Nanotechnology regulation context

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J. Nano Sc. Tech, **3**(2015)4-9

After more than a decade of sustained R&D in nanosciences and nanotechnologies, together with its growing presence within market, the countries are slowly starting to regulate those products which contain nano-objects. These materials evidence different properties as when their size is bigger [2]. So, for instance graphite, which is soft and an electrical conductor, when is worked in nanoscale and converted into carbon nanotube may be 100 times harder than steel and a superconductor. Gold, which is not chemically reactive as we know it, becomes reactive when in nanoscale and it is useful, therefore, for making sensors (Rao, 2011). According to the Woodrow Wilson International Center for Scholars there are over 1 800 products with engineered nano-objects in the market (WWICS, 2012). These range from sporting goods to weapons of war, and from food to cement and paints.

Nevertheless, there are a number of difficulties to define and classify such materials. Should they be considered as nano-objects when they have over 100 nanometers but develop different functions as when the material is in bulk? Taking into account that nano-objects can be functionalized, i.e., adapted to particular functions, is there any way to establish a homogeneous regulation criterion for hundreds or thousands of different particles? [3] Should be it considered as a "new material" the one which having been unregulated within market for several years is now introduced as nano size? Is current legislation regulating chemical products suitable for the nano-objects? Should legislation include the engineered nano-objects, the nano-objects which fortuitously arise from productive processes and the nano-objects produced by nature, or just those engineered nano-objects? These and many other questions are under discussion at the negotiating table.

In the past few years, two reasons have accelerated the discussion concerning the nanotechnology regulation. One refers to trade while the other concerns health. In order to market products they must be able to be identified, classified and registered, so as to meet the international

accounting requirements, insurances, national laws, international agreements and so on. When two countries have different regulations, trade becomes difficult. The European Union, for example, demands labeling of food, cosmetics and biocides containing nano-objects [4]. Therefore, if any country exports to the European Union, such products shall be labeled, even when not required in their domestic market. Some European countries (France, Belgium, Denmark) request the producers or marketers of nanotechnology products to be registered, including the characteristics and properties of such products; this means that if an exporter sends its product to these countries this information shall be enclosed, though the latter is not obtained from the producer in its country, thus arising a practical and administrative issue. There is an ongoing negotiation relating the regulatory harmonization between the United States and Europe, in accordance with a potential free trade agreement (Ahearn, 2009). Nanotechnologies represent one of the chapters on such agenda. It is known that the requirements imposed by the European Union to the chemical products overcomes those imposed by the United States (USA) (European Parliament, 2014). Some of the substantial differences between both economical blocs can be compared in Chart 1.

Subject	USA	EU
Precautionary principle	Known Risks Policy	Yes
Hazard vs. risk	Risk management	Address hazard over risk
Management of risks	Cost / benefit	ESLI included
Producer responsibility	Safety assumption	"No data no market"
Property rights	Priority	1st. Basic civil rights

Cart 1. Main differences in regulatory policy between USA and the European Union (source: the author)

This chart shows an overview of the substantial differences between the economical blocs. The precautionary principle, which is part of the European legislation, points out that whenever any activity represents a threaten or hazard to human health and/or the environment some precautionary measures should be taken, even though there are no causal relationships scientifically proven (European Union Legislation, 2000) [5]. USA, meanwhile, is against it, arguing

that the Precautionary Principle represents an obstacle to trade (Sunstein, 2005). According to the United States legislation, in order to remove a product from market or block its market entry it must be demonstrated that scientifically proven risks are involved.

The difference between hazard and risk is part of the already known environmental discussion. Hazard means, for example, a poison; but if it is controlled, may not represent a risk. USA always prefers to control risks, and tries not to include the term hazard in its agreements. The EU firstly intends to substitute the hazardous product or reduce it and when not possible or secondly, to control the risk; therefore, the terms are important, because they pose a legal background.

ELSI (Environmental, Legal, Social Issues) studies suggest that additionally to costs and economical benefits, monetarily calculable, there exist various social benefits and costs (ethical, cultural, working, etc.) which although unable to be measured monetarily must be included within the evaluation criteria concerning activities, processes and materials. USA, meanwhile, aims to use cost/benefit monetary criteria for its evaluations. What USA really intends is to manage the risk, by reducing it or establishing compensatory criteria, while the EU policy is to set broader social and political criteria before monetary analysis.

While the US policy implies that the producer is responsible and will not place risky products on the market, the EU policy requires the producer to prove that the product is safe.

Property rights are a basic element in the US policy, which explains why its governmental agencies are against any kind of registry, or labeling of nanotechnology products affecting business confidentiality. On the other hand, the EU stipulates that the civil rights are a priority over those of property; and certain national legislation, such as Belgium, requires the producer to report the workers about the risks of the materials they handle (InVS, 2014), which might be considered as an infringement to business confidentiality by the USA legislative framework.

These and many other theoretical differences between both economical blocs are not always met in practice, though that is no reason to avoid homogenization whenever possible. Besides, each bloc has institutions with different interests, which push for interpreting legislation one way or another. In general, the Ministries of Health, Environment and Labor are more prone to

regulations safeguarding health and the environment, while the Ministries of Finance, Economy, Commerce and the Executive Power press to make laws and regulations more flexible; this is inherent to the role of the institutions within society, some protecting health and the environment and the others protecting the free trade economical trend which permeates most of nowadays economical policies.

Another reason for nanotechnology regulation is the potential risk to health and the environment involving the nano-objects. This is also a matter of controversy. If we consider that ten years ago many politicians and scientists argued that the legislation in force was enough to take the risks of the nano-objects, or that nano-objects offered no risks, not many of them defend this position nowadays. On the one hand, because there is enough scientific literature about risks involving certain kind of nano-object, because they not only evidence different physical and chemical properties, but also biological activity and, subsequently, toxicological (Colvin, 2003; Donaldson, Stone, Clouter, Renwick, & MacNee, 2001; Nel, Xia, Mädler, & Li, 2006; Oberdörster, Oberdörster, & Oberdörster, 2005). On the other hand, because several institutions have already taken the lead in order to develop guidelines for workplace safety (e.g. CDC NIOSH, 2009), monitor the health of workers (InVS, 2014), or suggest more severe regulations for specific nanomaterials in certain products, due to their potential risks (Swedish Chemicals Agency, 2012). As an example we can mention the sunscreens with titanium dioxide nano-objects (TiO_2), which may be found in the market [6]; however, the NIOSH, the American agency researching Occupational Health, based upon the extrapolation of test results in mammals has classified this mineral as a potential carcinogenic for workers when present in nanoscale and recommends, the same as with carbon nanotubes, the least possible exposure (Murashov, 2011; NIOSH, 2010, 2011). Although there is no enough empirical information on adverse outcomes for health or the environment derived from nano-objects included in daily consumption stuff, the global pandemic provoked by chemical products within market is a wake-up call (UNEP, 2013a).

International organizations also play a relevant role in regulating nanotechnologies. For example, the ISO (International Organization for Standardization) has already issued several ISO standards for nanomaterials. Albeit voluntary, once the countries subscribe this type of regulations, its

application must be accepted. Another example is the SAICM (Strategic Approach to International Chemicals Management), a non-binding, multilateral international platform, aiming to sustain the chemicals management. SAICM actions derive from the consensual agreements of the ICCM (International Conference on Chemicals Management). The ICCM Third International Conference was held in 2012. It was then that the III/2 resolution on policy emerging issues was adopted, where manufactured nanomaterials and nanotechnologies were included (UNEP, 2013b). Although the agreements are non- binding, this represents a commitment of the signatory governments, among which almost all countries in Latin America are included.

In the light of this kind of differences between the major economic blocs, and due to their participation in the international organizations discussing these issues, the developing countries, lacking an important trade negotiating power and the conditions to perform independent toxicological evaluations, do not know which way to go. This is the case of most of the Latin American countries.

Nanotechnology regulation in Latin America

Almost all countries in Latin America have nanotechnology research groups (Foladori & Invernizzi, 2013). Moreover, the governments have declared nanotechnologies, together with the communications and information technologies and the biotechnologies, as priority development areas (Foladori, 2013). The latter does not imply the development of national programs or specific funding, although the major countries -Brazil, Mexico and Argentina- did develop them. Together with R&D carried out mostly with public funds and in public institutions, several companies, mostly private, also perform research, produce and/or commercialize nanotechnology products. In Brazil, for instance, it is estimated that there are over 200 products in the nanotechnology market (Invernizzi, 2009) [7], in Mexico over 150 (INEGI & CONACYT, 2013; Záyago, Foladori, & Arteaga, 2012), in Argentina around 30 (FAN, 2012).

Government representatives, as well as from NGOs and other Latin American institutions have participated in SAICM regional seminars where the nanotechnolgy issue was discussed, and

regulation specific measures were proposed (Bejarano, 2012; Foladori, Bejarano, & Invernizzi, 2013). Latin American unions and union federations have referred to nanotechnologies (Foladori, Appelbaum, Záyago Lau, & Invernizzi, 2013; Foladori & Invernizzi, 2008).

Progress on nanotechnology regulation in Latin America is emerging. Mexico, through its Secretary of Economy, has developed voluntary guidelines for the Federation bodies [8]. This is the most advanced in terms of governance in Latin America. In Brazil some Bills are under discussion and this issue has been taken into account during meetings of the Nanotechnology Interministerial Committee. The Red Venezolana de Nanotecnología (RedVNano) and Cuba have held joint meetings; and the Red Colombiana de Nanociencia y Nanotecnología (RedNanoColombia) created a National Advisory Council on Nanosciences and Nanotechnology (CNANANO) whose tasks, among others, are the nanomaterial standardization and regulation (Urquijo, 2015); Argentina has staff in the ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) and the INTI (Instituto Nacional de Tecnología Industrial) working on this issue.

Both Brazil and Mexico participate in the Technical Committee ISO/TC 229, *Nanotechnologies* for developing ISO standards on nanotechnology, which forces them to adopt them [9]. ISO defines nanotechnologies from two alternative criteria: size (typically but not exclusively less than 100 nanometers), and function (different versus larger material). This implies that when the material differs from its properties in larger size it can be considered as a product of nanotechnologies, even though size requirement is not met. And, any material below 100 nanometers can be also considered as such although no new properties are shown [10]. Mexico has already issued some national standards reproducing the ISO standards (e.g. NMX-R-80004-1-SCFI-2013 vocabulary and basic concepts). Despite being a member, Brazil has not participated at ISO meetings since 2008, and although the equivalence with national standards ABNT has not yet been performed, all indications are in favor of it.

Another common aspect between Brazil and Mexico refers to the Precautionary Principle. Several legislative documents concern precaution or precautionary measures in both countries. But more recently they have explicitly introduced the concept of “Precautionary Principle”. In the case of Brazil, it is included in Decree No. 5098, as of 06/3/2004 concerning the creation of the “Plano

Nacional de Prevenção, Preparação e Resposta Rápida a Emergências Ambientais com Produtos Químicos Perigosos – P2R2", and also in the Act No. 11105, as of 03/24/2005 (Biosecurity Act) [11]. In the case of Mexico it is included in the "Ley de Bioseguridad de Organismos Genéticamente Modificados" (LBOGM) as of 2005. Therefore, there is legal background in these countries for the eventual application of the Precautionary Principle to nanotechnologies.

Mexico, meanwhile, is part of NAFTA (North American Free Trade Agreement) which forces the country to discuss the regulations with its major business partners. In fact, it has been the US government the one to pose the need to regulate several products, including nanotechnologies, both with Mexico and Canada. In 2011, the High Level Regulatory Cooperation Council U.S. – México was created (High Level Regulatory Cooperation Council, 2011). Its purpose was the regulatory harmonization to simplify the commercial mechanisms [12]. Nanotechnologies were one of the issues included on the schedule of this council [13].

The starting point of the regulatory harmonization about nanotechnologies was a Memorandum prepared by the Office of Science and Technology, the Office of Information and Regulatory Affairs, and the Office of the United States Trade Representative under the title "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials" (hereinafter, Principles) (Holdren, Sustain, & Siddiqui, 2011). Although the Principles were addressed to the agencies in the United States, they were sent to the Mexican officials as a basic framework to be taken into account for nanotechnology regulation in Mexico (United States-Mexico High-Level Regulatory Cooperation Council, 2012). Mexico created a working team coordinated by the CENAM (Centro Nacional de Metrología – Secretaría de Economía) for the development of regulatory guidelines on the basis of the Principles submitted by the United States. At the end of 2012, the Undersecretary of Competitiveness and Regulations of the Secretary of Economy submitted the document known as "Lineamientos para regulaciones sobre nanotecnologías para impulsar la competitividad y proteger al medio ambiente, la salud y la seguridad de los consumidores" ("Guidelines for nanotechnology regulations to encourage competitiveness and protect the environment, health and consumer safety") (hereinafter, Lineamientos –Guidelines-) (Grupo de trabajo sobre regulaciones para la nanotecnología, 2012).

Between the Principles and the Lineamientos (Guidelines) there are a few differences. Both are very general documents as it corresponds to such guidelines. In the following chart the most important elements in both documents are compared

Subject[14]	**Principles – USA**	**Lineamientos -México. #.**
General criteria		
Aiming to increase competitiveness		
Case by case. No generalizing regulation		
Privilege risk over hazard		
Market entry of products with nano-objects not subject to the development of a regulation		
Principles		
Based on scientific evidence		#2
Develop information on potential effects to health and the environment		
Transparency of information when not threatening safety /or business confidentiality		#3 and #9
Public information on benefits and risks		#8
Cost / benefit analysis		Risk evaluation & ELSI #5
Flexibility to adapt to new knowledge		#2
Use risk evaluation standard procedures		#1
Mandatory risk evaluation according to the degree of risk identified		

Coordination with agents and authorities involved		#10
Internacional cooperation and coordination		#7 and #11 #12
Occupational health care		#4
Require toxicity information from producers and marketers		#6

Chart 2

Comparison between the “Principles” of the United States and the “Lineamientos” of Mexico

The general trend of both documents is to benefit trade, avoiding unnecessary obstacles and promoting competitiveness, as expected from working teams which arise associated to the Secretaries of Trade. It is also implicit that lack of regulation does not prevent product marketing, which are explicitly acknowledged as already being in the market and continue to enter. While the United States Principles conform to the argument of the key issues written down on Chart 1, in the case of the “Lineamientos” from Mexico the argument is not always enclosed. So, for example, while the “Lineamientos” match the Principles as regards regulation based on scientific evidences, closing doors to the Precautionary Principle –although this principle already exists in the Mexican biosecurity law- they stay apart from the US position as regards the cost / benefit analysis as an evaluation criterion, introducing the ELSI (Environmental, Legal, Social Issues) analysis, as well as when introducing an item related to occupational health and another one about toxicity request to producers and marketers. But these guidelines are just the beginning. The initial committee is holding meetings and making broader calls in order to take more significant steps, while developing the Mexican standards as a counterpart of the international ISO standards.

In Brazil the attempts to start the regulation date back to 2005 [15]. The first of them is the Bill No 5076/2005 which intended the creation of the Nanosafety National Technical Committee and the Nanotechnology Development Fund. In this draft it was argued that nanotechnology implies health and environmental risks and it is necessary that the consumer is aware of the

nanotechnology products and safety is controlled. The draft was rejected by arguing that it would inhibit the investments and that the existing legislation would suffice.

In 2010 a draft for labeling food, medicines and other products subject to the sanitary monitoring regime was submitted, such Bill, the PLS 131/2010, intended to ensure the consumer right to information about the nanotechnology products; this draft was also rejected with arguments stating that there is no scientific evidence showing risk, and that labeling might negatively induce the consumer perception.

In March and November 2013, Bills 5133/ 2013 and 6741/2013 were submitted. The first one intends to label all products based on nanotechnology; and in the case of cosmetics, food and drugs labeling should include the nano raw material used. The second one intends to set up a Nanotechnology National Policy, focusing on the research incentive, technological development and control by the Public Power of risks and impacts. Both Bills are under study by the Chamber of Deputies.

Parallel to the Bills, and regardless of these, the Nanotechnology Interministerial Committee has started to discuss the regulation issue. In the event that any of the Bills is passed, they could conflict with the work on progress of the Interministerial Committee.

Conclusions

The different Latin American countries have nanotechnology R&D, they also market and several of them produce nanotechnology end consumer products.

The various free trade agreements already signed or to be signed by the countries, the potential incorporation of some of them to the OCDE, together with their participation in instances of international discussion having working committees about nanotechnologies, such as the International Conference on Chemicals Management, the Strategic Approach to International Chemicals Management, the World Health Organization, the United Nations Environmental Program and the International Labor Organization, are pushing for countries to develop standards and regulate nanotechnologies.

Considering the evolution of regulations worldwide, several countries have started to discuss this topic. Mexico is the most advanced of them, having developed a few voluntary guidelines at the request of the United States, largely reproducing the document submitted by the USA government as a basis for discussion. In addition, Mexico has locally adopted the equivalent of several international ISO standards. Brazil has not participated in the ISO standards nanotechnology group since 2008, despite being a member of such group; that has obstructed and slowed down the development of equivalent domestic standards. Besides, Brazil faces the problem of having a pair of Bills under discussion in the Senate when the Nanotechnology Interministerial Committee is just starting to deal with this issue. Colombia, Argentina, Cuba and Venezuela have held specific meetings to progress on this field.

References

Ahearn, R. J. (2009). Transatlantic Regulatory Cooperation: Background and Analysis. Retrieved September 7, 2014, from http://www.europarl.europa.eu/meetdocs/2009_2014/documents/d-us/dv/d-us_transatlantic_regulatory/d-us_transatlantic_regulatory_4.pdf

Bejarano, F. (2012). Las nanotecnologías como tema emergente en la agenda ambiental internacional y los restos de la sociedad civil en América Latina. In G. Foladori, E. Záyago, & N. Invernizzi (Eds.), Perspectivas sobre el desarrollo de las nanotecnologías en América Latina. México, DF: Miguel Angel Porrúa.

CDC NIOSH. (2009, March). Approaches to Safe Nanotechnology. CDC (Center for Disease Control and Prevention). Retrieved from http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf

Colvin, V. L. (2003). The potential environmental impact of engineered nanomaterials. Nature Biotechnology, 21, 1166–1170.

Donaldson, K., Stone, V., Clouter, A., Renwick, L., & MacNee, W. (2001). Ultrafine particles. Occupational and Environmental Medicine, 58, 211–216.

European Parliament. (2014, November). ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP). European Parliament. Retrieved from http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2014)536293

European Union Legislation. (2000, February 2). The precautionary principle. Retrieved November 24, 2014, from http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm

FAN. (2012). Quién es quién en nanotecnología. Buenos Aires: Fundación Argentina de Nanotecnología.

Foladori, G. (2013). Nanotechnology Policies in Latin America: Risks to Health and Environment. Nanoethics, 7(2), 135–147. doi:10.1007/s11569-013-0178-2

Foladori, G., Appelbaum, R., Záyago Lau, E., & Invernizzi, N. (2013). Nanotecnología y trabajo: la declaración de Curitiba. Observatorio Del Desarrollo, 3(9), 73–79.

Foladori, G., Bejarano, F., & Invernizzi, N. (2013). Nanotecnología: gestión y reglamentación de riesgos pra la salud y el medio ambiente en América Latina y el Caribe. Trabalho, Educação E Saúde, 11(1), 145–167.

Foladori, G., & Invernizzi, N. (2008). The workers push to democratize nanotechnology. In E. Fisher, C. Selin, & J. Wetmore (Eds.), The Yearbook of Nanotechnology in Society. UK: Springer.

Foladori, G., & Invernizzi, N. (2013). Inequality gaps in nanotechnology development in Latin America. Journal of Arts and Humanities, 2(3), 36–45.

Foladori, G., & Záyago Lau, E. (2014). The regulation of nanotechnology in Mexico. Nanotechnology Law & Business, 11(2), 164–171.

Grupo de trabajo sobre regulaciones para la nanotecnología. (2012, November 26). Lineamientos para regulaciones sobre nanotecnologías para impulsar la competitividad y proteger al medio ambiente, la salud y la seguridad de los consumidores. Secretaría de Economía. Retrieved from

http://www.economia.gob.mx/files/comunidad_negocios/normalizacion/dgn/2012_11_27_Lineamientos_regulaciones_nanotecnologia.pdf

High Level Regulatory Cooperation Council. (2011, March 3). Terms of Reference for the High-Level Regulatory Cooperation Council. Retrieved from http://www.whitehouse.gov/sites/default/files/omb/oira/irc/high-level_regulatory_cooperation_council-terms_of_reference_final.pdf

Holdren, J. P., Sustain, C. R., & Siddiqui, I. A. (2011, June 9). Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials. Memorandum for the heads of executive departments and agencies. Retrieved from http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf

INEGI, & CONACYT. (2013). Presentan CONACYT e INEGI los principales resultados de la encuesta sobre investigación y desarrollo tecnológico y módulo sobre actividades de biotecnología y nanotecnología (ESIDET MBN) 2012 (Boletín de Prensa No. 485 /13) (p. 2). Aguascalientes, Ags. México: INEGI / CONACYT. Retrieved from http://www.inegi.org.mx/inegi/contenidos/espanol/prensa/Boletines/Boletin/Comunicados/Especiales/2013/noviembre/comunica35.pdf

Invernizzi, N. (2009, November 4). Nanotechnology in Brazilian firms: assessing potential implications for labor. Power Point presented at the Emerging Technologies/Emerging Economies: (Nano)Technologies for Equitable Development, Washington DC. Retrieved from http://nanoequity2009.cns.ucsb.edu/images/stories/presentations/presentation%20noela%20invernizzi.pdf

InVS. (2014, November 18). Le programme EpiNano, dispositif de surveillance épidémiologique des travailleurs potentiellement exposés aux nanomatériaux. Retrieved November 24, 2014, from http://veillenanos.fr/wakka.php?wiki=EpiNano

ISO. (2014, November 25). ISO 2011 Business Plan. Retrieved November 25, 2014, from https://www.google.com.br/?gfe_rd=cr&ei=BZR0VLPzMoaX8QevhYHoAg&gws_rd=ssl#q=the+fore

most+aim+of+international+standardization+is+to+facilitate+the+exchange+of+goods+and+services+through+the+elimination+of+technical+barriers+to+trade

ISO. (n.d.). ISO – Technical committees – ISO/TC 229 – Nanotechnologies. Retrieved November 25, 2014, from http://www.iso.org/iso/iso_technical_committee?commid=381983

Murashov, V. (2011, May 9). Titanium Dioxide: A Changing Paradigm in Occupational Risk Management. Retrieved from http://blogs.cdc.gov/niosh-science-blog/2011/05/tio2/

Nanowerk. (2014). Nanowerk Database. Retrieved from www.nanowerk.com/phpscripts/n_dbsearch.php

Nel, A., Xia, T., Mädler, L., & Li, L. (2006). Toxic potential of materials at the nanolevel. Science, 311, 622–627.

NIOSH. (2010). Occupational Exposure to Carbon Nanotubes and Nanofibers. NIOSH (National Institute for Occupational Safety and Health). NIOSH Current Intelligence Bulletin Department of Health and Human Services. Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-161-A/0161-A-110110-DraftDocument.pdf

NIOSH. (2011). Occupational Exposure of Titanium Dioxide. NIOSH (National Institute for Occupational Safety and Health). NIOSH Current Intelligence Bulletin 63. Department of Health and Human Services. Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf

Oberdörster, G., Oberdörster, E., & Oberdörster, J. (2005). Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. Environmental Health Perspectives, 113, 823–839.

Rao, C. N. . (2011). Nanoworld. An Introduction to Nanoscience and Technology. Bangalore: Navakarnataka.

Robles-Montoya, A. . (2013). Proposición al Senado de la República relativo al diseño de un progrma de investigación y desarrollo de la nano ciencia y la nanotecnología. Senado de La República. LXLI Legislatura Del Congreso de La Unión. México. Retrieved from http://www.senado.gob.mx/?ver=sp&mn=2&sm=2&id=43871

Sunstein, C. R. (2005). Laws of Fear: Beyond the Precautionary Principle. Cambridge University Press.

Swedish Chemicals Agency. (2012). Antibacterial substances leaking out with the washing water - analyses of silver, triclosan and triclocarban in textiles before and after washing. Swedish Chemicals Agency. Retrieved from http://www.kemi.se/Documents/Publikationer/Trycksaker/PM/PM1_12_Antibact_eng.pdf

The White House. (2011). UNITED STATES–CANADA REGULATORY COOPERATION COUNCIL. Joint Action Plan. The White House. Retrieved from http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf

UNEP. (2013a). Global Chemicals Outlook – Towards Sound Management of Chemicals. United Nations Environment Programme. Retrieved from http://www.unep.org/hazardoussubstances/Portals/9/Mainstreaming/GCO/The%20Global%20Chemical%20Outlook_Full%20report_15Feb2013.pdf

UNEP. (2013b, February 5). Outcomes of the Third International Conference on Chemicals Management (ICCM3) 17-21 September 2012, Nairobi, Kenya. United Nations Environment Programme.

UNESCO / COMEST. (2005, March). The Precautionary Principle. Retrieved November 25, 2014, from http://unesdoc.unesco.org/images/0013/001395/139578e.pdf

United States-Mexico High-Level Regulatory Cooperation Council. (2012, February 28). United States-Mexico High-Level Regulatory Cooperation Council Work Plan. Excecutive Office of the President of the United States. Retrieved from http://www.whitehouse.gov/sites/default/files/omb/oira/irc/united-states-mexico-high-level-regulatory-cooperation-council-work-plan.pdf

Urquijo, W. (2015). Colombia frente a la regulación de las nanotecnologías. In G. Foladori, E. Záyago Lau, N. Invernizzi, & A. Hasmy (Eds.), Nanotecnologías en América Latina. Trabajo y Regulación. México D.F.: Miguel Ángel Porrúa (en prensa).

WWICS. (2012). A nanotechnology consumer products inventory project on emerging nanotechnologies. Washington DC: WWICS (Woodrow Wilson International Centre for Scholars). Retrieved from http://www.nanotechproject.org/inventories/consumer/

Záyago, E., Foladori, G., & Arteaga, E. (2012). Toward an Inventory of Nanotechnology Companies in Mexico. Nanotechnology Law & Business Journal, 9, 283–292.

[1] ISO TS 27687 Definition for Nano-object: material with one, two or three external dimensions in the nanoscale (between 1 and 100 nanometers approximately) (ISO, n.d.).

[2] Biological, magnetic, optical, mechanical, chemical and physical properties. These new properties may be found in some materials having over 100 nanometers in any dimension.

[3] Nanowerk database had over 3 000 nano raw material in October 2014 (Nanowerk, 2014).

[4] *Cosmetics*. Regulation (EC 1223/2009). Product must be submitted 6 months in advance to market launching; with list of ingredients and exposure and toxicological characteristics. The product must be labeled including ingredients. *Food*. Regulation (EU No. 1169/2011). Similar to Cosmetics. *Biocides*. Regulation (EU) 528/2012. The product requires previous authorization, more specification than in previous cases and labeling as well.

[5] This principle became general as from the Conference on Development and Environment, held in Rio de Janeiro in 1992: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (UNESCO / COMEST, 2005, p. 12).

[6] According to NIOSH, the TiO2 is broadly used in commercial products such as paints, cosmetics, plastic, paper and food as anti-coagulant or bleaching agent.

[7] With information updated by the author.

[8] Moreover, at the end of 2013 a proposal by the Science and Technology Committee of the Senate required the establishment of a nanotechnology development program and its regulation, in order to speed up its development and taking into account the potential risks of the nano-objects manufactured to human health and the environment (Robles-Montoya, 2013). This proposal is still pending.

[9] As of today, there are about 42 ISO technical standards. ISO standards aim to ease the commercial exchange. "The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade" (ISO, 2014).

[10] "1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications, 2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties (ISO, n.d.).

[11] I thank Raquel Von Hohendorff for this information por esta información.

[12] Another similar Council, between the United States and Canada, was also created (The White House, 2011).

[13] Further information about the Mexican case may be seen in Foladori & Záyago Lau (2014).

[14] Here we summarize the main aspect of every one of the 10 Principles, or the 11 Lineamientos.

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