks.

The position of the nano-optimists rests on a solid platform of applications with high impact. By manipulating matter at the nanometer scale, new materials and devices can be created that are used in sectors such as electronics, robotics, telecommunications, energy or medicine. Currently, devices are being developed capable of exponentiating the human capacities themselves. However, in the development of the same devices, the potential risks are always perceived as well as the foreseeable impacts for both human health and the environment.

For example, contact lenses with augmented reality are already on the market. The company Innovega is developing contact lenses (Ioptik) through eMacula, which allow to simultaneously visualize virtual content with real vision; it works by projecting virtual images onto the retina that pass through the lens's central optic and, by joining with the real vision, it will be perceived as one. Its manufacture contains nanocomponents that do not interfere with vision. These lenses have also been designed to improve the vision capabilities of the eye and can correct and enhance the sharpness of real-world vision.³ Although these lenses are still experimental, they are already being tested on elements of the US Army. However, the lenses are made with nanoclays that help increase the range of colors perceived, nanoclays that, through the retina, can penetrate ocularly capable and settle in the brain, enabling the formation of tumors and cancer; The medical debate, moreover, lies in the opinion about the ability of the human brain to be able to perceive and manage two simultaneous realities without causing any kind of disorder, under the idea that human vision is designed to perceive and manage only a reality to the time

Water is life, an international non-profit organization, is already commercializing water purification filters (Nano Water Filter), which work with carbon nanotubes; Activated carbon has the ability to filter contaminated water and is used in traditional water treatment methods for many years. The nanoscale carbon has the ability to accelerate the process and sanitize the water in just a few minutes.⁴ However, the medical sector is still debating about the indiscriminate use of carbon nanotubes since, on a nanometric scale, coal is much more toxic, so its use and consumption should be normalized and moderate. While it is true that NTs could potentially offer a social benefit of enormous impact by offering drinking water, especially in those populations where climate change has caused a huge shortage of the vital liquid, it is also true that sufficient knowledge must be available make its use sensible and not generate a greater evil than it is fighting.

The Bayer Company, on its own, is already producing and marketing a transparent plastic film capable of blocking oxygen, carbon dioxide and moisture before they can reach food. The plastic contains silica nanoparticles in a polymeric compound that also makes it lighter, stronger and more resistant to heat. Some types of plastic can triple the shelf life of some products. Intelligent containers have also been developed. They are integrated sensors, which detect food pathogens and cause the container to change color and alert the consumer if the food has become contaminated.⁵ Laboratory studies on food and beverages packed with silica nanoparticle coatings show that of the analyzed subjects (mice and rabbits), a high percentage (close to 90%) developed various diseases of the heart, liver and lungs, as well as Cutaneous type (Mahmoudi, 2012).

³ <http://www.emacula.io/>

⁴ <http://waterislife.com/clean-water/filter-systems>

⁵ <http://www.nanotech-now.com/columns/?Article=421>

Scientists from the nanotechnology department of Tel Aviv University have created a battery capable of recharging in 60 seconds. The battery called Flos Bateria that works with nanocrystals formed by amino acids and endures thousands of charge / discharge cycles; this system combines fast charging with a higher energy accumulation than the Lithium battery, and a special charger has also been developed. This battery has the potential to become a standard in the market for fast charging and the possibility to use it in electric vehicles is also open.⁶ In addition to this, batteries the size of a grain of sand are being developed. They have been built with a 3D printer that deposits a lithium oxide (LiO) paste, forming two comb structures with tiny electrodes that are less than 100 µm in size. Its loading and unloading capacity and life cycle are comparable to any current battery. These batteries are designed to be used in multiple existing devices, and will also allow the manufacture of new, even smaller ones.⁷

To conclude this section, we will analyze how one of the products most used by the industry, carbon nanotubes, exemplifies this duality of the NT. Carbon nanotubes (buckyballs) are used for a variety of applications. Nanomedicine has suggested its use to fix them in cancer cells to attack one by one, avoiding current medical techniques for the treatment of cancer such as radiation treatments. Some others are studying their properties to make them react with stem cells and achieve regenerative effects on human cells. Due to their high conductivity, they are used recurrently in everyday electronic devices such as lap tops, television screens, cell phones and computers.

Thanks to their strength, they are 1000 times more solid than steel, the construction industry is making use of these for the construction of superstructures and projects unthinkable constructions with existing materials.

However, we have already studied the environmental effects that carbon nanotubes (NTC) have brought with them; thus, these can be observed from the same production of the NTC, since these are achieved only at high temperatures with the technique of vapor deposition, a fact that generates both benzene and graphene, both greenhouse gases (GHG) that attack directly the ozone layer and are proven generators of global warming. And although the NTC production industry has not reached significant levels, the growth of this premium nanomaterial has been exponentially in recent years,⁸ doubling the production potential in less than 10 years (Brian Wang, 2016).

In various laboratory tests, it has been proven that they can be stored in high amounts in the abdominal cavities of mice as if they were asbestos fibers, killing them with cancer (Takagi et al., 2008); it is reported that once the carbon nanotubes enter the interstitial spaces they are captured by the alveolar cells, inducing toxic effects due to the formation of reactive oxygen species, which results in alterations in the DNA and inflammation, generating, between other things, fibrosis and pneumoconiosis (Galera, 2016).

When inhaled, certain fractions of size are deposited in the respiratory tract.

⁶ <http://www.understandingnano.com/batteries.html>

⁷ <http://www.sciencemag.org/news/2016/05/how-build-better-battery-throughnanotechnology>

⁸ <https://www.nextbigfuture.com/2016/12/water-can-freeze-at-105-to-151-degrees.html#more-841>

Due to their size they can be captured by the epithelial and endothelial cells and reach the bloodstream where they are transported to organs such as the bone marrow, lymph nodes, spleen or heart (Oberdörster et al, 2007).

The extent to which the central nervous system and the ganglia are translocated along axons and dendrites of neurons have also been observed. This phenomenon is the result of the biokinetics of the nanoparticles, which is different from the larger particles (Galera, 2015).

The particles accumulated in the alveolar region can be eliminated through three important routes. The first is through the mucociliary system along the tracheobronchial tract, the second route through the lymphatic system and, finally, from the dissolution of the nanoparticles; this last route, however, has the consequence of incorporating these nanoparticles into the bloodstream (Takenaka et al., 2000; Ávalos, 2013).

It should not be overlooked that the lungs send oxygen to the blood and the nanoparticles can travel there, reaching the cardiovascular, hepatic, renal and nervous systems, thus multiplying their impact factor.

Despite this series of evaluations, regulation around the value chain of carbon nanotubes is poorly regulated. This example can be expanded for the NT world in general, where its regulation, regulation, labeling, etc., is in an incipient stage.

Although there are countries where this concern is reflected in increasingly stringent laws, regulations and regulations, the truth is that products of all kinds circulate on the market (food, beverages, cleaning products, sunblocks, clothing, dyes, medicines and in extensive etcetera) with nanoparticles and nanoincorporations without knowing for sure what their impacts will be.

We will briefly describe how this regulation is found in our country.

The regulation of NTs in Mexico

In 2002, the Mexican government approved a new Science and Technology Law (LCyT), which redefines decision making in the sector, affecting the Organic Law of the National Council of Science and Technology (CONACyT) and the creation of Branch 38 that sectorizes the support of this organization to the Research Centers.

The new government line was aimed at supporting projects that promote the country's technological innovation. The areas considered as strategic were information technologies, biotechnology and materials science. The NT are not mentioned explicitly, since they were included in the energy section, although, as we have already mentioned, the NT participate in a large number of sciences.

This model of support is corroborated in 2008 in the Special Program of Science, Technology and Innovation (PECiTI 2008-2012). It is within the framework of this program that NTs enter fully as a priority area and are incorporated as a strategic area capable of influencing various industrial branches.

Economic support has increased, although the figures continue to appear lower compared to those of other nations with economies similar to ours.

The Ministry of Economy, in collaboration with the Center for Advanced Materials Research (CIMAV), conducted a study on nanotechnologies in Mexico, where he illustrated that between 1998 and 2004 the Mexican government, through CONACyT, supported a total of 152 projects of research worth \$ 14.4 million (CIMAV / SE, 2008). Takeuchi and Mora (2011) estimated that the total funds for research and development in the field, between 2006 and 2009, amounted to about 60 million dollars.

On the other hand, as a subsection of the National Development Plan 2007-2012, the National Expenditure on Science, Technology and Innovation (GNCTI) was established with the aim of supporting the development of new technological platforms, including nanotechnologies (CONACyT, 2014); but there is no disaggregated data for the NT.

Monica Anzaldo (2014), meanwhile, estimated that from 2002 to 2011 the total amount allocated to the NT in our country amounted to 1,800 million pesos (128 million dollars)⁹.

We are interested in highlighting these amounts since most of them were allocated to Research and Development and to the support of research centers, that is, to the implementation of applied technology. This corroborates the hypothesis of Edgar Záyago, who asserts that the public policy of NT development in Mexico has been concentrated in three areas: the creation of research networks, national laboratories, and industrial clusters (Záyago et al., 2014).

It stands out the almost null support to the investigation on the repercussions of the NT and to nanotoxicological studies in our country.

In addition to the economic support and the visualization of the NT as a strategic governmental sector, the way in which the activities are regulated is framed by what is presented in the international context.

The regulation of NTs at the international level is no longer an issue that obeys those that governments only mention. In multilevel governance frameworks, there are international organizations that establish standardization criteria that, little by little, each nation has the obligation to incorporate into its national and / or regional criteria. This new feature of scientific regulation frames the production and commercialization activity of new technologies, including, of course, the NT.

In this framework, in 2005, the International Organization for Standardization (ISO, for its acronym in English)¹⁰ formed the Technical Committee 229 for the standardization of the NT (ISO/TC 229)¹¹, which is made up of the international metrology institutes. Through these standardized norms, the basic measures for NT are established, essential concepts, rules of use and management, incorporation, etc. The member countries commit themselves to translate these standards into the specific context.

⁹ In this same period, the US agencies invested in NT a figure around 1.666 billion dollars. <http://nanodashboard.nano.gov/>

¹⁰ ISO is an international non-governmental and independent organization made up of 163 nations whose objective is that, through its members, it brings together

experts to share knowledge and develop voluntary international standards, based on consensus and relevant to the market, that support innovation and provide solutions to global challenges. <https://www.iso.org/about-us.html>

¹¹ <https://www.iso.org/committee/381983.html>

The NT regulation focuses on four aspects: 1, the enormous variety of nanomaterials and their potential applications; 2, the creation of data on the toxicological properties of nanomaterials, as well as their effects on the environment and on living organisms; 3, barriers in accessing information about these new materials, since copyright often interferes with toxicity studies; and 4, the lack of nomenclature and terminology.

In this regard, in 2006 the Organization for Economic Cooperation and Development (OECD) created the Working Group on Manufactured Nanomaterials (WPMN), which is one of the first efforts to establish regulation in the Manufacture of nanomaterials internationally. Until 2017, this body has established 59 direct responsibility standards on NT and 37 are under review and development process; It has 37 participating members, as well as 14 observer members.

In our country, it is the National Technical Committee for Standardization in Nanotechnologies (CTNNN) that is responsible for incorporating the parameters established by these organizations into the Mexican reality. The CTNNN was established in 2007 by order of the Mexican Institute for Standardization and Certification (IMNC), leaving the National Metrology Center (CENAM) as technical president in charge of the agency.

Its operation is, in turn, supervised by the Directorate General of Standards (DGN), which belongs to the Energy Secretariat, and is the coordinator of the provisions of the Federal Law on Metrology and Standardization (LFMN). According to this law there are three types of standards: the Official Mexican Standards (NOM), the Mexican Standards (NMX) and the Reference Standards. (NRF).

At the same time, the CTNNN acts as the International Standardization Committee Mirror of ISO / TC 229, whose function is to respond, in a collegial way, through the DGN, to the documents issued by ISO / TC 229. The Committee is made up of 33 institutions (13 from the academic sector, 11 from the industrial sector, 5 from the government sector, two national standardization bodies and a mirror committee).

Six are the fields of action: 1, terminology and nomenclature; 2, measurement and characterization; 3, health, safety and environment; 4, specifications of the materials; 5, social and consumer dimensions; and 6, relationship between nano and biotechnology.

To date, the CTNNN has already started 10 Mexican Standards (NMX)¹²:

1. NMX-J-699-ANCE-2014

Nanoscale electrical contacts and interconnections;

2. NMX-R-10867-SCFI-2014

Nanotechnologies Characterization of single-layer carbon nanotubes (NTCUC) using photoluminescence spectroscopy in the near infrared (EFL-IRC).

3. NMX-R-10929-SCFI-2015

Nanotechnologies Characterization of multilayer carbon nanotube samples (NTCMC).

4. NMX-R-12901-1-SCFI-2015

Nanotechnologies Occupational risk management applied to manufactured nanomaterials. Part 1. Principles and approaches.

5. NMX-R-13830-SCFI-2014

¹² <http://www.economia-nmx.gob.mx/normasmx/consulta.nmx>

Nanotechnologies Guide for the labeling of manufactured nano-objects and products containing manufactured nano-objects.

6. *NMX-R-27687-SCFI-2014*

Nanotechnologies Terminology and definitions for nano-objects, nanoparticle, nanofibre and nanoplate.

7. *NMX-R-62622-SCFI-ANCE-2014*

Nanotechnologies Description, measurement and description of dimensional quality parameters of artificial grids.

8. *NMX-R-80004-1-SCFI-2014*

Nanotechnologies Vocabulary. Part 1: basic concepts.

9. *NMX-R-80004-3-SCFI-2014*

Nanotechnologies Vocabulary Part 3: carbon nano-objects.

10. *NMX-R-80004-5-SCFI-2015*

Nanotechnologies Vocabulary Part 5: nano / bio interface.

There are also 4 NMX projects for different NT branches:

1. *PROY-NMX-J-699-ANCE-2014*

Nanoscale contacts and interconnections.

2. *PROY-NMX-R-10798-SCFI-2016*

Nanotechnologies Characterization of carbon nanotubes of a scanning electron microscopy layer and X-ray energy dispersion spectrometry.

3 *PROY-MNX-R-12901-2-SCFI-2016*

Nanotechnologies Occupational risk management applied to manufactured nanomaterials. Part 2: Use of the band control approach.

4. *PROY-NMX-R-80004-6-SCFI-2015*

Nanotechnologies Vocabulary. Part 6: caracerization of nano-objects.

While it is true that the effort to incorporate the standardization chain that ISO / TC 229 provides globally, so is the fact that in Mexico it is progressing at a very slow pace and with a smaller scale. Only ¼ of the technical standards published by this agency in the NT branch have been adapted by the CTNNN, and it should also be considered that of the 10 already stipulated in the Official Gazette, 5 are of terminology, and only 5 they are applicable to some stage of the NT value chain.

We would like to highlight, finally, that of the 11 members belonging to the industrial sphere within the CTNNN, 3 are business groups: the National Chamber of the Cosmetic Products Industry (CANIPEC)¹³, the Society of Cosmetology Chemists (SQC) and the Nanotechnology Cluster of Nuevo León, A.C. The first two have such a global economic power that they have stopped the legislation regarding the use of chemical materials in beauty, cosmetics and hair products. It is striking that no Mexican Standard, nor any project, touches those issues.

¹³ Quien agrupa a poderosas empresas del ramo como Procter & Gamble, Frabel (L'Óreal), Avón, Revlon, entre otras.

Conclusions

NTs are a technological package that has been placed at the forefront of modern scientific knowledge. Being a knowledge of the matter at a still unknown scale, its uses and applications have generated amazement for its innovative devices until a debate for the repercussions that can cause both human health and the environment.

The R & D in this field of science is mainly inclined towards applied science, where the amounts of investment from national governments and international organizations, to private investors and large capitals. However, this R & D does not address the repercussions that nanoparticles and the series of incorporations made with nanomaterials are known to bring.

Nanotoxicology has raised its voice to make public alarming results in laboratories about the use of nanotechnologies in animals, so it is expected that its indiscriminate use in humans will have large-scale repercussions. Some even claim that we are the generation samples of the NT.

At the international level, organizations such as ISO, OECD, Friends of the Earth, PETA, etc., have managed to put the issue on the table, in such a way that some national governments and international standardization systems are already taken into account by governments to implement policies and production standards with respect to the NT.

However, these only reach the level of partial obligations or voluntary implementations, so the ground to follow remains broad.

The discussion should focus on making an analysis of the value chains where the NTs are involved in order to accurately locate in what stage it is involved, in what degree and in what way it can affect human health and the environment.

In Mexico there are already 10 Mexican Standards that try to establish production and management standards for those industries that manage and incorporate NT; there are 4 more that are in draft Standards. There is a Committee specialized in the field where they meet, in an interesting exercise of governance, governmental entities, academics and industry, where these issues are discussed in diverse analysis tables. This Committee serves as a body / mirror of what ISO / TC 229 points out internationally, although until now it has only managed to implement 1 of every 4 norms that this organism has stipulated for its member countries.

The professionalization, as well as the incorporation of knowledgeable members in the subject, are two priorities that this Committee must take into account, since, according to data from the ETC, every day four new products with NT are incorporated into the market without necessarily having been tested. its possible effects, without proper labeling and without precise knowledge of its benefits.

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