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Engineered nanomaterials in the global regulatory arena and Mexico's regulatory path

Nanomateriales manufacturados en el ámbito regulatorio mundial y la trayectoria regulatoria de México

Luis Mauricio Ortiz-Galvez,*,♦ Blanca Suarez-Merino**

ABSTRACT: Engineered nanomaterials (ENMs) exhibit novel properties that offer significant benefits across various industrial sectors and are increasingly present in consumer products worldwide. However, safety assessments have predominantly focused on specific regions, such as the European Union (EU), leaving potential human and environmental risks in other areas insufficiently understood. The absence of a globally harmonized regulatory framework further complicates risk management, due to data variability, uncertainty, and the complexity of ENMs. In response, some countries have developed diverse tools and methodologies to address these regulatory challenges. This article presents an overview of current safety assessment methodologies and reviews international regulatory approaches for ENMs. It also proposes general recommendations for initiating a regulatory framework in Mexico, informed by existing scholarly insights. The aim is to support the development of locally relevant strategies that align with international best practices.
KEYWORDS: nanomaterial, regulation, risk governance, standards.

RESUMEN: Los nanomateriales manufacturados (ENMs) presentan propiedades novedosas que ofrecen importantes beneficios en diversos sectores industriales y están cada vez más presentes en productos de consumo en todo el mundo. Sin embargo, las evaluaciones de seguridad se han centrado principalmente en regiones específicas, como la Unión Europea, lo cual ha dejado sin comprender suficientemente los posibles riesgos para las personas y el medio ambiente en otras zonas. La ausencia de un marco normativo armonizado a nivel mundial complica aún más la gestión de riesgos, debido a la variabilidad de los datos, la incertidumbre y la complejidad de los ENMs. En respuesta a ello, algunos países han desarrollado diversas herramientas y metodologías para abordar estos retos normativos. Este artículo presenta una visión general de las metodologías actuales de evaluación de la seguridad y revisa los enfoques normativos internacionales para los ENMs. También propone recomendaciones generales para iniciar un marco normativo en México, basándose en los conocimientos académicos existentes. El objetivo es apoyar el desarrollo de estrategias locales relevantes que se ajusten a las mejores prácticas internacionales.
PALABRAS CLAVE: nanomaterial, regulación, gobernanza del riesgo, estándares.

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Introduction

Engineered nanomaterials (ENMs) or manufactured nanomaterials are intentionally designed and manufactured materials on the nanoscale, from approximately 1 to 100 nm, with novel properties that differ from their bulk counterparts (Hochella *et al*., 2019). In the 21st century, some of these materials have already jumped to the global market. For instance, ENMs are used in multiple industrial applications and commercialized in consumer products, named nano-enabled products, expected to grow to around 3 million metric tons by 2031, such as in solar panels, fuel cells, coatings, sunscreens, in the automotive industry, construction, environmental remediation, among others (Keller *et al*., 2023).

These materials opened potential doors to innovative products and benefits for our society; however, they also introduced some uncertain health and environmental risks due to their unknown releases and toxicity profiles throughout the life cycle of their corresponding applications. Consequently, the scientific community started investigating their potential risk. This article presents an overview of how the safety of engineered nanomaterials is assessed and how ENMs are regulated internationally. It also provides general recommendations for developing a regulatory framework in Mexico, building on common suggestions from other authors.

Safety assessment of engineered nanomaterials

Experts should assess the safety of using a substance, typically by conducting a risk assessment. Therefore, the risk assessor should follow a series of steps (figure 1). In this process, one first needs to identify the hazard (dose-response relationship) and evaluate the relevant exposure scenarios, considering the potential exposure routes (i.e., inhalation, dermal interaction, ingestion). Meaning that estimated exposure levels are compared to a recommended exposure limit to evaluate the potential risk (Tsang *et al*., 2017). For example, in environmental risk assessment, the ratio between the predicted environmental concentration (PEC) and the predicted no-effect concentration (PNEC) is usually estimated.

Some researchers have pointed out that conventional risk assessment tools must be adapted to complete a human and environmental risk assessment (HERA) for ENMs to account for unique nanoscale properties such as particle size, reactivity, and surface area (Isigonis *et al*., 2019; Mech *et al*., 2022). Thus, researchers have developed or modified tools, methodologies, and models to fit the corresponding challenges of ENMs (Banard, 2009; Mancardi *et al*., 2023), such as physicochemical properties-dependent toxicity, and species-specific sensitivity along the life stage of the corresponding organisms. In table 1, we presented some examples. While this article does not aim to provide an exhaustive overview of all available methods, it

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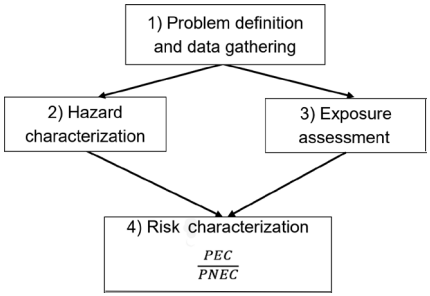
FIGURE 1. . Simplified steps in (environmental) risk assessment of chemicals.



Source: Author's elaboration.

highlights key approaches relevant to the topic. Readers interested in exploring additional techniques or gaining deeper insights are warmly encouraged to consult the referenced literature for further information.

Table 1. Examples of approaches used in human and environmental risk assessment (HERA) of ENMs.*

Approach	Description	References
Experimental material release methods.	Laboratory experiments that simulate multiple scenarios in which release can occur, along with the corresponding physical or chemical stresses that the product could experience during its life cycle.	Wohlleben *et al.* (2024)
Substance or material flow analysis (MFA).	Method to quantify the inputs, stocks, and outputs of a substance or material in a specific system based on the principle of mass conservation. This method could also integrate uncertainty in the input data (probabilistic), consider the system dynamics over time (dynamic), and extend/or to a future perspective (prospective).	Brunner, and Rechbwerger (2016); Keller *et al.* (2024)
Particle flow analysis.	Similar to MFA, but based on particle number instead of mass to describe the magnitude of flows and stocks of the material.	Arvidsson, Molander and Sandén (2012)
Occupational and consumer exposure assessment.	Models for assessing how an EMN could enter an individual or group in the workplace or during their use (consumers) via different exposure routes.	OECD (2021); Vermoolen *et al.* (2025)
Multimedia environmental fate and transport models.	Mathematical models that represent the behavior and transformations of an ENM in environmental compartments, such as homo- and hetero-agglomeration, dissolution, and sedimentation.	Sørensen *et al.* (2019); Williams *et al.* (2019)
Mesocosm studies.	Small-scale experimental setups that simulate ecosystems to study the behavior of ENMs and their ecotoxicological effects under controlled conditions.	Auffan *et al.* (2014); Clark *et al.* (2022); Metreveli *et al.* (2021)
Quantitative structure–activity relationships / Quantitative property–activity relationships (QSAR/QSPR) models.	Models that predict the desired response of interest of a corresponding ENM based on computational and/or experimentally developed nano-descriptors.	Lebre *et al.* (2022); Mancardi *et al.* (2023); OECD (2023)

Continue ▶

Table 1. Examples of approaches used in human and environmental risk assessment (HERA) of ENMs.* (continuation).

Approach	Description	References
(Eco)toxicity assessment.**	Test guidelines, standards, and new proposed methodologies to study the toxic effects of an ENM on living organisms.	Lebre *et al.* (2022)
Species sensitivity distribution (SSD).	Models that estimate the hazardous concentration of a certain percentage of species based on the distribution of toxicity data, mainly from lab- or field-based assessments. SSDs could be probabilistic.	Sørensen *et al.* (2020)
Quantitative *in-vitro* to *in-vivo* extrapolation (QIVIVE).	Methods that predict *in vivo* effects from *in vitro* data (dose-response relationship), establishing toxicological thresholds (points of departure).	Bhat *et al.*, (2025); Wu *et al.* (2024)
Grouping and read-across.	Concepts used to reduce the necessity for specific testing for regulatory purposes, using hypotheses to predict specific hazards from a limited set of known physicochemical properties and toxicity testing.	Oomen *et al.* (2015); Stone *et al.* (2020); Chatterjee *et al.* (2022)
Integrated approach to testing and assessment (IATA).	Integrated approaches for testing and assessment (IATAs) support the efficient and effective collection of data, enabling the support or rejection of a set of predefined hypotheses.	Cross *et al.* (2024)
Physiologically based pharmacokinetic (PBPK) model.	Multi-compartment mechanistic models that simulate the absorption, distribution, metabolism, and excretion (ADME) characteristics of the materials that enter the body of a living organism to study their biodistribution.	Bachler *et al.* (2015); Chen, Riviere and Lin (2022); Ozbek *et al.* (2024); Ramadan *et al.* (2021)
New approach methodologies (NAMs).	Recent strategies for providing hazard and risk information based on in silico approaches, in chemico assays, and *in vitro* assays, alongside high-throughput screening and omics technologies.	Furxhi *et al.*, (2023); Nymark *et al.*, (2020)
Prospective environmental risk screening.	Proxy measurement of an early environmental risk using annual production volumes and (aquatic) ecotoxicity data of a corresponding ENM to screen the potential risk of producing it	Arvidsson *et al.* (2022)

* Some tools are now available as user-friendly models, for example, via the NovaMechanics Ltd online platform (NovaMechanics Enalos Cloud Platform). https://www.enaloscloud.novamechanics.com/index.html.
** NANOMET: Towards tailored safety testing methods for nanomaterials. https://www.oecd.org/en/topics/sub-issues/testing-of-chemicals/nanomet.html.
Source: Author's elaboration.

Among the approaches, experimental release tests are needed to understand the release amounts of the corresponding material from a specific matrix in realistic scenarios (Wohlleben *et al.*, 2024), which can occur from mechanical, thermal, or chemical stress to a combination of different stresses, such as simulating an environmental process (i.e., weathering). These results can then be used in material flow analysis (MFA) to illustrate the mass release and streams of a material incorporated into one or several products throughout their life cycles within the system under study (Keller *et al.*, 2024). Then, the mass released in environmental compartments can be used as input va-

lues for a fate model to further investigate environmental transformations of the ENM.

Therefore, multiple of these methods are necessary to complete the HERA of ENMs. Finally, it is essential to note that HERA can be deterministic, utilizing specific, point-estimate values for input variables to model a single, defined risk scenario and predict a single point estimate for the potential outcome, or probabilistic, considering probability distributions to produce a range of possible outcomes, characterizing uncertainty (Franken *et al*., 2020; Hong and Nowack, 2024; Tsang *et al*., 2017).

Importance of the regulation of nanotechnological innovation: case of nanosized titanium dioxide

There are instances where nanomaterials have been thoroughly investigated to understand their potential risks to society and the environment. For instance, one of the most widely discussed cases is that of nanosized titanium dioxide (nano-TiO_2). Nano-TiO_2, a UV-absorbing, transparent material, has different crystalline structures and is widely used in applications ranging from photocatalysis, in the anatase form, to UV filtration, in the rutile form (Zheng and Nowack, 2021).

Some researchers have studied the cytotoxicity of nano-TiO_2 (spherical particles < 50 nm) in human cell lines, showing that anatase particles induced a lethal concentration 50 (LC50) of 3.6 μg/ml, while rutile particles induced an LC50 of 550 μg/ml (Sayes *et al*., 2006). In addition, other toxicological studies of nano-TiO_2 (20-40 nm) on mouse macrophages and immune cells presented the half-maximal inhibitory concentration (IC50) values for anatase and rutile as 221 mg/L and 194 mg/L, respectively. In this study, researchers stated that rutile cause a more severe lysosomal impact than anatase, thereby increasing the potential for necrosis; however, anatase can induce a greater likelihood of apoptosis (Yu *et al*., 2017).

In Europe, researchers have conducted HERA studies to investigate whether nano-TiO_2 remains safe for use in various applications. For example, Adam, Caballero-Guzman and Nowack (2018) determined the specific forms of nano-TiO_2 releases to freshwater, considering multiple product categories commercialized in Europe. They showed that most of the nano-TiO_2 is in its pristine form, with a mean mass value of 2,227 tons per year, compared to the matrix-embedded form, which releases around 50 tons per year. Then, Hong, Adam and Nowack (2021) further performed the ERA, including the uncertainty within the model input parameters. They combined these previous results with the hazard evaluation to obtain the corresponding probability distribution, with a mean risk characterization ratio (RCR) of 0.026 (RCR < 1 indicates no immediate risk in the predefined system). Meaning that, according to their model, there is a limited environmental risk in European freshwaters.

Moreover, for human safety, the scientific community has discussed the risk of oral administration as a potential human exposure route due to consuming food with white additives based on nano-TiO_2. For instance, the European Food Safety Authority (EFSA) conducted an extensive safety assessment of the food additive nano-TiO_2 (E-171), with a primary focus on genotoxicity due to the unclear risk based on previous evidence (2021). According to their assessment, there is no indication of adverse effects from the food additive at a dose of up to 1,000 mg/kg bw per day.

On the other hand, they commented that nano-TiO_2 has the potential to induce DNA strand breaks and chromosomal damage, but not gene mutations, suggesting that several modes of action for genotoxicity may operate in parallel. As a result, they concluded that genotoxicity was a possibility, indicating that it cannot considered safe when used as a food additive. Consequently, the E-171 food additive has banned from the European market (Conley, 2025; Isibor, 2024; Saldivar-Tanaka, 2024).

Recently, a group of researchers has also evaluated several food categories in the French market, from national to international imported products (Bucher *et al*., 2024). They confirmed the presence of nano-TiO_2, in the form of the E-171 additive, in approximately 40% of the food samples. In addition, they mentioned that the ban was effective because the presence of nano-TiO_2 in food products dropped, mainly from products in the internal EU market, and they stated that imported food products were indeed more likely to contain nano-TiO_2.

The case of nano-TiO_2 highlights the importance of evaluating the risk of using an ENM, mainly from a life cycle and systems thinking perspective, because multiple products can differ in their release profiles and exposure routes to people at different life cycle stages. Nonetheless, there are other ENMs that have assessed due to their potential market demand and unknown toxicity, such as nano-silver and nano-zinc oxide (Hong, Adam, and Nowack, 2021).

Therefore, due to the complexity of the situation with knowledge gaps, variability, and uncertainty related to the available data, the global trading of nano-enabled products, and considering the risk perception of several stakeholders (e.g., Porcari *et al*., 2019), mainly governmental institutions are investigating governance risk strategies to apply to these emerging technologies.

Risk governance of engineered nanomaterials

Risk governance of ENMs has emerged as a common theme in regulatory-based discussions, mainly in industrial sectors where significant human exposure to those materials may occur. In this context, risk governance refers to the process covering all dimensions of risk analysis and decision-making with multiple stakeholders (Isigonis *et al*., 2019; Rasmussen *et al*., 2023), and it is

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beneficial because it supports a better understanding and interpretation of the available knowledge to evaluate and manage potential risks from ENMs and nano-enabled products. Nevertheless, according to various researchers, there are still challenges that need to be considered (Allan *et al*., 2021; Lai *et al*., 2018; OECD, 2022), as illustrated in figure 2.

FIGURE 2. . Challenges in risk governance of engineered nanomaterials.

Source: Prepared by the authors based on Allan *et al*. (2021), Lai *et al*. (2018) and OECD (2022).

Furthermore, research evidence suggests that effective regulation of nanomaterials is closely linked to cultivating public trust. This transparent communication mitigates public fears and misconceptions, potentially facilitating cooperation with industry stakeholders during the policy development process. The emphasis on data FAIRness, mainly data transparency, is intertwined with risk governance and reflects an evolution toward more inclusive regulatory practices (Isigonis *et al*., 2019).

Although some researchers have proposed risk governance frameworks, there is a special need to standardize and harmonize the methods and tools applied for this purpose (Rasmussen *et al*., 2023; Teunenbroek, Baker and Dijkzeul, 2017), especially in a globalized economy, due to trading activities (Devasahayam, 2017). Therefore, promoting international collaboration and transdisciplinarity is essential to engage stakeholders impacted along the supply chain and life cycle of the ENMs and nano-enabled products.

The regulatory governance of engineered nanomaterials has also fostered the development of specialized regulatory agencies and working groups at national and regional levels. These dedicated bodies often comprise experts in scientifically diverse fields, such as toxicology, chemistry, and materials science, who establish test guidelines, best practices protocols, and monitor compliance.

For example, the EU Observatory for Nanomaterials provides information and guidance to support risk assessment and regulation of ENMs (Allan *et al*., 2021; Isibor, 2024). The creation of such agencies reflects an acknowledgment that nanotechnology demands specialized oversight mechanisms operating effectively in a rapidly and dynamically evolving technological landscape (Shandilya *et al*., 2020). Thus, their work provides a foundation for ongoing risk assessments and policy adjustments that are data-driven and evidence-based (Isigonis *et al*., 2019; Mech *et al*., 2022).

In addition to regulatory agencies, several national standards organizations and metrological centers have been instrumental in defining testing protocols. These organizations collaborate closely with international partners to develop standardized methods for characterizing and measuring nanoparticle properties, including size, shape, and surface reactivity. Harmonization and standardization are vital to obtaining the necessary information to address regulatory requirements and to ensure that risk assessments are consistent and transferable across different regulatory jurisdictions (Mech *et al*., 2022). For instance, the International Organization for Standardization (ISO), within the ISO/Technical Committee 229 (ISO/TC 229) working on standards for nanotechnologies since 2005, and the Organization for Economic Cooperation and Development (OECD), established the Working Party on Manufactured Nanomaterials (WPMN) in 2006, are the leading globally operating organizations that provide such methods (Bleeker *et al*., 2023; Park and Yeo, 2016).

Governmental agencies in various countries have increasingly adopted a multi-tiered approach to nanomaterial regulation. Typically, going from low-tiered approaches with higher uncertainty to a higher-tiered approach with reduced uncertainty, using qualitative and quantitative approaches, respectively (Creutzenberg, 2021; Hristozov *et al*., 2024). This approach typically combines overarching national policies with sector-specific guidelines and local implementation measures. For example, while national regulatory frameworks set general safety guidelines and testing requirements, local authorities often might oversee industry-specific compliance within their jurisdictions (Mech *et al*., 2022).

Finally, a key dimension of regulatory innovation in the field of ENMs is the focus on long-term monitoring and evaluation of regulation effectiveness. It is crucial to highlight that regulatory frameworks are not static but are continuously assessed and refined based on empirical outcomes and performance indicators, as exemplified by the previous example of nano-TiO_2 as a food additive. In many countries, these periodic reviews of nanomaterial-related policies serve as the basis for recommendations to update safety testing methodologies and compliance measures (Isigonis *et al*., 2019). This iterative process helps ensure underlying policies remain robust, relevant, and aligned with innovation cycles and emerging risk profiles (Mech *et al*., 2022). In the following section, we provide a brief overview of regulatory approaches worldwide.

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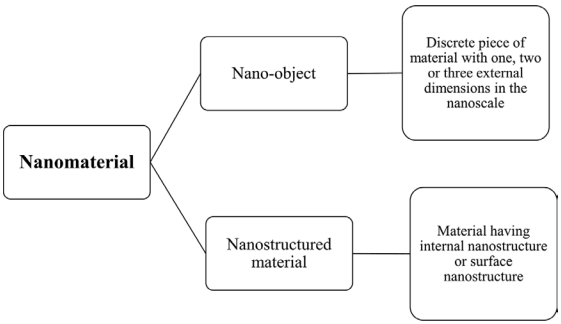
International regulatory approaches applied to engineered nanomaterials and nano-enabled products

In the regulatory context, ENMs have primarily defined based on size and morphology. However, this definition has evolved to cover the complexity as knowledge has expanded. Besides, the concept might vary among different institutions. For example, according to ISO 80004-1:2023, a nanomaterial is a material with any external dimension in the nanoscale (1 - 100 nm) or having internal structure or surface structure in the nanoscale (ISO, 2023). Additionally, ISO went further and implemented the concepts of nano-object and nanostructured material, referring to the surface or internal structure in the nanoscale in at least one of its dimensions (figure 3).

FIGURE 3. ISO definition of nanomaterial.



Source: Prepared by the authors based on ISO (2023).

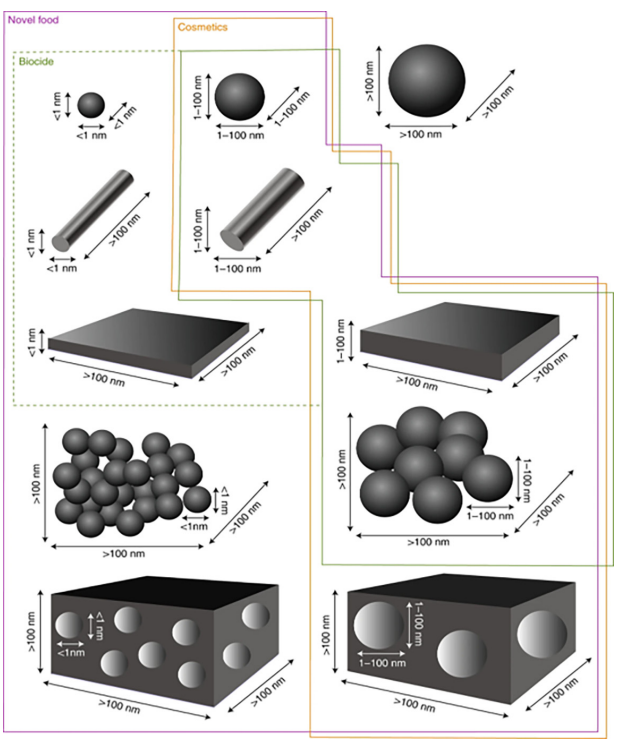
Another example comes from the European Commission (EC), which in 2022 updated the recommended definition, which focuses on solid particles (and aggregates) within at least 50% of the particle number-based size distribution below 100 nm in at least one (external) dimension, and the shape of the ENM (Rauscher *et al*., 2023a). Nevertheless, different European regulatory bodies additionally base their regulatory framework on specific industrial sectors when using ENMs (Karlaganis *et al*., 2019; Miernicki *et al*., 2019; Nielsen *et al*., 2021; Nielsen *et al*., 2023; Rauscher *et al*., 2023b; Rasmussen *et al*., 2023).

For example, in Europe, the European Food Safety Authority (EFSA) assesses the risk of using an ENM as a food additive. In case a company wants to import or produce an ENM, the company should follow a compulsory premarket evaluation following the EU's REACH regulation (registration, evaluation, authorization and restriction of chemicals), where ENMs are referred to as "nanoforms" and introducing the option of grouping a set of similar nanoforms, representing several ENMs which share a commonality, which could be even more than one common property in a physical, chemical, exposure, (eco) toxicological, toxicokinetics or fate sense (Abbasi, 2025).

There might be an alignment in available definitions (see more definitions on: Ali, Neha and Parveen, 2023; Miernicki *et al*., 2019; Rasmussen, Riego and Rauscher, 2024; Wohlleben *et al*. 2014); however, there is no global legal convention, which would be a step in the direction of more transparency and effective communication, guaranteeing consistency in nano-FAIR data (Rasmussen *et al*., 2023). As illustrated in figure 4, even within an economic region, several (sector-specific) regulatory frameworks (and definitions) could exist.

Such sector-specific approaches can bring a benefit because these allow regulators to tailor safety assessments appropriately, ensuring that all critical points of potential exposure are addressed effectively (Isigonis *et al*., 2019). As a result, it is unsurprising to recognize that some countries or regions have their own national or regional approaches (figure 5), as summarized already in multiple articles (e.g., Ali, Neha and Parveen, 2023; Allan *et al*., 2021; Chávez-Hernández *et al*., 2024; Abbasi, 2025; Isibor, 2024; Karlaganis *et al*., 2019; Kumari *et al*., 2023; Lai *et al*., 2018; Mishra *et al*., 2019; Park and Yeo, 2016; Saldívar-Tanaka, 2020; Subhan *et al*., 2024; Zolkipli *et al*., 2024).

FIGURE 4. Illustration of the classification of a nanomaterial under different EU regulations based on size specifications.

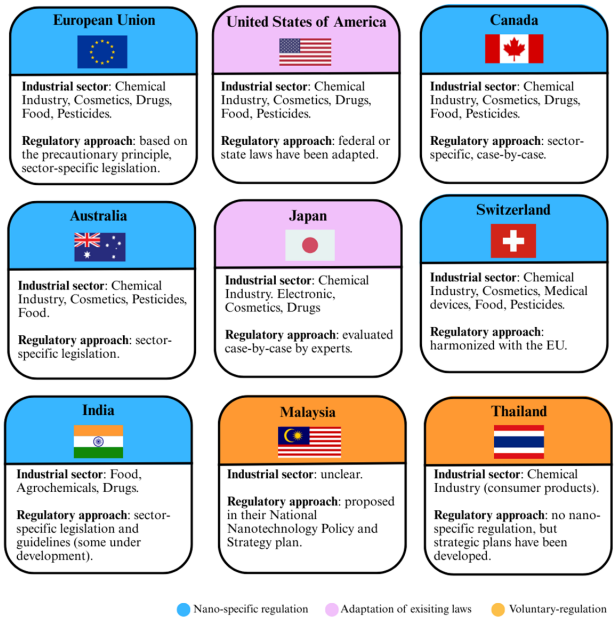


Source: Taken from Miernicki *et al*. (2019).

Such sector-specific approaches can benefit because they enable regulators to tailor safety assessments appropriately, ensuring that all critical points of potential exposure are effectively addressed. As a result, it is unsurprising to recognize that some other countries or regions have their own national approaches. Some examples are summarized in figure 5.

In addition, regulatory frameworks might differ in their ethical and legal grounds. Nonetheless, the discussions surrounding nanomaterial regulation reveal a preference for precautionary rather than reactive regulatory stances (Saldívar-Tanaka and Hansen, 2021). A precautionary approach supports instituting safety measures in anticipation of risks not yet fully quantified in scientific studies. Such regulatory foresight has been documented in European and some Asian frameworks, while, in other countries, reactive regulation might still be in place, such as in the US.

FIGURE 5. Examples of national and regional regulatory approaches to ENMs.



Source: Prepared by the authors based on Ali, Neha and Parveen (2023), Allan *et al.* (2021), Chávez-Hernández *et al.* (2024), Abbasi (2025), Isibor (2024), Karlaganis *et al.* (2019), Kumari *et al.* (2023 , Lai *et al.* (2018), Mishra *et al.* (2019), Park and Yeo (2016), Saldívar-Tanaka (2020), Subhan *et al.* (2024), Zolkipli *et al.* (2024).

According to Saldivar-Tanaka (2020), the regulation of nanotechnological innovation and its products can be divided mainly into what is called hard regulation, which is mandatory, as in the case of the US, and soft regulation, which is voluntary and more flexible, for example, the case of Thailand. As shown in figure 5, some countries adopted a bottom-up approach

(linked more to soft regulation). On the one hand, this means that the scientific community and industry developed certification programs, such as the NanoQ Certification in Thailand and the NanoVerify Certification in Malaysia (Karlaganis *et al*., 2019; Jaya, 2021) and followed or adapted ISO standards and OECD test guidelines to self-regulate the national market.

On the other hand, some countries have proposed various legislative initiatives, such as in the cases of Brazil and Argentina. For example, in Brazil, the Federal Senate's Constitution and Justice Committee approved the Legal Framework for Nanotechnology and Advanced Materials a couple of years ago (Berger and Berger, 2022; Fonseca and Pereira, 2014; Hupffer and Lazzaretti, 2019). Nonetheless, not every country has succeeded in this regard, and they lack a nano-specific legal framework. Therefore, some regulatory bodies or public-private institutions have taken over and offer other self-regulatory initiatives. Similarly, Mexican researchers have tried to promote a National Plan on Nanotechnologies and a corresponding regulatory approach, but without success. Thus, we focus on the last section to explore the nano-specific regulatory arena in Mexico.

Regulation of nanotechnological innovation and its applications in Mexico

The Mexican Government has recognized Nanotechnology as an area of opportunity since 2001, consecutively within the framework of the Special Science and Technology Program (Camarillo *et al*., 2019; CIMAV, 2008). There has been an increase in educational programs since 2006 (CIMAV, 2008; Villa, 2022). Similarly, the market is growing. For instance, the Latin American Network of Nanotechnology and Society (ReLANS, by its acronym in Spanish) keeps an online database of around 160 companies that manufacture or import ENMs or nano-enabled products in Mexico (Ortiz-Galvez *et al*., 2024). Nonetheless, to the best of our knowledge, Mexico still lacks a national nano-specific regulatory framework (Ortiz-Galvez *et al*., 2024); however, there have been efforts over time that align with this purpose. Therefore, in the following sections, we will explain what has taken place in Mexico in relation to the attempt to regulate ENMs and nano-enabled products.

Mexico has adopted the Harmonized system for identifying and communicating hazards and risks from hazardous chemicals in workplaces (NOM-018-STPS-2015).[1] However, this norm does not explicitly mention the kind of substances, nor does it mention if ENMs are included. Besides, it is applied in workplaces, so hazard communication with other parties, such as citizens,

[1] NOM-018-STPS-2015. Sistema armonizado para la identificación y comunicación de peligros y riesgos por sustancias químicas peligrosas en los centros de trabajo (Harmonized system for the identification and communication of hazards and risks posed by hazardous chemicals in the workplace). https://dof.gob.mx/nota_detalle.php?codigo=5411121&fecha=09/10/2015.

is omitted. So far, Mexico has a voluntary labelling norm for nano-enabled products (Saldívar-Tanaka, 2020), which could help to inform society.

Recently, the government, with the National Institute of Ecology and Climate Change (INECC, by its acronym in Spanish), implemented a National Catalogue of Chemical Substances in Mexico, the INSQ (acronym in Spanish, *Inventario Nacional de Substancias Químicas*)[2] List. The group responsible for updating this database has made some progress in implementing this voluntary catalogue, which only focuses on individual compounds (Ochoa, 2021). Saldívar-Tanaka (2019) commented that the inventory is divided into the health, phytosanitary, and environmental regulations. Nevertheless, there is no scenario that incorporates ENMs. For instance, those responsible for implementing the improvements should consider that ENMs could be included in the list or in a separate section.

The Office of the Federal Prosecutor for the Consumer (Profeco, by its acronym in Spanish) is the national institution that oversees the safety of citizens and legal entities who acquire or enjoy the final goods or services. Therefore, Profeco should demand more detailed information on nano-enabled products and require the labeling of nano-ingredients, as is now applied in developed countries (i.e., Europe with the CLP regulation), as authorized by the Federal Consumer Protection Law. It is acknowledged that for imported products, it is sometimes necessary for the company or distributor to complete paperwork for product approval in Mexico (Mendoza and Ize, 2017; Cofepris, 2018). Nevertheless, it should also be done more rigorously, both for international products and for national ones, to manage the globalized market and to protect the environment and the consumers.

Regulatory issues regarding engineered nanomaterials in Mexico throughout history

There have been some controversial cases regarding ENMs in Mexico's market. For example, a small business was selling graphene as a dietary supplement. Additionally, the company stated that graphene could potentially cure certain diseases (Bonfil, 2018). However, the scientific community persuaded Profeco and the Federal Commission for Protection against Health Risks (Cofepris, by its acronym in Spanish) to step in due to the lack of scientific evidence to use it for that purpose and toxicological data to prove it was safe for its oral consumption. Ultimately, the company removed the product from its website.

Another case involved a nanotechnological company that requested donations to develop a gel for health treatment (Arteaga, 2020). Nevertheless, this product never appeared on the market. Thus, it might have been an intended fraud by referring to nanotechnology as a novel treatment, which could be, but it must be supported by scientific evidence and clinical exami-

[2] INSQ. https://datos.gob.mx/busca/dataset/sustancias-quimicas.

nations in this situation, and not only used for marketing reasons, because this creates misinformation and mistrust in the public.

In both cases, the corresponding federal institution could have uncovered the fake promises faster if proper management and regulations had already been in place. From now on, the government should carefully supervise the marketing and commercialization of ENMs and nano-enabled products. Additionally, collaboration among governmental institutions, such as Profeco, Cofepris, and the Ministry of Environment and Natural Resources (Semarnat), may be beneficial. Additionally, consumers' safety should have been protected more quickly if a group of experts had verified and certified the product, as soon as a company or person expressed interest in placing it on the market.

It is also relevant that, before the experimental pre-market evaluation of new nano-enabled products is performed, the investigation of the possible effects and risks of the on-market nano-enabled products is reviewed, as there is a lack of research in the nanosafety field in Mexico that sustains their safe use (Záyago-Lau *et al*., 2016). There is also a lack of well-established legal tools to protect the environment, workers, and consumers from the use or production of ENMs (Saldívar-Tanaka, 2022; Aguilar-Aguilar *et al*., 2023). Thus, it is important to increase research on the risks of exposure to ENMs, conducted in parallel with regulatory efforts, to help policymakers propose better regulation of ENMs and nano-enabled products.

In the past, the Mexican government promoted projects related to the potential regulation of those materials. For example, Mexico was part of the bilateral commission for regulatory purposes with the USA (Chávez-Hernández *et al*. 2024). Then, the federal government created a working group on regulations for nanotechnology (Delgado-Ramos, 2014). In 2012, they published guidelines to help federal national institutions issue regulations regarding the application of nanotechnology, when needed (Mundo Nano, 2014a). Furthermore, some national networks, such as the National Network of Nanoscience and Nanotechnology, have proposed research lines related to the protection of human health and the environment (Mundo Nano, 2010).

In the same direction, the creation of the LABnano, the Socioeconomic Laboratory in Nanoscience and Nanotechnology, in 2012 (Mundo Nano, 2014b) was another achievement. Researchers at LABnano investigated various aspects of Nanoscience and Nanotechnology progress, including social, ethical, legal, and environmental issues. Moreover, the ReLANS has also conducted research projects on similar topics. Additionally, in 2015, the National Nanotoxicological Evaluation System initiative (SINANOTOX), a consortium of Mexican Universities and research centers, was established as a platform to evaluate and analyze the impact of ENMs (Chávez-Hernández *et al*., 2024; CIMAV, 2008; Saldívar-Tanaka, 2019, 2020, 2; UIN, 2018).

In 2017, the International Union of Pure and Applied Chemistry (IUPAC) established the Workshop on Safety of Engineered Nanomaterials (Cenam, 2017). In 2018, Cofepris, in coordination with the National College of Phar-

maceutical Chemists Biologists of Mexico A.C., held the Symposium on Regulatory Sciences (Cofepris, 2018). Moreover, international cooperation on nanosafety was augmented. For instance, Mexico contributed to projects with European, Asian, and other Latin-American countries (Avila *et al*., 2015; Luizink, 2009; Malsch *et al*., 2016; UIN, 2018).

Unfortunately, Mexico lacks a national initiative or plan for the development of nanoscience and nanotechnology, resulting in an uncertain evolution in the field and a poor focus on national projects (Lazos-Martínez and Gonzálz-Rojano, 2013; Záyago-Lau and Foladori, 2010). In consequence, "Mexico is forced to allow private standardization organizations and agencies to regulate internal law" (Foladori *et al*., 2015). The most significant action on the regulatory side is the work of the special group for ENMs at the National Metrology Centre (Cenam, by its acronym in Spanish) regarding voluntary standards.

Future regulatory perspective of nanotechnological innovation and its applications in Mexico

There are two types of norms in Mexico, based on what is expressed in the Federal Law on Metrology and Standardization. The first ones are the Official Mexican Norms (NOM, by the acronym in Spanish), which are mandatory technical regulations in the country. The second one is the Mexican Norms (NMX, by the Spanish acronym), which are voluntary quality standards (Landeros, 2008). In the case of nanotechnology, Mexico has participated in the ISO/TC229[3] since 2007 (Lazos-Martínez and González-Rojano, 2013). Nowadays, the Technical Committee for National Standardization in Nanotechnologies (CTNNN, by its acronym in Spanish), within the Cenam, has elaborated a couple of NMX (Anzaldo-Montoya and Chauvet, 2016; Saldívar-Tanaka, 2020; Chávez-Hernández *et al*., 2023). Nonetheless, it is essential to evaluate whether industries and researchers have actually adopted these voluntary norms or if, instead, the implementation of mandatory ones would be more effective.

Something is clear: Mexico should implement a strategic plan to improve the development of nanotechnology, which should include nanosafety research. Furthermore, it is also necessary to implement a nano-specific legal policy or act that ensures the development and meets the country's socio-environmental needs (Saldívar-Tanaka, 2022). Because of these shortcomings of public policies, industries, entrepreneurs, and researchers must consider using other indispensable mechanisms in the co-regulation of ENMs to guarantee the development of nanotechnology, such as corporate social responsibility, ethical codes, voluntary register databases, the best laboratory practices guidelines with the best available techniques and equipment, transparency when sharing their data, and the globally harmonized system of classification, pac-

[3] ISO/TC229. Nanotechnologies. https://www.iso.org/committee/381983.html.

kaging, and labelling (Delgado-Ramos, 2014; Saldívar-Tanaka, 2020). Based on Delgado-Ramos (2014), Foladori and Záyago-Lau (2014), Isigonis and colleagues (2019), Malsch and colleagues (2015), Mundo Nano (2014a), Saldívar-Tanaka (2022), table 2 summarized some challenges and recommendations commonly mentioned and applied to the ENMS in the regulatory arena in Mexico.

Table 2. Challenges and corresponding strategies for regulating ENMs and nano-enabled products in Mexico.

Challenges	Strategies
1. Insufficient and non-binding regulatory framework.	– Develop a legally binding nano-security Law with enforceable standards. – Harmonize national regulations with international norms (e.g., ISO, OECD).
2. Lack of specific legislation for nanotechnology.	– Enact dedicated nanotechnology legislation integrating precautionary and sustainability principles.
3. Limited knowledge of risks and long-term effects.	– Promote interdisciplinary research in nanotoxicology and environmental impacts. – Fund long-term risk assessment studies.
4. Institutional capacity constraints.	– Invest in regulatory infrastructure and human capital. – Homogenize and accredit educational programs. – Create specialized regulatory bodies or units (i.e., the SINANOTOX is not a legal entity under Mexican law).
5. Predominantly economic development focus.	– Design public policies that integrate economic, environmental, and social priorities.
6. Weak public participation and transparency.	– Establish inclusive governance mechanisms (e.g., citizen forums, open discussions, and consultations). – Improve access to information on nano-enabled products.
7. Early implementation of product labeling and lack of traceability systems.	– Promote mandatory product labeling (i.e., CLP regulation). – Implement nanomaterial registries (i.e., using the ReLANS' open data as a starting point).

Source: Author's elaboration.

It is essential to stress again the importance of the involvement of the government (Saldívar-Tanaka, 2022). Thus, the government and the Secretariat of Science, Humanities, Technology and Innovation (Secihti, by its acronym in Spanish), previously known as the National Council of Humanities, Sciences and Technologies (Conahcyt, by its acronym in Spanish), should actively participate in and promote this initiative.

Additionally, the integration of a group of interested and active researchers, entrepreneurs, companies, NGOs, and other interested stakeholders in the field would have to pick up the previous work of their colleagues in

order to work together on a National Initiative, and to promote and collaborate on the implementation of a National Plan, including the mentioned ones in table 2. Considering the perspectives and interests of multiple stakeholders, adopting a nano-specific regulatory framework and risk governance could lead to greater success and impact on the development of nanotechnology and nanoscience in Mexico.

Finally, Mexican researchers should engage actively in international nano-risk governance discussions, not only due to its role in the global market but also because of the uncertainty that implicates regulating ENMs and nano-enabled products, and to maintain the pace that other countries in this evolving regulatory arena.

Contributions by author

Both authors contributed to:
Article conception and design, methodological development.
Data mining, analysis, and interpretation, preparation of supplementary materials.
Writing the original draft, review and final editing of the text.

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