

The Regulation of Nanotechnologies in Mexico

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Abstract

Mexico, perhaps second only to Brazil, is one of the most important countries developing nanotechnologies in Latin America. In November 2012, the Mexican Secretary of Economy released a set of guidelines for regulating nanotechnologies. U.S. businesses need to be aware of these guidelines because they form a part of a bilateral agreement between Mexico and the U.S. In this article, the authors analyze the policy context surrounding the development of these guidelines and the substantive content within the guidelines. The Mexican principles align themselves with the content of the U.S. guidelines for the regulation of nanotechnology and nanomaterials, which reflect an interest towards advancing a lighter or less restrictive regulation platform and a pro-trade stance.

Introduction

In November 2012, the Mexican Secretary of Economy released a set of guidelines for the regulation of nanotechnologies. This was the first formal step towards the regulation of nanotechnologies in the country. The guidelines are important for all companies doing business in Mexico, but particularly important for U.S. businesses, as they are a part of a bilateral agreement between Mexico and the U.S.

In this article, we analyze the policy context surrounding the development of these guidelines and the substantive content within the guidelines. The article is divided into 3 sections. In section one, we summarize the state of nanotechnology development in Mexico. In section two, we analyze the policy context leading to regulating nanotechnologies in the country. Finally, in section three, we go in depth to analyze the guidelines that are designed to regulate nanotechnologies in Mexico.

1. The development of nanotechnology in Mexico

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Mexico, second only to Brazil, is one of the most important countries developing nanotechnologies in Latin America.¹ Nanotechnology development was first considered as part of the Special Program of Science and Technology (PECYTI) 2001-2006, which was a policy document issued as part of the National Development Plan. The PECYTI highlighted the need to design and implement a national policy or plan to develop nanotechnology in Mexico as well as the need to create a research network.² The PECYTI 2001-2006 led, in part, to the creation of the National Nanotechnology and Nanoscience Network (RN&N) in 2009 with a budget of \$700,000 USD. The RN&N brings together more than 160 researchers to pursue several areas of nanotechnology research and development (R&D) and applications.³ In addition, the government created two National Nanotechnology Laboratories; one in Chihuahua at the Center of Advanced Materials Research Center, and the other in San Luis Potosí at the Potosí Institute of Scientific and Technological Research. The flagship program, however, is the creation of several innovation parks, with the most prominent located at the Research and Technological Innovation Park (PIIT) in the city of Monterrey. As part of the PIIT, the Nanotechnology Cluster of Nuevo Leon groups more than 40 companies using nanotechnology in their manufacturing process or engaging in nanotechnology R&D.⁴

From the start, nanotechnologies were portrayed as tools to achieve an increase in competitiveness and create more jobs. This argument continues to serve at the basis for most nanotechnology ventures throughout the country.

2. The policy context

In May 2010, a joint statement issued by the President of the United States and the President of Mexico preceded several initiatives of bilateral collaboration.⁵ One of these initiatives was the creation of the U.S.-Mexico High-Level Regulatory Cooperation Council (the "Council") in May 2010.⁶ The Council's main focus was directed towards harmonizing the regulations between the two countries to simplify trade mechanisms and foster competitiveness. A similar council was also created between the U.S. and Canada (in both Councils, U.S. – Mexico and U.S. – Canada,

¹ Guillermo Foladori et al., *Nanotechnology: Distinctive Features in Latin America*, 9 NANOTECH. L. & BUS. J. 88 (2012).

² See Consejo Nacional de Ciencia y Tecnología (CONACYT), PROGRAMA ESPECIAL DE CIENCIA Y TECNOLOGÍA 2001-2006. CONSEJO NACIONAL DE CIENCIA Y TECNOLOGÍA (2002).

³ See CONACYT, *Red Temática de Nanociencias y Nanotecnología, Dirección de Redes*, DAIC (2009), available at <http://2006-2012.conacyt.gob.mx/fondos/institucionales/Tecnologia/Avance/Documents/Red-Nanociencias-y-Nanotecnologia.pdf>.

⁴ Egar Záyago Lau, *A Nanotech Cluster in Nuevo Leon, Mexico: Reflections on its Social Significance*, 8 Nanotech. L. & Bus. J. 49 (2011).

⁵ Office of the Press Secretary, Joint Statement from President Barack Obama and President Felipe Calderón. The White House (May 19, 2010) available at <http://www.whitehouse.gov/the-press-office/joint-statement-president-barack-obama-and-president-felipe-calder-n>.

⁶ U.S. OFFICE OF MANAGEMENT AND BUDGET, HIGH LEVEL REGULATORY COOPERATION COUNCIL: TERMS OF REFERENCE FOR THE HIGH-LEVEL REGULATORY COOPERATION COUNCIL (Mar. 3, 2011), available at http://www.whitehouse.gov/sites/default/files/omb/oira/irc/high-level_regulatory_cooperation_council-terms_of_reference_final.pdf.

nanotechnologies became a topic of discussion)⁷ and talks are underway to form a council with the European Union.⁸

On June 9, 2011, the Council started the path towards nanotechnology regulation with the release of a memo from the U.S. Executive Office of the President entitled, "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials" (the "Memo").⁹ The Memo was signed jointly by leaders from each of the Office of Science and Technology Policy, the Office of Information and Regulatory Affairs, and the Office of the United States Trade Representative. It was issued with the intent "to develop a set of principles to guide development and implementation of policies for the oversight of nanotechnology applications and nanomaterials."¹⁰ Although these principles "do not supersede existing legal authorities or hinder Federal agencies from enforcing or applying their existing statutory and regulatory authority as mandated by law,"¹¹ it may have a significant impact on most government agencies, perhaps with the exception of the EPA and the FDA, which already have specific research initiatives on nanotechnology.

But, our interest here lies in the impact of this Memo vis-à-vis other countries, especially the ones that have signed trade agreements with the U.S., such as Mexico and Canada. As stated in the U.S. – Mexico Council Workplan, the Memo was sent to Mexican officials to set forth a basic framework for the regulation of nanotechnologies in Mexico.¹² As such, the Memo serves as a foundational element for the Mexican nano-regulation platform.

The Memo sets forth a protocol to regulate nanotechnologies and highlights 10 key principles. While the principles have a generally wide scope, the wording discloses a specific agenda regarding the regulation of nanotechnologies, namely that any regulation will likely put the interests of the market ahead of health and environmental concerns. Below, we discuss some noteworthy examples from the Memo.

- **Example 1. "Federal agencies should avoid making scientifically unfounded generalizations that categorically judge all applications of nanotechnology as intrinsically benign or harmful."**

On the one hand, this statement sets forth an apparently reasonable approach. On the other hand, the Memo argues, from the very beginning, that the key aspect of nanomaterials is not so much the size, but the *novel properties* that nanoparticles develop. If novel properties are intrinsic

⁷ THE WHITE HOUSE, UNITED STATES – CANADA REGULATORY COOPERATION COUNCIL, JOINT ACTION PLAN (2011), available at http://www.whitehouse.gov/sites/default/files/us-canada_rcc_joint_action_plan3.pdf.

⁸ OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2013 REPORT ON TECHNICAL BARRIERS TO TRADE (2013), available at www.ustr.gov/sites/default/files/2013%20TBT.pdf.

⁹ John P. Holdren, Cass R. Sunstein & Islam A. Siddiqui, *Memorandum for the Heads of Executive Department and Agencies: Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials* (June 9, 2011), available at <http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf> (Executive Office of the President: Office of Management & Budget, U.S. Trade Representative, and Office of Science and Technology Policy).

¹⁰ *Id.* at 2.

¹¹ *Id.*

¹² EXECUTIVE OFFICE OF THE PRESIDENT OF THE UNITED STATES, UNITED STATE-MEXICO HIGH-LEVEL REGULATORY COOPERATION COUNCIL WORK PLAN (Feb. 28, 2012), available at <http://www.whitehouse.gov/sites/default/files/omb/oira/irc/united-states-mexico-high-level-regulatory-cooperation-council-work-plan.pdf>.

to nanoparticles, as most of them display different physical, chemical and biological properties, then, should not all nanotechnology applications have a common regulatory framework? Implementing, for example, a mandatory risk assessment protocol before such particles enter the market seems reasonable given the potential consequences. As such, advocating that generalizations should be avoided when evaluating nanoparticles, while doing the opposite when characterizing nanoparticles is questionable.

- **Example 2. "[R]egulation should be based on risk, not merely hazard, and in all cases the identification of hazard, risk or harm must be evidence-based."**

There is an ongoing, sometimes contentious, debate in sustainability forums about whether policy should champion the replacement of hazardous materials or just reduce the risks associated with their manipulation. The stress on risk rather than hazards downgrades policies aimed to reduce the use and/or replacement of hazardous materials. For example, Europe's REACH regulation on chemicals tends to substitute hazardous materials instead of just reducing risks. The issue of risks pertains to the use of, or the exposure to, hazardous materials. For instance, a hazardous material could be handled safely by taking extra care; but this does not eliminate the intrinsic hazard of the material, which is latent and potentially could emerge at any given moment. There are innumerable catastrophes that illustrate that hazards can never be eliminated; most recently, for example, the Fukushima Daiichi nuclear power plant disaster in Japan.¹³ The position expressed by this phrase in the Memo is in line with the argument that the risks associated with hazardous materials should be reduced, as opposed to the argument promoted by most environmentalists, namely that policy should champion the replacement of such hazardous materials given the possible disaster that even one incident could have on the environment.

- **Example 3. "[B]est available scientific evidence."**

This phrase, while obvious, may also be necessary in light of the history surrounding the discussion on hazards and risks between corporations and environmental advocates. For example, the tobacco industry once accused NGOs of basing their criticisms on perceived risk instead of real (scientific) risk regarding the carcinogenic effects of cigarettes.¹⁴ Similarly, there was a controversy raised in the late 1970s between junk science vs. sound science, where, again, corporations attempted to dismiss civil society organization's arguments.

A major issue raised by the Memo's direction to use the "best available scientific evidence," is who should be in charge of defining what is the best available scientific evidence? How are policy stakeholders to choose when contradictory scientific evidence is present on a specific topic? This problem is one that already exists in the nanotechnology space, where contradictory evidence exists for several nanoparticles and nanostructures, such as carbon nanotubes. Similarly, what legal repercussions will these choices have? Do they merely set the foundation for future lawsuits?

- **Example 4. "To the extent feasible and subject to valid constraints (involving, for example, national security and confidential business information), develop relevant information in an open and transparent manner."**

¹³ See e.g., Martin Fackler, *Flow of Tainted Water Is Latest Crisis at Japan Nuclear Plant*, NYTIMES.COM, Apr. 29, 2013, <http://www.nytimes.com/2013/04/30/world/asia/radioactive-water-imperils-fukushima-plant.html>.

¹⁴ See e.g., Dr. Howard Markel, *Tracing the Cigarette's Path From Sexy to Deadly*, NYTIMES.COM, Mar. 20, 2007, <http://www.nytimes.com/2007/03/20/health/20essay.html>; ALLAN BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* (2007).

This sentence seems to suggest that national security information and business information are equal in importance. If the need to address potential risks of certain materials arises, relevant information might not be obtained because of confidentiality issues. In other words, this sentence seems to suggest that trade will surpass matters of health.

This Memo is far from a ‘neutral principles guide,’ and instead appears to be a manifest to subordinating any health or environmental matter to the interest of the market. Given the parties that authored the Memo, this is not a surprise.

2. Nanotechnology regulation in Mexico

In Mexico, the discussion on regulating nanotechnology is grounded in the commercial relationship between Mexico and the United States. The Council was created with the aim to “align the regulatory processes of both countries to reduce unnecessary costs for business and bilateral investment.”¹⁵ The fourth topic in the Council’s work-plan establishes the creation of guidelines for the implementation of technical regulations and norms related to nanotechnology and nanomaterials. Mexico established a working group coordinated by the National Metrology Center (CENAM), which is part of the Secretary of Economy to further elaborate guidelines. The Sub-Secretary of Competitiveness and Standards of the Secretary of Economy published the guidelines at the end of 2012.¹⁶

The Guidelines, called the “Regulatory guidelines on nanotechnologies for the achievement of competitiveness and protection of the environment, health and consumer safety,” are divided into four chapters with chapter three setting forth the specific principles. From the title, and throughout the Guidelines, the guarantee of competitiveness appears to justify both consumer protection and protecting the environment. But, the focus on competition also makes clear that the Guidelines were drafted with commercial relations in mind. As such, while the Guidelines encompass various issues (*e.g.*, trade) they also make commercial competitiveness the centerpiece of a document, which should focus on risks.

Additionally, these Guidelines can also serve as a means to equalize the playing field for all competitors by setting rules of behavior, testing requirements, and trade, and thereby increasing the ability of U.S. and Mexican companies to compete on a global scale. The U.S. is concerned with the rapid development of nanotechnologies in other countries, principally in China.¹⁷ The implementation of international standards for nanotechnology products on the part of one or a group of countries, based on criteria that their industries are able to fulfill, helps to limit the competition from other countries and/or businesses whose industrial capabilities are not designed to meet the country-specific or region-specific requirements.¹⁸ The same argument is later

¹⁵ Secretaría de Economía, Mexico Consejo de Alto Nivel para la Cooperación Regulatoria (CCR) entre México y Estados Unidos, <http://www.economia.gob.mx/comunidad-negocios/competitividad-normatividad/cooperacion-regulatoria-mexico-eu> (last visited May 4, 2014) (quote as translated).

¹⁶ Secretaría de Economía, Lineamientos Para Regulaciones Sobre Nanotecnologías (Nov. 26, 2012), available at <http://www.economia.gob.mx/eventos-noticias/informacion-relevante/9199-boletin289-12> (Grupo de trabajo sobre regulaciones para la nanotecnología. “Lineamientos para regulaciones sobre nanotecnologías para impulsar la competitividad y proteger al medio ambiente, la salud y la seguridad de los consumidores.”) [hereinafter Secretaría de Economía].

¹⁷ See *e.g.*, Gerald Hane, *Science, Technology, and Global Reengagement*, ISSUES IN SCI. & TECH., Nov. 27, 2013, <http://www.issues.org/25.1/hane.html> (2008).

¹⁸ See U.S. Government Accountability Office, *Nanomanufacturing: Emergence and Implications for U.S. Competitiveness, the Environment, and Human Health*, GAO-14-181SP p. 39-40 (2014), available at <http://www.gao.gov/assets/670/660591.pdf>.

reiterated “with the aim of establishing concrete regulations based on clear scientific data that provides the means to avoid technical barriers to trade,”¹⁹ placing the avoidance of barriers to trade ahead of guarantees for consumer safety and environmental protection.

The Guidelines set forth 12 principles in the second chapter. We briefly discuss each principle in turn below.²⁰

The 1st principle states that the goal is “To implement new regulations to take effect when existing regulations do not cover them or do so insufficiently.” This principle appears restrictive and contradictory, when compared with the statements set out in the previous chapter in the Guidelines. That is, the first chapter of the document states that, compared to their larger counterparts, particles at the nanoscale exhibit different behaviors. But, if the conventional criteria of chemical composition is insufficient for understanding the toxicity of nanoparticles; and, if, there are no conclusive studies on nanomaterials, why, then, would “implement[ing] new regulations to take effect when existing regulations do not cover them or do so insufficiently” be the answer? In fact, because of uncertainties regarding nanotechnologies, it seems that precisely the opposite should be true. Given that existing regulations are based on traditional criteria of toxicity, which are incapable of assessing manufactured nanoparticles that have never before existed, the first principle would have been more properly aligned with the rest of the Guidelines if it had called for specific regulation. Importantly, the problem of nanoparticles is not what *is not* known, but rather what *is* known: that they exhibit different properties (including toxicity); that many nanoparticles have been shown to be toxic in *in vitro* or live-animal experiments; that they have great mobility within organisms and even within certain matrices; and that since many of them are “new” and unknown to nature, biological organisms do not have the mechanisms for immunity that are the result of thousands and millions of years of evolution. These known characteristics should be sufficient to demonstrate the need for specific regulations.

The 2nd principle states that, “[when m]aking decisions regarding regulation based upon solid technical and scientific evidence[, it] is important to take into consideration formal declarations from manufacturers and wholesalers in agreement with each case.” This principle appears to make a declaration in favor of the market – and, consequently, against health and the environment. Moreover, this principle, while stating that regulatory decisions should be made based on solid technical and scientific evidence, says nothing about the nano-based products entering the marketplace without any kind of solid technical or scientific evidence showing they are harmless to health and the environment.²¹

The 3rd principle only serves to deepen the hegemony of the market over health, noting that “the requirements in the regulations must not be of such character that they unnecessarily limit innovation and competitiveness of national industry, but that are sufficient to preserve and protect the population and the condition of the environment.” The 4th principle addresses the need to protect the health of workers exposed to nanomaterials through their job-related activities. However, it fails to make reference to a key aspect of protecting the workforce: transparency of information from the firm to the workers. Workers do not generally know either the materials they are handling or the associated risks. When working with toxic substances, workers have historically demanded transparency. This principle is reflected in Article 154 of the International Labor

¹⁹ See Secretaría de Economía, *supra* note 16.

²⁰ The principles are in Spanish. For purposes of this discussion, we translated several of the key points into English.

²¹ This position, typical of U.S. policy toward nanotechnological products, is the opposite of the “no data no market” position of the European Union, where the intent is only to allow products into the market once information is available that attests to the innocuous nature of those products to health and the environment.

Organization, which is the basis for the guarantee of precautionary measures, and to which Mexico is a signatory.

The 5th principle espouses the need “To carry out activities to manage the risks associated with nanotechnologies with a multidisciplinary and integral focus, considering social, economic and ethical aspects.” Put simply, this principle calls for the need for multidisciplinary and integral studies of risk analysis. However, the guidelines of the United States and Canada also consider whether risk analyses should be “mandatory,” as well as the need for a reduction of exposure. These two concepts are very different from the assessment and management of risk approaches that we see in Mexico’s principle number five.

The 6th principle calls for the gathering of toxicological information from manufacturers, importers and retailers of products containing nanotechnology. However, this is not identified as mandatory, nor does it guarantee the delivery of records attesting to the security of the product prior to its sale.

Principle 7 refers to collaborative research at the national and international levels.

The 8th principle calls for “Informing society, particularly consumers, about the products containing nanomaterials and the possible short, medium and long term effects.” This principle fails to mention labeling, even a voluntary labeling mechanism; but, Europe has begun to make labeling mandatory for certain products (e.g., Regulation on Cosmetic Products 1223/2009). Additionally, the ISO is producing a voluntary labeling guide.²²

The 9th principle addressed the need “To promote and to take into consideration the opinion of society regarding technical, environmental, social, economic, ethical and legal aspects related to the regulation for the development, commercialization ... of nanotechnologies.” This principle fails to call for the participation of organized society (e.g., unions, NGOs) in the decision-making bodies that create nanotechnology science and technology policies, but it does call for participation by the business sector. This principle contrasts with the position espoused in the 2th principle, namely that, it “is important to take into consideration formal declarations from manufacturers and wholesalers in agreement with each case.” Thus, it should be asked: why should the positions of organized society not be taken into consideration?

The 10th principle calls for “Promoting a common vision [or nanotechnology] in association with the industry, public organizations and private institutions of research and development, and other interested parties.” As such, this principle addresses the need to coordinate regulatory activities among the various stakeholders, including government agencies, research centers and others. Here, again, the presence of unions is not explicitly identified, although that of businesses most definitely is.

Principle 11 calls for “Promoting compatibility of regulation schemes with our commercial partners.” This principle refers to harmonizing regulations across commercial partners, which is why the High Level Councils was created by the U.S. administration.

Lastly, the 12th principle stresses the importance of dialogue among commercial partners, specifically stating: “Maintaining and open and effective communication regarding regulation of nanotechnologies with our commercial partners.” Neither principle 11 nor this principle 12, which both refer to international commerce, open the way for Mexico to look to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) for certain nanoparticles or nanostructures considered to be dangerous, or to include nanomaterials that could be identified as

²² See ISO Technical Specification (TS) 13830: 2013: Nanotechnologies -- Guidance on Voluntary Labelling for Consumer Products Containing Manufactured Nano-objects, http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=54315.

hazardous on lists that set forth requirements for manufacturers or retailers to obtain specific advanced authorization prior to their use.

Taken as a whole, the Guidelines replicate, to some extent, the content in the U.S. Memo. However, the Guidelines go further and are more pro-trade than the Memo. Beyond the issues raised in each of the previous items, the issue of the “precautionary principle” with respect to nanotechnologies merits highlighting given its importance. The principle of precaution is explicitly set forth in “Principle 15” of the Río Declaration (1992) on Environment and Development²³ and was a watershed moment. The use of precaution was recommended in cases where there are indications of irreversible risks to health and/or the environment, even if there is no conclusive scientific evidence.

Since 1992, however, a difference in interpretation of that Principle has arisen between the United States and Europe. While the former allude to a “precautionary approach,” which is voluntary, Europe embraces precaution as a principle in the legislation.²⁴ In the case of nanoparticles, while the European Union and other countries call for the application of precaution as a mandatory principle, the United States, Canada and the international chemical corporations vigorously oppose it.²⁵ It is true that the Mexican legislation on the environment is already aligned with that of the United States, and does not speak of precaution, but the Biosecurity Law on Genetically-Modified Organisms (LBOGM) of 2005, in Article 9 (IV), does make mention of the precautionary approach, to which the Guidelines could have alluded. The Guidelines are almost a copy of the guidelines presented in the U.S. Memo, completely oriented toward questions of commercial standardization, rather than taking seriously the question of risks to health and/or the environment.²⁶

Conclusion

After more than a decade of funding nanotechnology research and development, Mexican authorities have decided to take the first steps toward the regulation of this technology. Nevertheless, these steps did not originate from national demands; instead they came from a set of guidelines provided by U.S. authorities intent on facilitating trade. The Mexican principles align themselves with the content of the U.S. guidelines for the regulation of nanotechnology and nanomaterials, which reflect an interest towards advancing a lighter or less restrictive regulation platform and a pro-trade stance. The topic of risks to health and the environment are subordinated or downgraded to facilitate the movement of nano products across the border of both countries.

²³ Principle 15 states that, “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.” UNITED NATIONS, REPORT OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT, ANNEX I, RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT (UN-GA, 1992), available at <http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>.

²⁴ See Robert Falkner & Nico Jaspers, *Regulating Nanotechnology: Risk, Uncertainty and the Global Governance Gap*, 12 GLOBAL ENVTL. POLITICS 30 (2012), available at http://personal.lse.ac.uk/falkner/private/2012_Falkner_Jaspers_RegulatingNanotechnologies.pdf.

²⁵ Corporations have a decisive role in U.S. regulation. See e.g., CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW, TOXIC PARTNERSHIP: A CRITIQUE OF THE ACC-CEFIC PROPOSAL FOR TRANS-ATLANTIC COOPERATION ON CHEMICALS (2014), available at http://www.ciel.org/Publications/ToxicPartnership_Mar2014.pdf.

²⁶ Similar to the Mexican Guidelines, the Canadian Guidelines also closely follow the U.S. Memo.